UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2019

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM TO**

Commission File Number : 001-14895

Sarepta Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**93-0797222**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
215 First Street **Suite 415** **Cambridge, MA**	**02142**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 274-4000

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value	**SRPT**	**The NASDAQ Stock Market LLC (The NASDAQ Global Select Market)**

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☒ NO ☐

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). YES ☒ NO ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on The Nasdaq Global Select Market on June 28, 2019, was approximately $11,294,104,196.

The number of shares of Registrant's Common Stock outstanding as of February 21, 2020 was 77,776,779.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant has incorporated by reference into Part II and Part III of this Annual Report on Form 10-K portions of its definitive Proxy Statement for the 2020 Annual Meeting of Stockholders to be filed no later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Sarepta Therapeutics, Inc.
FORM 10-K INDEX

Forward-Looking Information

This Annual Report on Form 10-K, including the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section in Item 7, and other materials accompanying this Annual Report on Form 10-K contain forward-looking statements or incorporate by reference forward-looking statements. Statements that are not purely historical are forward-looking statements. Forward-looking statements are often identified by words such as "believe," "anticipate," "expect," "intend," "plan," "will," "may," "estimate," "could," "continue," "ongoing," "predict," "potential," "likely," "seek" and other similar expressions, as well as variations or negatives of these words. These statements address expectations, projections of future results of operations or financial condition, or other "forward-looking" information. These statements relate to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. These forward-looking statements include, but are not limited to:

- *our belief that our proprietary technology platforms and collaborations can be used to develop novel pharmaceutical products to treat a broad range of diseases and address key currently unmet medical needs;*
- *our intention to leverage our technology platforms, organizational capabilities, collaborations and resources to lead the field of precision genetic medicines, including the treatment of rare, neuromuscular and other diseases, with a diversified portfolio of product candidates;*
- *our intention to focus on continuing building our gene therapy engine, advancing our RNA technologies and potentially commercializing approved products, investing in next-generation precision medicine, and continuing nurturing our culture;*
- *our intention to manufacture and supply all clinical and commercial supplies of SRP-9001;*
- *our expectations regarding the continued growth of our business operations due, in part, to the commercialization of our products;*
- *our technologies and programs, including those with strategic partners, and their respective potential benefits, including our PMO based compounds' potential to be designed to create more, less, or none of certain proteins, or produce analogues of endogenous proteins; the potential of our PPMO to be tailored to reach other organs beyond muscle and result in enhanced delivery into the cell with less frequent dosing than PMOs; and the benefits of the AAVrh.74 vector, the MHCK7 promoter and the transgene;*
- *our belief that our partnerships with manufacturers will provide us access to additional commercial manufacturing capacity for our micro-dystrophin DMD gene therapy program, as well as a manufacturing platform for future gene therapy programs, and our belief that our current network of manufacturing partners are able to fulfil the requirements of our commercial plan;*
- *our plan to continue building out our network for commercial distribution in jurisdictions in which our products are approved;*
- *estimated timelines and milestones for 2020 and beyond, including having safety and dosing insights for SRP-5051 by the middle of 2020, commencing a trial evaluating SRP-9001 using commercial supply in the middle of 2020, pending regulatory feedback, having the results of the additional cohort of our Phase 1/2a trial of SRP-9003 and making a dose selection in the third quarter of 2020, and completing dosing in our global Phase 2/3 clinical trial of LYS-SAF302 in the first half of 2020;*
- *the timely completion and satisfactory outcome of our post-marketing requirements and commitments, including verification of a clinical benefit for EXONDYS 51 and VYONDYS 53 in confirmatory trials;*
- *our belief that our current network of manufacturing partners is able to produce raw materials and active pharmaceutical ingredients in the quantities that we require, and are capable of continuing to expand capacity as needed;*
- *the impact of regulations and regulatory decisions by the FDA and other regulatory agencies on our business, as well as the development of our product candidates and our financial and contractual obligations;*
- *our plan to evaluate future engagement with the European Medicines Agency ("EMA");*
- *the possible impact of any competing products on the commercial success of our products and product candidates and our ability to compete against such products;*

- *our ability to enter into research, development or commercialization alliances with universities, hospitals, independent research centers, non-profit organizations, pharmaceutical and biotechnology companies and other entities for specific molecular targets or selected disease indications and our ability to selectively pursue opportunities to access certain intellectual property rights that complement our internal portfolio through license agreements or other arrangements;*
- *our expectations regarding the potential benefits of the partnership, licensing and/or collaboration arrangements and other strategic arrangements and transactions we have entered into or may enter into in the future;*
- *the extent of protection that our patents provide and our pending patent applications may provide, if patents issue from such applications, to our technologies and programs, and our ability to obtain and maintain patent protection for our technologies and programs;*
- *our plans and ability to file and progress to issue additional patent applications to enhance and protect our new and existing technologies and programs;*
- *our belief that our owned and licensed patents and patent applications provide us with a competitive advantage;*
- *our belief that our current facilities in Cambridge, Andover and Burlington, Massachusetts and Dublin and Columbus, Ohio are suitable and will provide sufficient capacity to meet the projected needs of our business for the next 12 months;*
- *our estimates regarding how long our currently available cash and cash equivalents will be sufficient to finance our operations and business plans and statements about our future capital needs;*
- *our estimates regarding future revenues, research and development expenses, other expenses, capital requirements and payments to third parties;*
- *our ability to comply with applicable environmental laws and regulations; and*
- *our beliefs and expectations regarding milestone, royalty or other payments that could be due to third parties under existing agreements.*

We undertake no obligation to update any of the forward-looking statements contained in this Annual Report on Form 10-K after the date of this report, except as required by law. We caution readers not to place undue reliance on forward-looking statements. Our actual results could differ materially from those discussed in this Annual Report on Form 10-K. The forward-looking statements contained in this Annual Report on Form 10-K, and other written and oral forward-looking statements made by us from time to time, are subject to risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements, including the risks, uncertainties and assumptions identified under the heading "Risk Factors" in this Annual Report on Form 10-K.

PART I

Item 1. Business.

Overview

We are a commercial-stage biopharmaceutical company focused on helping patients through the discovery and development of unique RNA-targeted therapeutics, gene therapy and other genetic therapeutic modalities for the treatment of rare diseases. Applying our proprietary, highly-differentiated and innovative technologies, and through collaborations with our strategic partners, we are developing potential therapeutic candidates for a broad range of diseases and disorders, including Duchenne muscular dystrophy ("DMD"), Limb-girdle muscular dystrophies ("LGMDs"), Mucopolysaccharidosis type IIIA ("MPS IIIA") and other neuromuscular and central nervous system ("CNS") related disorders.

Our first commercial product, EXONDYS 51 (eteplirsen) Injection ("EXONDYS 51"), was granted accelerated approval by the U.S. Food and Drug Administration ("FDA") on September 19, 2016. EXONDYS 51 is indicated for the treatment of DMD in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping. EXONDYS 51 uses our phosphorodiamidate morpholino oligomer ("PMO") chemistry and exon-skipping technology to skip exon 51 of the dystrophin gene.

Our second commercial product, VYONDYS 53 (golodirsen) Injection ("VYONDYS 53"), was granted accelerated approval by the FDA on December 12, 2019. VYONDYS 53 is indicated for the treatment of DMD in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. VYONDYS 53 uses our PMO chemistry and exon-skipping technology to skip exon 53 of the dystrophin gene.

In addition to our commercial-stage products, we have a PMO-based product candidate in clinical development that is designed to treat those patients with DMD who have genetic mutations amenable to skipping exon 45 of the DMD gene (SRP-4045) (casimersen). In January 2020, we commenced our rolling submission of a New Drug Application ("NDA") to the FDA seeking accelerated approval for casimersen. We also have other PMO-based product candidates in discovery and preclinical development that are designed to skip other exons of the DMD gene.

Exon skipping is intended to promote the production of an internally truncated but functional dystrophin protein. The original PMO structure and variations of this structure that are so-called PMO-based (collectively "PMO-based") are central to our proprietary chemistry platform. PMO technologies can be used to selectively up-regulate or down-regulate the production of a target protein through pre-mRNA splice alteration. PMO-based compounds have the potential to be designed to create more, less, or none of certain proteins, or produce analogues of endogenous proteins. This technology can be used to correct disease-causing genetic errors by inducing the targeted expression of novel proteins.

The PMO chemistry platform is highly adaptable, and we have developed next-generation PMO-based chemistries for advancing RNA-targeted therapeutics. These next-generation chemistries are specifically designed to enhance tissue targeting, intracellular delivery, target selectivity and drug potency. One of these novel technologies is based on cell-penetrating peptide-conjugated PMO ("PPMO"). The PPMO features covalent attachment of a cell-penetrating peptide to a PMO with the goal of enhanced delivery into the cell. Our most advanced PPMO product candidate is SRP-5051, which is designed to treat DMD in patients with genetic mutations amenable to exon 51 skipping. In 2017, we commenced a first-in-human, single ascending dose, Phase 1 clinical trial for this product candidate. In 2019, we commenced a multiple ascending dose study for the treatment of DMD with SRP-5051 in patients who are amenable to exon 51 skipping, and we expect to have safety and dosing insights for this study by the middle of 2020.

As part of our multifaceted approach to DMD, we are also developing gene therapy technologies to treat DMD. We are clinically developing a product candidate, SRP-9001, that aims to express a smaller but still functional version of dystrophin ("micro-dystrophin"). We use a unique adeno-associated virus ("AAV") vector called AAVrh.74 to transport the transgene – the genetic material that will make the protein of interest – to the target cells. Micro-dystrophin is used because naturally-occurring dystrophin is too large to fit in an AAV. On October 3, 2018, Nationwide Children's Hospital ("Nationwide") presented positive results from a Phase 1/2a clinical trial testing SRP-9001 in four individuals with DMD enrolled in the trial. On March 25, 2019, we presented nine-month functional and creatine kinase ("CK") data from baseline from these four individuals, and twelve-month CK data from baseline from one of these individuals. In the fourth quarter of 2018, we commenced a randomized, double-blind, placebo-controlled trial with the goal to establish the functional benefits of micro-dystrophin expression. We have dosed all 41 participants in that trial and have begun dosing participants in the crossover phase of the study. We plan to commence a trial evaluating SRP-9001 using commercial supply in the middle of 2020, pending regulatory feedback.

We are also developing gene therapy programs for various forms of LGMDs. Our most advanced LGMD product candidate, SRP-9003, is designed to transfer a gene that codes for and restores beta-sarcoglycan protein with the goal of restoring the dystrophin associated protein complex. SRP-9003 utilizes the AAVrh.74 vector, the same vector used in SRP-9001. We commenced a Phase 1/2a trial of SRP-9003 in the fourth quarter of 2018. On February 27, 2019, we announced positive two-month biopsy data from the first three-patient cohort dosed in the SRP-9003 trial and on October 4, 2019, we announced positive nine-month functional data from these three patients. We have recently dosed one additional cohort of three patients at a higher dose per the study protocol. We expect to have the results from the second cohort and to make a dose selection in the third quarter of 2020.

Our pipeline includes more than 40 programs at various stages of discovery, pre-clinical and clinical development, reflecting our aspiration to apply our multifaceted approach and expertise in precision genetic medicine to make a profound difference in the lives of patients suffering from rare diseases.

Objectives and Business Strategy

We believe that our proprietary technology platforms and collaborations can be used to develop novel pharmaceutical products to treat a broad range of diseases and address key currently-unmet medical needs. We intend to leverage our technology platforms, organizational capabilities, collaborations and resources to lead the field of precision genetic medicines, including the treatment of rare, neuromuscular and other diseases, with a diversified portfolio of product candidates. In pursuit of this objective, we intend to focus on the following activities:

- continuing to build our gene therapy engine, including developing gene therapy product candidates, operationalizing our manufacturing strategy and furthering our commercial capabilities in preparation for potential regulatory approvals;
- advancing our RNA technologies (e.g., PMO and PPMO), launching potential approved products and supporting commercialization of approved products;
- investing in next-generation precision medicine through internal research, strategic partnerships, collaborations and other potential opportunities; and
- continuing to nurture our culture, which is based on strong patient focus, bias to action, a self-starter mentality, smart and appropriate risk-taking and high ethics.

Core Therapeutic Areas

DMD: We primarily focus on rapidly advancing the development of our potentially disease-modifying pipeline of exon-skipping, gene therapy and gene editing product candidates targeting DMD. DMD is a rare X-linked recessive genetic disorder affecting children (primarily males) that is characterized by progressive muscle deterioration and weakness. It is the most common type of muscular dystrophy. DMD is caused by an absence of dystrophin, a protein that protects muscle cells. The absence of dystrophin in muscle cells leads to significant cell damage and ultimately causes muscle cell death and fibrotic replacement. In the absence of dystrophin protein, affected individuals generally experience the following symptoms, although disease severity and life expectancy vary:

- muscle damage characterized by inflammation, fibrosis and loss of myofibers beginning at an early age;
- muscle weakness and progressive loss of muscle function beginning in the first few years of life;
- decline of ambulation and respiratory function after the age of seven;
- total loss of ambulation in the pre-teenage or early teenage years;
- progressive loss of upper extremity function during mid- to late-teens; and
- respiratory and/or cardiac failure, resulting in death before the age of 30.

LGMDs are autosomal recessive, monogenic, rare neuromuscular diseases caused by missense and deletion mutations. These diseases affect males and females equally. Some types of LGMDs affect skeletal muscle and cardiac muscle. More severe forms of LGMDs mimic DMD. LGMDs as a class affect an estimated range of approximately 1 in every 14,500 to 1 in every 123,000 individuals. Currently, there are no available treatment options for LGMDs.

MPS IIIA is a rare inherited neurodegenerative lysosomal storage disorder characterized by intractable behavioral problems and developmental regression resulting in early death. It is caused by mutations in the SGSH gene, which encodes an enzyme called Heparan-N-sulfamidase necessary for heparan sulfate (“HS”) recycling in cells. The disrupted lysosomal degradation and resulting storage of HS and glycolipids such as gangliosides leads to severe neurodegeneration. MPS IIIA affects approximately 1 in 100,000 individuals and is inherited in an autosomal recessive pattern. There are currently no treatment options for patients.

CMT is a group of hereditary, degenerative nerve diseases that are caused by mutations in genes that produce proteins involved in the structure and function of either the peripheral nerve axon or the myelin sheath. CMT can cause degeneration of motor skills, resulting in muscle weakness, and limiting patients' ability to walk or use their hands, and in some cases, can cause degeneration of sensory nerves, resulting in a reduced ability to feel heat, cold, and pain. CMT affects approximately 1 in every 2,500 individuals, while CMT type 1A, which is most often caused by an extra copy of the PMP22 gene, affects approximately 50,000 patients in the U.S. Most patients are diagnosed at infancy, while other patients develop symptoms at adolescence. Currently, there are no available treatment options.

Our Commercial Products

EXONDYS 51, our first commercial product, approved by the FDA on September 19, 2016, is indicated for the treatment of DMD in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping. EXONDYS 51 uses our PMO chemistry and exon-skipping technology to skip exon 51 of the dystrophin gene. PMO-based compounds are synthetic compounds that bind to complementary sequences of RNA by standard Watson-Crick nucleobase pairing. The two key structural differences between PMO-based compounds and naturally occurring RNA are that the PMO nucleobases are bound to synthetic morpholino rings instead of ribose rings, and the morpholino rings are linked by phosphorodiamidate groups instead of phosphodiester groups. Replacement of the negatively charged phosphodiester in RNA with the uncharged phosphorodiamidate group in PMO eliminates linkage ionization at physiological pH. Due to these modifications, PMO-based compounds are resistant to degradation by plasma and intracellular enzymes. Unlike the RNA-targeted technologies such as siRNAs and DNA gapmers, PMO-based compounds operate by steric blockade rather than by cellular enzymatic degradation to achieve their biological effects. Thus, PMOs use a fundamentally different mechanism from other RNA-targeted technologies.

We are in the process of conducting various EXONDYS 51 clinical trials, including studies that are required to comply with our post-marketing FDA requirements/commitments to verify and describe the clinical benefit of EXONDYS 51.

EXONDYS 51 targets the most frequent series of mutations that cause DMD. Approximately 13% of DMD patients are amenable to exon 51 skipping. For the years ended December 31, 2019, 2018, and 2017, the Company recorded net revenue of $380.7 million, $301.0 million, and $154.6 million, respectively, related to the sale of EXONDYS 51.

VYONDYS 53, our second commercial product, approved by the FDA on December 12, 2019, is indicated for the treatment of DMD in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. VYONDYS 53 uses our PMO chemistry and exon-skipping technology to skip exon 53 of the dystrophin gene.

We are in the process of conducting various VYONDYS 53 clinical trials, including studies that are required to comply with our post-marketing FDA requirements/commitments to verify and describe the clinical benefit of VYONDYS 53.

VYONDYS 53 targets the second most frequent series of mutations that cause DMD. Up to 8% of DMD patients are amenable to exon 53 skipping. As of December 31, 2019, we had commenced shipment of VYONDYS 53 but revenue from VYONDYS 53 was immaterial.

Our Pipeline – Key Programs

Casimersen (SRP-4045) uses our PMO chemistry and exon-skipping technology to skip exon 45 of the DMD gene. Casimersen is designed to bind to exon 45 of dystrophin pre-mRNA, resulting in exclusion, or "skipping", of this exon during mRNA processing in patients with genetic mutations that are amenable to exon 45 skipping. We are enrolling and dosing patients in ESSENCE (4045-301), our Phase 3 placebo controlled confirmatory trial in patients who have a confirmed mutation of the DMD gene that is amenable to exon 45 or 53 skipping using casimersen and golodirsen, respectively. On March 28, 2019, we announced results from our interim analysis of muscle biopsy endpoints comparing casimersen treatment to placebo in the ESSENCE study. In January 2020, we commenced a rolling submission of an NDA to the FDA seeking accelerated approval for casimersen.

SRP-5051 uses our next-generation chemistry platform, PPMO, and our exon-skipping technology to skip exon 51 of the dystrophin gene. The PPMO technology features covalent attachment of a cell-penetrating peptide to a PMO with the goal of enhanced delivery into the cell. In pre-clinical research, our proprietary class of PPMO compounds demonstrated an increase in dystrophin production and a more durable response compared to PMO. In addition, PPMO treatment in non-human primates results in high levels of exon-skipping in skeletal, cardiac and smooth muscle tissues. Pre-clinical trials also indicate that PPMOs may require less frequent dosing than PMOs, and that PPMOs could potentially be tailored to reach other organs beyond muscle.

In the fourth quarter of 2017, we commenced a first-in-human, single ascending dose, trial for the treatment of DMD using SRP-5051 in patients who are amenable to exon 51 skipping. In 2019, we commenced a multiple ascending dose study for the treatment of DMD with SRP-5051 in patients who are amenable to exon 51 skipping, and we expect to have safety and dosing insights by the middle of 2020.

SRP-9001 (DMD, micro-dystrophin gene therapy program), aims to express micro-dystrophin – a smaller but still functional version of dystrophin. A unique, engineered micro-dystrophin is used because naturally-occurring dystrophin is too large to fit in an AAV vector. SRP-9001 employs the AAVrh.74 vector, which is designed to be systemically and robustly delivered to skeletal, diaphragm and cardiac muscle without promiscuously crossing the blood brain barrier, which we believe makes it a strong candidate to treat peripheral neuromuscular diseases. An MHCK7 promoter was chosen for its ability to robustly express in the heart, which is critically important for patients with DMD, who typically die from pulmonary or cardiac complications. Lastly, the transgene was designed to maintain spectrin-like repeats 2 and 3, which has been reported to be critical to maintaining muscle force.

In the fourth quarter of 2017, an investigational new drug ("IND") application for the micro-dystrophin gene therapy program was cleared by the FDA, and a Phase 1/2a clinical trial in individuals with DMD was initiated. On October 3, 2018, Nationwide presented what we believe to be positive updated results from the Phase 1/2a clinical trial in four individuals with DMD enrolled in the trial. On March 25, 2019, we presented nine-month functional and CK data from baseline from these four individuals, and twelve-month CK data from baseline from one of these individuals. In the fourth quarter of 2018, we commenced a randomized, double-blind, placebo-controlled trial of SRP-9001 with the goal to establish the functional benefits of micro-dystrophin expressions. We have dosed all 41 participants in that trial and have begun dosing participants in the crossover phase of the study. We plan to commence a trial evaluating SRP-9001 using commercial supply in the middle of 2020, pending regulatory feedback.

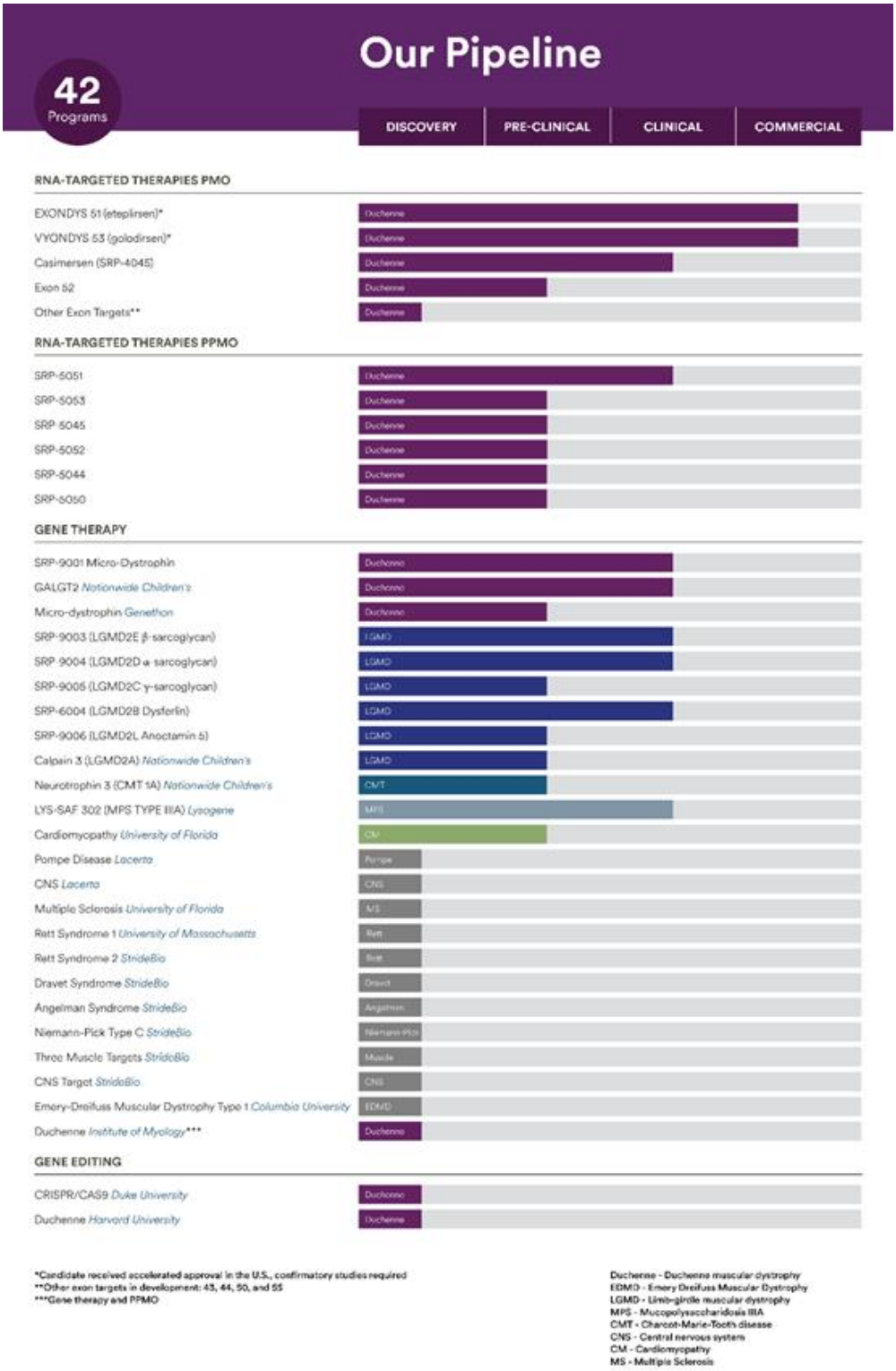
SRP-9003 (LGMD, gene therapy program). We are developing gene therapy programs for various types of LGMDs. Our LGMD programs use the AAVrh.74 vector, the same vector used in the micro-dystrophin gene therapy program, to transfect a restorative gene. The most advanced of our LGMD product candidates, SRP-9003, aims to treat LGMD2E, also known as beta-sarcoglycanopathy, a severe and debilitating form of LGMD characterized by progressive muscle fiber loss, inflammation and muscle fiber replacement with fat and fibrotic tissue. SRP-9003 is designed to transfect a gene that codes for and restores beta-sarcoglycan protein with the goal of restoring the dystrophin associated protein complex. SRP-9003 has generated positive pre-clinical safety and efficacy data utilizing the AAVrh.74 vector.

A Phase 1/2a trial of SRP-9003 was commenced in the fourth quarter of 2018. On February 27, 2019, we announced positive two-month biopsy data from the first three-patient cohort dosed in the SRP-9003 trial, and on October 4, 2019, we announced positive nine-month functional data from these three patients. We have recently dosed one additional cohort of three patients at a higher dose per the study protocol. We expect to have the results from the second cohort and make a dose selection in the third quarter of 2020.

LYS-SAF 302. We are collaborating with Lysogene S.A. ("Lysogene") to develop a gene therapy, LYS-SAF302, to treat MPS IIIA. LYS-SAF302 is an AAV-mediated gene therapy, the goal of which is to replace the faulty N-sulfoglucosamine sulfohydrolase ("SGSH") gene with a healthy copy of the gene. LYS-SAF302 employs the AAVrh.10 virus, chosen for its ability to target the CNS. Proof-of-concept was established in MPS IIIA pre-clinical models demonstrating strong expression, broad distribution, and the ability of the compound to correct lysosomal storage defects by producing the missing enzyme.

Lysogene is conducting a global Phase 2/3 clinical trial of LYS-SAF302 (AAVance), aiming at evaluating the effectiveness of a one-time delivery of an AAVrh.10 virus carrying the N-SGSH gene. We expect to complete dosing in this trial in the first half of 2020.

The chart below summarizes the status of our programs, including those with our strategic partners:



Manufacturing, Supply and Distribution

We have developed proprietary state-of-the-art Chemistry, Manufacturing and Controls ("CMC") and manufacturing capabilities that allow synthesis and purification of our products and product candidates to support both clinical development as well as commercialization. Our current main focus in manufacturing is to continue scaling up production of our PMO-based therapies and optimizing manufacturing for PPMO and gene therapy-based product candidates. We have entered into certain manufacturing and supply arrangements with third-party suppliers which will in part utilize these capabilities to support production of certain of our product candidates and their components. In 2017, we opened a facility in Andover, Massachusetts, which significantly enhanced our research and development manufacturing capabilities. However, we currently do not have internal large scale Good Manufacturing Practices ("GMP") manufacturing capabilities to produce our products and product candidates for commercial and/or clinical use. For our current and future manufacturing needs, we have entered into supply agreements with specialized contract manufacturing organizations (each a "CMO") to produce custom raw materials, the active pharmaceutical Ingredients ("APIs"), drug product and finished goods for our products and product candidates for both commercial and clinical use. All of our CMO partners have extensive technical expertise, GMP experience and experience manufacturing our specific technology.

For our commercial DMD program, we have commenced work with our existing manufacturers to increase product capacity from mid-scale to large-scale. While there are a limited number of companies that can produce raw materials and APIs in the quantities and with the quality and purity that we require for our commercial products, based on our diligence to date, we believe our current network of manufacturing partners are able to fulfill these requirements, and are capable of expanding capacity as needed. Additionally, we have, and will continue to evaluate further relationships with additional suppliers to increase overall capacity as well as further reduce risks associated with reliance on a limited number of suppliers for manufacturing.

Our commercial products are distributed in the U.S. through a limited network of home infusion specialty pharmacy providers that deliver the medication to patients and a specialty distributor that distributes our products to hospitals and hospital outpatient clinics. With respect to the pre-commercial distribution of our products to patients outside of the U.S., we have contracted with third party distributors and service providers to distribute our products in certain countries through our ex-U.S. early access programs ("EAP"). We plan to continue building out our network for commercial distribution in jurisdictions in which our products are approved.

Our gene therapy manufacturing capabilities have been greatly enhanced through partnerships with Brammer Bio LLC, which has recently been acquired by Thermo Fisher Scientific Inc. ("Brammer"), Paragon Bioservices, Inc., which has recently been acquired by Catalent, Inc. ("Paragon") and Aldevron LLC ("Aldevron"). We have adopted a hybrid development and manufacturing strategy in which we are building internal manufacturing expertise relative to all aspects of AAV-based manufacturing, including gene therapy and gene editing supply, while closely partnering with first-in-class manufacturing partners to expedite development and commercialization of our gene therapy programs. We expect that our partnerships with Brammer and Paragon will support our clinical and commercial manufacturing capacity for our micro-dystrophin DMD gene therapy programs and LGMD programs, while also acting as a manufacturing platform for potential future gene therapy programs. The collaboration integrates process development, clinical production and testing, and commercial manufacturing. Aldevron is expected to provide GMP-grade plasmid for our SRP-9001 micro-dystrophin DMD gene therapy program and LGMD programs, as well as plasmid source material for future gene therapy programs, such as CMT, MPS IIIA and other neuromuscular and CNS related disorders.

Manufacturers and suppliers of our commercial products and product candidates are subject to the FDA's current GMP ("cGMP") requirements and other rules and regulations prescribed by foreign regulatory authorities. We depend on our third-party partners for continued compliance with cGMP requirements and applicable foreign standards.

Material Agreements

We believe that our RNA-targeted and gene therapy technologies could be broadly applicable for the potential development of pharmaceutical products in many therapeutic areas. To further exploit our core technologies, we have and may continue to enter into research, development or commercialization alliances with universities, hospitals, independent research centers, non-profit organizations, pharmaceutical and biotechnology companies and other entities for specific molecular targets or selected disease indications. We may also selectively pursue opportunities to access certain intellectual property rights that complement our internal portfolio through license agreements or other arrangements.

Roche

License, Collaboration, and Option Agreement

On December 21, 2019, we entered into a License, Collaboration, and Option Agreement (the "Collaboration Agreement") with F. Hoffman-La Roche Ltd ("Roche") pursuant to which we granted Roche an exclusive license under certain of our intellectual property rights to develop, manufacture, and commercialize SRP-9001 in all countries outside of the U.S. We retained all rights to SRP-9001 in the U.S.

Also, under the terms of the Collaboration Agreement, Roche granted us a license to use certain of its intellectual property rights to perform development activities worldwide under a joint global development plan, commercialize SRP-9001 in the U.S., and perform certain manufacturing and medical affairs activities worldwide. Such license is non-exclusive under Roche's background intellectual property rights, exclusive in the U.S. under intellectual property rights developed by Roche under the Collaboration Agreement, and non-exclusive outside the U.S. under intellectual property rights developed by Roche under the Collaboration Agreement.

We intend to manufacture and supply all clinical and commercial supply of SRP-9001.

Roche Options and Negotiation Rights

Pursuant to the Collaboration Agreement, we granted Roche an exclusive option to obtain an exclusive license to develop, manufacture and commercialize the following products outside of the U.S.: (i) certain exon-skipping products that target the dystrophin gene to induce exon skipping, including eteplirsen, golodirsen, casimersen and SRP-5051; (ii) certain gene therapy products other than SRP-9001 that encode and directly express dystrophin or a derivative thereof; and (iii) certain gene-editing products that modify, repair, or activate an endogenous dysfunctional dystrophin gene. The products subject to Roche's options are collectively referred to as the "Option Products." Upon option exercise, the Option Product that is the subject of the option exercise will be included under the Collaboration Agreement as a product licensed to Roche subject to similar obligations, including with respect to development, manufacturing, commercialization, and cost-sharing as those that apply to SRP-9001.

Pursuant to the Collaboration Agreement, Roche has a right of first negotiation if we seek to grant a third-party license to (a) commercialize SRP-9001 in the U.S. or (b) commercialize any of our LGMDs products.

Exclusivity

Other than under the Collaboration Agreement, Roche may not perform any clinical trials for, or commercialize, any gene therapy product, gene-editing product, or antisense oligonucleotide for DMD for a period of five years following the execution of the Collaboration Agreement. The exclusivity period for one or more types of products may be extended if Roche exercises its option with respect to one or more exon-skipping products, gene therapy products, or gene-editing products, in each case, for a period of five years from the time of option exercise.

Development

The parties will use commercially reasonable efforts to conduct development activities with respect to SRP-9001 under the Collaboration Agreement pursuant to agreed-upon development plans. We will perform all development activities directed to obtaining and maintaining regulatory approvals for SRP-9001 in the U.S. and the European Union ("EU"), as set forth in a joint global development plan. Subject to certain exceptions, the parties will share the costs of the development activities under such joint global development plan. Roche will perform all development activities set forth in a territory-specific development plan for SRP-9001, including additional activities not set forth in the joint global development plan that are specifically directed to obtaining and maintaining regulatory approvals for SRP-9001 outside of the U.S. Roche will be solely responsible for costs arising from the territory-specific development plan for SRP-9001.

Governance

Governing committees will facilitate collaboration between the parties with respect to development, manufacturing, medical affairs, intellectual property protection, and commercialization of SRP-9001 and any other licensed products.

Financial Terms

In February 2020, Roche and Roche Finance Ltd, an affiliate of Roche ("Roche Finance"), together paid us an up-front payment of $1.2 billion, comprised of $750.0 million in cash from Roche and approximately $400.0 million from Roche Finance in exchange for 2,522,227 shares of our common stock, priced at $158.59 per share under the Stock Purchase Agreement described below. Additionally, we are eligible to receive up to $1.7 billion in regulatory and sales milestone payments with respect to SRP-9001.

In addition, the Collaboration Agreement provides that Roche will pay us royalties on net sales of SRP-9001, anticipated to be in the mid-teens.

In the event that Roche chooses to exercise its option with respect to one or more Option Products, we will be paid an option exercise fee upon each such exercise and the Option Products that are the subject of the option exercise will be subject to separate milestone payments and royalties on sales of such Option Product.

Term; Termination

Unless earlier terminated as described below, the Collaboration Agreement will continue with respect to SRP-9001 or any Option Product for which Roche has exercised its option, on a product-by-product and country-by-country basis, until the end of the royalty term for such product in such country. The royalty term expires on the later of (a) twelve years after first commercial sale in such country, (b) loss of regulatory exclusivity in such country and (c) expiration of all valid claims of specific licensed patents in such country.

Either party may terminate the Collaboration Agreement for the other party's material breach, if such breach is not cured within a specified cure period.

If Roche breaches its development or commercialization diligence obligations with respect to a licensed product or fails to develop or commercialize a particular licensed product in a particular region for a specified period of time, then we may terminate the Collaboration Agreement with respect to such licensed products in such regions.

Roche may terminate the Collaboration Agreement if we fail to supply SRP-9001 to Roche in accordance with the terms of the Collaboration Agreement and the supply agreements to be entered into between the parties. Roche may also terminate the Collaboration Agreement for convenience with extended advance notice, in its entirety or on a licensed product-by-licensed product and region-by-region basis.

The foregoing description of the terms of the Collaboration Agreement is not complete and is qualified in its entirety by reference to the text of the Collaboration Agreement, a copy of which is filed as an exhibit to this Annual Report.

Stock Purchase Agreement

On December 21, 2019, pursuant to the Collaboration Agreement, we entered into a Stock Purchase Agreement with Roche Finance (the "Stock Purchase Agreement") pursuant to which, in February 2020, we issued and sold 2,522,227 shares (the "Shares") of common stock to Roche Finance in a private placement for an aggregate purchase price of approximately $400.0 million, or $158.59 per share.

The Shares are subject to lock-up restrictions, which, without our prior approval, prohibit Roche Finance from selling the Shares for a period of 180 days after the closing of the Share issuance. The Stock Purchase Agreement contains other customary terms and conditions, including mutual representations, warranties, and covenants.

Myonexus

On May 3, 2018, we purchased from Myonexus, a privately-held Delaware corporation, a warrant to purchase common stock of Myonexus (the "Warrant"), which, in combination with amendments to the Myonexus certificate of incorporation, provided us with an exclusive option (the "Option") to acquire Myonexus. In consideration for the Warrant, we made an up-front payment of $60.0 million to Myonexus. On February 27, 2019, we announced that we exercised the exclusive option to acquire Myonexus and, on April 4, 2019, we paid the Myonexus shareholders approximately $173.8 million and completed the acquisition of Myonexus. We are required to make contingent payments to the former shareholders of Myonexus upon achievement of a threshold amount of net sales of Myonexus products and the receipt and subsequent sale of a priority review voucher with respect to a Myonexus product.

BioMarin

License Agreement

On July 17, 2017, we executed a License Agreement (as amended on April 14, 2019, the "License Agreement") with BioMarin Leiden Holding BV, BioMarin Nederlands BV and BioMarin Technologies BV (collectively, "BioMarin"), pursuant to which BioMarin granted us a royalty-bearing, worldwide license under patent rights ("Licensed Patents") and know-how ("Licensed Know-How") controlled by BioMarin with respect to BioMarin's DMD program, which are potentially necessary or useful for the treatment of DMD, to practice and exploit the Licensed Patents and Licensed Know-How in all fields of use and for all purposes, including to develop and commercialize antisense oligonucleotide products that target one or more exons of the dystrophin gene to induce exon skipping, including eteplirsen and golodirsen (collectively, the "Products").

The license granted by BioMarin is exclusive, even as to BioMarin, with respect to the Licensed Patents, and is non-exclusive with respect to Licensed Know-How. Under the License Agreement, BioMarin has the option to convert the exclusive license under the Licensed Patents into a co-exclusive license (co-exclusive with BioMarin) ("BioMarin Co-Exclusive Option").

Under the terms of the License Agreement, we were required to pay BioMarin an up-front payment of $15.0 million, and BioMarin is eligible to receive up to $20.0 million from us per dystrophin gene exon (other than exon 51) targeted by one or more Products in specified regulatory milestones, as well as an additional $10.0 million milestone, payable following the regulatory approval of eteplirsen by the EMA. BioMarin is also eligible to receive $15.0 million from us upon the achievement of $650.0 million in sales, as well as royalties segmented by specified geographic markets, in some jurisdictions dependent on the existence of a patent, ranging from four (4) to eight (8) percentages of net sales on a product-by-product and country-by-country basis.

Milestones and royalties are payable with respect to eteplirsen (an exon 51 skipping Product), golodirsen (an exon 53 skipping Product), casimersen (an exon 45 skipping Product) and other Products. For eteplirsen, golodirsen and casimersen, the royalty term will expire upon March 31, 2024 in the U.S., upon December 31, 2024 in the EU and no later than December 31, 2024 in other countries provided certain conditions are met. For Products other than exon 51 skipping Products, exon 53 skipping Products and exon 45 skipping Products, the royalty term will end on a country-by country basis upon expiration of granted Licensed Patents covering the applicable Product. The royalties for all Products are subject to reduction upon BioMarin's exercise of the BioMarin Co-Exclusive Option. All royalties are subject to further potential reductions, including for generic competition and, under specified conditions, for a specified portion of payments that we may become required to pay under third-party license agreements, subject to a maximum royalty reduction.

Unless earlier terminated, the License Agreement will expire upon the expiration of the last-to-expire royalty term. Either party may terminate the License Agreement in the event of the other party's uncured material breach. BioMarin may also terminate the License Agreement on a Licensed Patent-by-Licensed Patent basis under specified circumstances relating to patent challenges by us.

Settlement Agreement

On July 17, 2017, Sarepta and The University of Western Australia ("UWA") on the one hand, and the BioMarin Parties and Academisch Ziekenhuis Leiden ("AZL") on the other hand (collectively, the "Settlement Parties"), executed a Settlement Agreement pursuant to which all legal actions in the U.S. and certain legal actions in Europe (the "Actions") would be stopped or withdrawn as between the Settlement Parties. Specifically, the terms of the Settlement Agreement required that existing efforts pursuing ongoing litigation and opposition proceedings would be stopped as between the Settlement Parties, and the Settlement Parties would cooperate to withdraw the Actions before the European Patent Office (except for actions involving third parties), the U.S. Patent and Trademark Office, the U.S. Court of Appeals for the Federal Circuit and the High Court of Justice of England and Wales, except for the cross-appeal of the Interlocutory Decision of the Opposition Division dated April 15, 2013 of the European Patent Office of EP 1619249B1 ("EP '249 Appeal") in which Sarepta agreed to withdraw its appeal and BioMarin/AZL agreed to continue with its appeal with Sarepta having oversight of the continued appeal by BioMarin/AZL.

Additionally, under the terms of the Settlement Agreement, the Settlement Parties agreed to release each other and the customers, end-users, agents, suppliers, distributors, resellers, contractors, consultants, services and partners of Sarepta or BioMarin (as applicable) from claims and damages related to (i) the patent rights controlled by the releasing party that are involved in the Actions, (ii) with respect to Sarepta and UWA, its patent rights related to the patent rights involved in the Actions, and (iii) with respect to BioMarin and AZL, all of the Licensed Patents and Licensed Know-How.

Under the terms of the Settlement Agreement, Sarepta made an up-front payment of $20.0 million to BioMarin.

University of Western Australia

In April 2013, we entered into an agreement with UWA under which an existing exclusive license agreement between the two parties was amended and restated and, in June 2016, we entered into the first amendment to the license agreement (the "UWA License Agreement"). The UWA License Agreement grants us specific rights to compounds for the treatment of DMD by inducing exon skipping. EXONDYS 51, VYONDYS 53 and casimersen fall under the scope of the license agreement. Under the UWA License Agreement, we are required to make payments of up to $6.0 million in the aggregate to UWA based on the successful achievement of certain development and regulatory milestones relating to EXONDYS 51, VYONDYS 53 and up to four additional product candidates. As of December 31, 2019, $2.7 million of the $6.0 million development and regulatory milestone payments has been made. We are also obligated to make payments to UWA of up to $20.0 million upon the achievement of certain sales milestones. Additionally, we are required to pay a low-single-digit percentage royalty on net sales of products covered by issued patents licensed from UWA during the term of the UWA License Agreement. However, we have the option to purchase future royalties up-front for a one-time payment to UWA of $23.0 million.

Currently, the latest date on which an issued patent covered by the UWA License Agreement expires is November 2030 (excluding any patent term extension, supplemental protection certificate or pediatric extensions that may be available); however, patents granted from pending patent applications could result in a later expiration date.

Key Strategic Alliances

In connection with our multi-front battle against DMD and other rare neuromuscular diseases, we have entered into multiple partnering opportunities, including the ones described below. We believe that these collaborations, taken along with our own programs, represent a comprehensive approach to treating these rare neuromuscular diseases.

Nationwide Children's Hospital

In December 2015, we entered into an exclusive license agreement with Nationwide to acquire exclusive rights to its GALGT2 gene therapy program for neuromuscular related disorders.

In addition, in December 2016, we entered into an exclusive option agreement with Nationwide to acquire exclusive rights to their micro-dystrophin gene therapy program as well as a sponsored research agreement to conduct pre-IND research and conduct the first clinical trial with the lead micro-dystrophin gene therapy. In October 2018, we exercised our exclusive license option and an option under the sponsored research agreement and entered into an exclusive license agreement with Nationwide to acquire exclusive rights to its micro-dystrophin gene therapy program.

Furthermore, in October 2018, we entered into an exclusive option agreement with Nationwide with respect to exclusive rights to its NT-3 gene therapy program for the treatment of certain CMT neuropathy subtypes, including CMT Type 1A. The option agreement contains pre-determined economic terms for the exclusive license to be entered into upon us exercising our option.

In addition, in March 2019, we entered into an exclusive option agreement with Nationwide with respect to exclusive rights to its calpain-3 gene therapy program for the treatment of LGMD Type 2A. The option agreement contains pre-determined economic terms for the exclusive license to be entered into upon us exercising our option.

Lysogene

In October 2018, we entered into a license and collaboration agreement with Lysogene, a gene therapy company focused on the treatment of orphan diseases of the CNS, for the development of a gene therapy, LYS-SAF302, to treat MPS IIIA. Concomitantly, we also entered into an option with Lysogene to acquire an exclusive license to an additional CNS-targeted gene therapy candidate. Lysogene is responsible for completion of the pivotal trial for LYS-SAF302. We have exclusive commercial rights to LYS-SAF302 and exclusive option rights for the additional CNS-targeted gene therapy program in the U.S. and all territories outside of Europe, and Lysogene will retain exclusive commercial rights to each program in Europe. We will be responsible for global manufacturing of LYS-SAF302 and will supply Lysogene for its territory. If all milestones are met, we may be required to pay up to $130.8 million in development and commercial milestones and tiered royalties upon commercialization.

Duke University

In October 2017, we entered into a sponsored research and exclusive option agreement with Duke University, granting us an exclusive option to an exclusive license to intellectual property and technology related to certain CRISPR/Cas9 technology developed in the laboratory of Charles A. Gersbach, Ph.D. The underlying premise of Dr. Gersbach's approach is to restore dystrophin expression by removing or "excising" exons from the dystrophin gene. This includes a strategy to excise exons potentially enabling treatment for a majority of the DMD patient population.

Genethon

In May 2017, we entered into a sponsored research agreement with Genethon, under which we have been collaborating with Genethon on the pre-clinical development of its micro-dystrophin gene therapy products for the treatment of DMD. In November 2019, we entered into a license and collaboration agreement with Genethon, under which we will collaborate and share costs with Genethon on the clinical development of such products for the treatment of DMD. Under such agreement, we received the exclusive right to commercialize such products in the majority of the world (primarily excluding the EU). For the rights we received under such agreement, we made an up-front payment of $28.0 million; may be required to pay up to $236.3 million in development, regulatory and sales milestones; and upon commercialization, will be required to make tiered royalty payments based on net sales of licensed products.

StrideBio

On November 13, 2019, we entered into a collaboration and license agreement with StrideBio, Inc. ("StrideBio"), a leading developer of novel AAV capsids, to develop in vivo AAV-based therapies for up to eight CNS and neuromuscular targets. Pursuant to the agreement, we were granted an exclusive license on selected targets to leverage StrideBio's capsid technology intended to enhance specific tropism to tissues of interest and evade neutralizing antibodies. StrideBio will conduct all IND enabling research, development and manufacturing for the first four CNS targets, which are MECP2 (Rett syndrome), SCN1A (Dravet syndrome), UBE3A (Angelman syndrome), and NPC1 (Niemann-Pick). Additionally, we have an exclusive option for up to four additional targets based on StrideBio's capsid technology.

Under the terms of the agreement, StrideBio will be responsible for AAV capsid development, non-clinical development and manufacturing of preclinical candidates to be selected for advancement into clinical studies. The parties will also share early clinical development activities for certain selected targets, with Sarepta responsible for late stage development and commercialization of all targets. StrideBio received up-front consideration of $46.9 million, of which $29.4 million was in the form of Sarepta common stock and the balance in cash. In addition, StrideBio will receive significant future development, regulatory and commercial milestones upon the achievement of specified milestone events for each of the four programs. StrideBio will also receive royalties on worldwide net sales of any commercial products developed through the collaboration. Sarepta has also obtained an exclusive option to expand the collaboration to include up to an additional four targets with an up-front option payment of up to $42.5 million along with future downstream milestone and royalty payments, while StrideBio has an option to obtain co-development and co-commercial rights in the U.S. to one of the collaboration targets. In addition, Sarepta has made a commitment to invest in StrideBio's next financing round that meets certain conditions.

Patents and Proprietary Rights

Our success depends in part upon our ability to obtain and maintain exclusivity for our products, product candidates and platform technologies. We typically rely on a combination of patent protection and regulatory exclusivity to maintain exclusivity for our products and product candidates, whereas exclusivity for our platform technologies is generally based on patent protection and trade secret protection. In addition to patent protection, regulatory exclusivity, and trade secret protection, we also protect our products, product candidates and platform technologies with copyrights, trademarks, and contractual protections.

We actively seek patent protection for our product candidates and certain of our proprietary technologies by filing patent applications in the U.S. and other countries as appropriate. These patent applications are directed to various inventions, including, but not limited to, active ingredients, pharmaceutical formulations, methods of use, and manufacturing methods. In addition, we actively acquire exclusive rights to third party patents and patent applications to protect our in-licensed product candidates and corresponding platform technologies.

We do not have patents or patent applications in every jurisdiction where there is a potential commercial market for our product candidates. For each of our programs, our decision to seek patent protection in specific foreign markets, in addition to the U.S., is based on many factors, including:

- our available resources;
- the number and types of patents already filed or pending;
- the likelihood of success of the product candidate;
- the size of the commercial market;
- the presence of a potential competitor in the market; and
- whether the legal authorities in the market effectively enforce patent rights.

We continually evaluate our patent portfolio and patent strategy and believe our owned and licensed patents and patent applications provide us with a competitive advantage; however, if markets where we do not have patents or patent applications become commercially important, our business may be adversely affected. A discussion of certain risks and uncertainties that may affect our patent position, regulatory exclusivities and other proprietary rights is set forth in Item 1A. Risk Factors included in this report, and a discussion of legal proceedings related to the key patents protecting our products and product candidates are set forth below in the footnotes to the tables in this section.

Certain of our product candidates are in therapeutic areas that have been the subject of many years of extensive research and development by academic organizations and third parties who may control patents or other intellectual property that they might assert against us, should one or more of our product candidates in these therapeutic areas succeed in obtaining regulatory approval and thereafter be commercialized. We continually evaluate the intellectual property rights of others in these areas in order to determine whether a claim of infringement may be made by others against us. Should we determine that a third party has intellectual property rights that could impact our ability to freely market a compound, we consider a number of factors in determining how best to prepare for the commercialization of any such product candidate. In making this determination we consider, among other things, the stage of development of our product candidate, the anticipated date of first regulatory approval, whether we believe the intellectual property rights of others are valid, whether we believe we infringe the intellectual property rights of others, whether a license is available upon commercially reasonable terms, whether we will seek to challenge the intellectual property rights of others, the term of the rights, and the likelihood of and liability resulting from an adverse outcome should we be found to infringe the intellectual property rights of others.

Currently, U.S. patents, as well as most foreign patents, are generally effective for 20 years from the date the earliest regular application was filed. In some countries, the patent term may be extended to recapture a portion of the term lost during regulatory review of the claimed therapeutic. For example, in the U.S., under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly known as the Hatch-Waxman Act, a patent that covers an FDA-approved drug may be eligible for patent term extension (for up to 5 years, but not beyond a total of 14 years from the date of product approval) as compensation for patent term lost during the FDA regulatory review process. In the U.S., only one patent may be extended for any product based on FDA delay. In addition to patent term extension, patents in the U.S. may be granted additional term due to delays at the U.S. Patent and Trademark Office ("USPTO") during prosecution of a patent application. We actively strive to maximize the potential for patent protection for our products and product candidates in accordance with the law.

Key Patents & Regulatory Exclusivities

Our products, product candidates and our technologies are primarily protected by composition of matter and methods of use patents and patent applications. A summary of granted composition of matter and/or methods of use patents that we own or control in the U.S. and Europe, which cover our products and late-stage clinical product candidates, is provided below. To the extent the product or product candidate indicated above the tables that immediately follow the name of such product is covered by a patent that is licensed to Sarepta, we may owe milestones and/or royalties to the indicated licensor in connection with the development and/or commercial sale of the product or product candidate.

Eteplirsen

Patent Number	Country/Region*	Patent Type	Expiration Date**	Owner/Licensor (if not Sarepta)
U.S. 9,416,361	United States	Composition of Matter	May 4, 2021	Sarepta
U.S. 10,533,174	United States	Composition of Matter	May 4, 2021	Sarepta
U.S. RE47,751[1]	United States	Methods of Use	June 28, 2025	UWA
U.S. 9,018,368	United States	Composition of Matter	June 28, 2025	UWA
U.S. RE47,769[2]	United States	Composition of Matter	June 28, 2025	UWA
U.S. 9,243,245[3]	United States	Methods of Use	October 27, 2028	BioMarin/AZL
U.S. 9,506,058	United States	Methods of Use	March 14, 2034	Sarepta
U.S. 10,364,431	United States	Methods of Use	March 14, 2034	Sarepta
U.S. 10,337,003	United States	Methods of Use	March 14, 2034	Sarepta

1 Reissue of U.S. 8,486,907, which previously was involved in U.S. Patent Interference No. 106,013 and ordered to be cancelled pursuant to Judgment dated September 29, 2015 (Decision dated December 29, 2015 denied our (UWA) Request for Rehearing. Appeal by us (UWA) to the Court of Appeals for the Federal Circuit (Case Nos. 2016-1937, 2016-2086 (consolidated)) voluntarily dismissed July 27, 2017.)

2 Reissue of U.S. 7,807,816, which previously was involved in U.S. Patent Interference No. 106,008 (Judgment dated September 20, 2016 ordered cancellation of all claims of U.S. Application No. 13/550,210 to BioMarin (AZL). Appeal by BioMarin (AZL) to the Court of Appeals for the Federal Circuit (Case No. 2017-1078) voluntarily dismissed July 27, 2017.)

3 Reissue application of U.S. 9,243,245 pending.

Patent Number	Country/Region*	Patent Type	Expiration Date**	Owner/Licensor (if not Sarepta)
EP 1 619 249 B1[1]	Europe	Methods of Use	September 21, 2021	BioMarin/AZL
EP 2 284 264 B1	Europe	Composition of Matter & Methods of Use	September 21, 2021	BioMarin/AZL
EP 2 801 618 B1	Europe	Composition of Matter & Methods of Use	September 21, 2021	BioMarin/AZL
EP 1 766 010 B1	Europe	Composition of Matter & Methods of Use	June 28, 2025	UWA
EP 2 203 173 B1[2]	Europe	Methods of Use	October 27, 2028	BioMarin/AZL

1 Previously involved in EPO Opposition and appeal procedure. EPO decision of Appeal Board dated December 12, 2019 maintained the patent in amended form.

2 Involved in EPO Opposition proceedings initiated on September 22, 2016. EPO ordered revocation of our (BioMarin/AZL) patent on April 4, 2018. Appeal filed June 8, 2018 is pending.

The various types of regulatory exclusivity for which our products have been granted and our product candidates are anticipated to be eligible to receive are generally discussed below, under 'Government Regulation' – 'Data and Market Exclusivities' and 'Orphan Drug Designation and Exclusivity'. In connection with its FDA approval on September 19, 2016, the FDA granted EXONDYS 51 (eteplirsen) New Chemical Entity ("NCE") exclusivity until September 19, 2021, and Orphan Drug Exclusivity until September 19, 2023.

Golodirsen

Patent Number	Country/Region*	Patent Type	Expiration Date**	Owner/Licensor (if not Sarepta)
U.S. 9,416,361	United States	Composition of Matter	May 4, 2021	Sarepta
U.S. 10,533,174	United States	Composition of Matter	May 4, 2021	Sarepta
U.S. RE47,691[1]	United States	Composition of Matter	June 28, 2025	UWA
U.S. 9,024,007	United States	Composition of Matter	June 28, 2025	UWA
U.S. 9,994,851	United States	Composition of Matter	June 28, 2025	UWA
U.S. 10,266,827	United States	Methods of Use	June 28, 2025	UWA
U.S. 10,227,590	United States	Composition of Matter	June 28, 2025	UWA
U.S. 10,421,966	United States	Composition of Matter	June 28, 2025	UWA

1 Reissue of U.S. 8,455,636, which previously was involved in U.S. Patent Interference No. 106,007. (Judgment dated April 29, 2016 ordered cancellation of (i) all claims, except claim 77, of U.S. Application No. 11/233,495 to BioMarin (AZL); and (ii) U.S. 8,455,636 to us (UWA). Appeal by BioMarin (AZL) to the Court of Appeals for the Federal Circuit (Case No. 2016-2262) voluntarily dismissed July 27, 2017.)

Patent Number	Country/Region*	Patent Type	Expiration Date**	Owner/Licensor (if not Sarepta)
EP 2 602 322 B1[1]	Europe	Composition of Matter & Methods of Use	September 21, 2021	BioMarin/AZL
EP 2 206 781 B1[2]	Europe	Composition of Matter & Methods of Use	June 28, 2025	UWA
EP 2 970 964 B1	Europe	Composition of Matter	March 14, 2034	Sarepta

1 Involved in Opposition proceedings initiated on November 28, 2016. EPO Opposition decision dated July 15, 2019 maintained our (BioMarin/AZL) patent without amendment. Appeal filed September 2, 2019 is pending.

2 Involved in Opposition proceedings initiated on August 25, 2016. EPO ordered revocation of patent on December 19, 2017. Appeal filed February 19, 2018 is pending.

The various types of regulatory exclusivity for which our products have been granted and our product candidates are anticipated to be eligible to receive are generally discussed below, under 'Government Regulation' – 'Data and Market Exclusivities' and 'Orphan Drug Designation and Exclusivity'. In connection with its FDA approval on December 12, 2019, the FDA granted VYONDYS 53 (golodirsen) NCE exclusivity until December 12, 2024, and Orphan Drug Exclusivity until December 12, 2026.

Casimersen

Patent Number	Country/Region*	Patent Type	Expiration Date**	Owner/Licensor (if not Sarepta)
U.S. 9,416,361	United States	Composition of Matter	May 4, 2021	Sarepta
U.S. 10,533,174	United States	Composition of Matter	May 4, 2021	Sarepta
U.S. 9,447,415	United States	Composition of Matter	June 28, 2025	UWA
U.S. 8,524,880[1]	United States	Composition of Matter & Methods of Use	April 2, 2026	UWA
U.S. 9,228,187	United States	Composition of Matter	November 12, 2030	UWA
U.S. 9,758,783	United States	Methods of Use	November 12, 2030	UWA
U.S. 10,287,586	United States	Composition of Matter	November 12, 2030	UWA

1 Reissue application of U.S. 8,524,880 pending.

Patent Number	Country/Region*	Patent Type	Expiration Date**	Owner/Licensor (if not Sarepta)
EP 2 499 249 B1	Europe	Composition of Matter & Methods of Use	November 12, 2030	UWA

* Granted patents in the U.S. and Europe (EP) are shown here. Additional patent protection in the U.S., Europe (EP) or other countries or regions through pending or granted foreign counterparts may be available.

****** Stated expiration dates do not account for any patent term extension, supplemental protection certificate or pediatric extensions that may be available.

In addition to the foregoing composition of matter and method of use patents that protect eteplirsen, casimersen and golodirsen, we either solely own or exclusively license from UWA, BioMarin or AZL patents and patent applications in the U.S. and in major foreign markets that provide additional protection for eteplirsen, casimersen, and golodirsen, which cover the composition of matter, preparation and/or uses of the products and product candidates. These patents, and patent applications, if granted, would expire through at least 2038, such expiration dates not accounting for any patent term extension, patent term adjustment, supplemental protection certificate or pediatric extensions that may be available.

Platform Technologies

We separately own patents and patent applications in the U.S. and in major foreign markets that cover our proprietary PMO-based platform technologies (e.g., PPMO, PMOplus, PMO-X). These patents, and patent applications, if granted, expire through at least 2038, such expiration dates not accounting for any patent term extension, supplemental protection certificate or pediatric extensions that may be available.

Trademarks

Our trademarks are important to us and are generally filed to protect our corporate brand, our products and platform technologies. We typically file trademark applications and pursue their registration in the U.S., Europe and other markets in which we anticipate using such trademarks. We are the owner of multiple federal trademark registrations in the U.S. including, but not limited to, Sarepta, Sarepta Therapeutics, the double-helix logo, EXONDYS, and EXONDYS 51. In addition, we have multiple pending trademark applications in the U.S. and in major foreign markets, including, but not limited to, VYONDYS and VYONDYS 53. Trademark protection varies in accordance with local law, and continues in some countries as long as the trademark is used and in other countries as long as the trademark is registered. Trademark registrations generally are for fixed but renewable terms.

Government Regulation

The testing, manufacturing, labeling, advertising, promotion, distribution, exportation and marketing of our products are subject to extensive regulation by governmental authorities in the U.S. and in other countries. In the U.S., the FDA, under the Federal Food, Drug and Cosmetic Act and its implementing regulations, regulates pharmaceutical products. Failure to comply with applicable U.S. requirements may subject us to administrative or judicial sanctions, such as FDA refusal to approve pending marketing applications, withdrawal of approval of approved products, warning letters, untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, civil penalties and/or criminal prosecution.

U.S. Drug Approval Process

To obtain FDA approval of a product candidate, we must, among other things, submit clinical data providing substantial evidence of safety and efficacy of the product for its intended use, as well as detailed information on product composition, its manufacture and controls and proposed labeling. The testing and collection of data and the preparation of necessary applications are expensive and time-consuming. The FDA may not act quickly or favorably in reviewing these applications, and we may encounter significant difficulties or costs in our efforts to obtain FDA approvals that could delay or preclude us from marketing our products.

The steps required before a drug may be approved for marketing in the U.S. generally include the following:

- pre-clinical laboratory tests and animal toxicity testing;
- submission of an IND for conducting human clinical testing to the FDA, which must become effective before human clinical trials commence;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug product for each indication, including controlled studies or comparison of treated group from clinical trials to data from natural history data or studies;
- submission of a complete and compliant marketing application containing chemistry, manufacturing and control information for the drug substance and drug product, reports of nonclinical and clinical trials, product labeling and administrative information;
- satisfactory completion of an FDA inspection of the commercial manufacturing facilities at which the drug substance and drug product are made to assess compliance with cGMP;
- satisfactory FDA audit of the clinical trial site(s) that generated the pivotal safety and efficacy data included in the marketing application and also potentially the nonclinical trial site(s) in the form of pre-approval inspections; and
- FDA review and approval of the marketing application.

Pre-clinical trials may include laboratory evaluations of the product chemistry, pharmacology, toxicity and formulation, as well as animal studies to assess the pharmacokinetics, metabolism, bio-distribution, elimination and toxicity of the product candidate. The conduct of the pre-clinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the pre-clinical trials, manufacturing information, analytical data and a proposed first in human clinical trial protocol are submitted to the FDA as part of the IND, which must become effective before clinical trials may be initiated. The IND will become effective approximately 30 days after receipt by the FDA, unless the FDA raises concerns or questions about the supportive data, or the study design, particularly regarding potential safety issues with conducting the clinical trial as described in the protocol. In this situation, the trials are placed on clinical hold and the IND sponsor must resolve any outstanding FDA concerns before clinical trials can proceed.

Clinical trials involve the administration of the product candidate to healthy volunteers or patient participants under the supervision of a qualified principal investigator. Clinical trials are conducted under protocols detailing the objectives of the study, the administration of the investigational product, study procedures, parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as a submission to the IND. Clinical trials must be conducted in accordance with the FDA's Good Clinical Practice ("GCP") requirements and federal and state laws and regulations protecting study subjects. Further, each clinical trial must be reviewed and approved by the Institutional Review Board ("IRB") at or servicing each institution in which the clinical trial will be conducted. The IRB will consider, among other things, rationale for conducting the trial, clinical trial design, participant informed consent, ethical factors, the safety and rights of human subjects and the possible liability of the institution. The FDA can temporarily or permanently halt a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial subjects. The IRB may also require the clinical trial at a particular site be halted, either temporarily or permanently, for failure to comply with GCP or the IRB's requirements, or may impose other conditions.

Clinical trials typically are conducted in three sequential drug development phases (Phases 1, 2 and 3) prior to approval, and a portion of these phases may overlap. A fourth post-approval phase (Phase 4) may include additional clinical trials. A general description of clinical trials conducted in each phase of development is provided below. However, the number of study subjects involved in each phase of drug development for rare diseases can be significantly less than typically expected for more common diseases with larger patient populations:

- Phase 1. Phase 1 clinical trials involve the initial introduction of the drug into human subjects. These studies are usually designed to determine the safety of single and multiple doses of the compound and determine any dose limiting toxicities or intolerance, as well as the metabolism and pharmacokinetics of the drug in humans. Phase 1 studies usually involve less than 100 subjects and are conducted in healthy adult volunteers, unless it is unethical to administer the study drug to healthy volunteers, in which case they are tested in patients.
- Phase 2. Phase 2 clinical trials are usually conducted in a limited patient population to evaluate the safety and efficacy of the drug for a specific indication to determine optimal dosage and to identify possible adverse effects and safety risks. Phase 2 studies usually involve patients with the disease under investigation and may vary in size from several dozen to several hundred.
- Phase 3. If an investigational drug is found to be potentially effective and to have an acceptable safety profile in early phase studies, larger Phase 3 clinical trials are conducted to confirm clinical efficacy, dosage and safety in the intended patient population, which may involve geographically dispersed clinical trial sites. Generally, two adequate and well-controlled Phase 3 clinical trials which establish the safety and efficacy of the drug for a specific indication are required for approval of a marketing application. Phase 3 studies usually include several hundred to several thousand patients for larger, non-orphan drug indications/diseases. However, clinical trials for rare or orphan diseases generally have fewer patients due to their lower prevalence. For these orphan diseases, a company may also try to demonstrate efficacy and safety by comparing treated patients in clinical trials to untreated patients participating in placebo-controlled clinical trials or to observational natural history studies.
- Phase 4. Phase 4 trials are clinical trials conducted after the FDA has approved a product for marketing. Typically there are two forms of Phase 4 trials: those that are conducted to fulfill mandatory conditions of product approval and those that are voluntarily conducted to gain additional experience from the treatment of patients in the intended therapeutic indication. The mandatory studies are used to confirm clinical benefit in the case of drugs approved under the accelerated approval regulations or to provide additional clinical safety or efficacy data for “full” approvals. Failure to promptly conduct and complete mandatory Phase 4 clinical trials could result in withdrawal of approval for products approved under accelerated approval regulations.

A company seeking marketing approval for a new drug in the U.S. must submit the results of the pre-clinical and clinical trials to the FDA in the form of a marketing application, together with, among other things, detailed information on the manufacture and composition of the product candidate and proposed labeling, including payment of a user fee for FDA review of the application. The user fee is waived for an application for a product intended to treat an Orphan Indication. The FDA assesses all submitted marketing applications for completeness before it accepts them for filing. In some cases, the FDA may request additional information before accepting a marketing application for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the marketing application. Applications receive either standard or priority review. Under the current goals mandated under the Prescription Drug User Fee Act (the “PDUFA”), the FDA has ten months in which to complete its initial review of a standard marketing application and respond to the applicant, and six months for a priority marketing application. The FDA does not always meet its PDUFA goal dates for standard or priority marketing applications. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the marketing application sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date. The FDA may refer an application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. Though the FDA is not bound by such recommendations, it considers them carefully when making decisions. If the FDA’s evaluations of the marketing application and the clinical and manufacturing procedures and facilities are favorable, the FDA may issue an approval letter. If the FDA finds deficiencies in the marketing application, it may issue a complete response letter, which defines the conditions that must be met in order to secure final approval of the marketing application. If and when those conditions have been met to the FDA’s satisfaction, the FDA will issue an approval letter, authorizing commercial marketing of the drug. Sponsors that receive a complete response letter may submit to the FDA information that represents a complete response to the issues identified by the FDA. Resubmissions by the marketing application sponsor in response to a complete response letter trigger new review periods of varying length (typically two to six months) based on the content of the resubmission. If the FDA’s evaluation of the marketing application and the commercial manufacturing procedures and facilities is not favorable, the FDA may not approve the marketing application.

A sponsor may also seek designation of its drug candidates under programs designed to accelerate the FDA's review and potential approval of marketing applications. For instance, a sponsor may seek FDA designation of a drug candidate as a "fast track product." Fast track products are those products intended for the treatment of a serious or life-threatening disease or condition and which demonstrate the potential to address unmet medical needs for such disease or condition. If fast track designation is obtained, the FDA may initiate early and frequent communication and begin reviewing sections of a marketing application before the application is complete. This "rolling review" is available if the applicant provides, and the FDA approves, a schedule for the remaining information. Eteplirsen was granted fast track status in 2007.

The Food and Drug Administration Safety and Innovation Act ("FDASIA") enacted and signed into law in 2012 amended the criteria for the fast track and accelerated approval pathways and, as a result, the pathways now share many common eligibility criteria. FDASIA provides both the sponsor companies and the FDA with greater flexibility and expedited regulatory mechanisms. The statute clarifies that a fast track product may be approved pursuant to an accelerated approval (Subpart – H) or under the traditional approval process. In addition, FDASIA codified the accelerated approval pathway as separate and apart from the fast track pathway, meaning that for drugs to be eligible for accelerated approval, they do not need to be designated under the fast track pathway. FDASIA reinforces the FDA's authority to grant accelerated approval of a drug that treats a serious condition and generally provides a meaningful advantage over available therapies and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality ("IMM") that is reasonably likely to predict an effect on IMM or other clinical benefit (i.e., an intermediate clinical endpoint). Approvals of this kind typically include requirements for appropriate post-approval Phase 4 clinical trials to confirm clinical benefit. FDASIA retains this requirement and further requires those studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit.

Additionally, FDASIA established a new, expedited regulatory mechanism referred to as breakthrough therapy designation. Breakthrough therapy designation, fast track, and accelerated approval are not mutually exclusive and are meant to serve different purposes. The breakthrough therapy designation is focused on expediting the development and review process and by itself does not create an alternate ground for product approval. A sponsor may seek FDA designation of a drug candidate as a breakthrough therapy if the drug is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA issued guidance entitled "Expedited Programs for Serious Conditions—Drugs and Biologics" in May 2014.

Finally, if a drug candidate demonstrates a significant benefit over existing therapy, it may be eligible for priority review, which means it will be reviewed within a six-month timeframe from the date a complete marketing application is accepted for filing. A Regenerative Medicine Advanced Therapy ("RMAT") designation is also designed to accelerate approval for regenerative advanced therapies such as our gene therapy product candidates, but the exact mechanisms have not yet been announced by FDA.

We cannot be sure that any of our drug candidates will qualify for any of these expedited development, review and approval programs, or that, if a drug does qualify, that the product candidates will be approved, will be accepted as part of any such program or that the review time will be shorter than a standard review.

Holders of an approved marketing application are required to:

- report serious adverse drug reactions to the FDA;
- submit annual and periodic reports summarizing product information and safety data;
- comply with requirements concerning advertising and promotional labeling;
- continue to have quality control and manufacturing procedures conform to cGMP after approval; and
- conduct any post-marketing study designated as a required condition of the marketing application approval.

The FDA periodically inspects the sponsor's records related to safety reporting and/or manufacturing; this latter effort includes assessment of compliance with cGMP. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved marketing application, including withdrawal of the product from the market.

Foreign Regulatory Requirements

We are pursuing regulatory approval of eteplirsen in jurisdictions outside of the U.S. In November 2016, we submitted a marketing authorization application ("MAA") for eteplirsen to the EMA and the application was validated in December 2016. As we announced on June 1, 2018, the Committee for Medicinal Products for Human Use ("CHMP") within the EMA adopted a negative opinion for eteplirsen. In September 2018, the CHMP confirmed its negative opinion for eteplirsen, and the European Commission adopted the CHMP opinion in December 2018. During 2019, we sought follow-up EMA scientific advice for eteplirsen. Once data from our ongoing studies is available, we plan to evaluate future engagement with the EMA on potential next steps.

We have initiated key activities in support of the potential launch of our products in the EU, such as building out commercial infrastructure and scaling-up manufacturing. As of the date of this Annual Report, EXONDYS 51 and VYONDYS 53 have only been approved for sale and marketing in the U.S. by the FDA, and EXONDYS 51 has been approved in addition for sale and marketing in Israel by the Israeli Ministry of Health.

Thus, in addition to regulations in the U.S., our business is subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products. Irrespective of whether it concerns an FDA approved or investigational drug, the commencement of clinical trials and the subsequent marketing of a drug product in foreign countries are subject to preliminary approvals from the corresponding regulatory authorities of such countries. For example, the conduct of clinical trials in the EU is currently still governed by the Clinical Trials Directive 2001/20/EC and Directive 2005/28/EC laying down the principles and guidelines on GCP. Both Directives provide a system for the approval of clinical trials, which has been implemented through national legislation in the member states in the EU. Under this system, a sponsor must obtain approval from the competent national authority of an EU member state in which the clinical trial is to be conducted, or in multiple member states if the clinical trial is to be conducted in a number of countries. Furthermore, the sponsor may only start a clinical trial at a specific study site after the competent ethics committee has issued a favorable opinion. The Clinical Trials Application ("CTA") must include the supporting information prescribed by Directive 2001/20/EC and Directive 2005/28/EC, corresponding national laws of the member states, and as further detailed in the applicable guidance documents.

In April 2014, the EU adopted a new Clinical Trials Regulation (EU) No 536/2014 to replace the current Clinical Trials Directive 2001/20/EC. Although the new Clinical Trials Regulation has been adopted and has entered into force in 2014, it will only come into application in the EU Member States six months after the European Commission has confirmed the functionality of the new Clinical Trials Information System ("CTIS"), which is the centralized EU portal and database for clinical trials introduced by the Regulation. The Regulation is currently expected to enter into application mid-2021. When the Regulation enters into application, it will repeal the currently applicable Clinical Trials Directive 2001/20/EC and its national implementation legislations. It will also apply to clinical trials that were authorized under the previous legislation if they are still ongoing three years after the Regulation has come into operation. No legislation needs to be adopted to implement the new Regulation into national law. The new Regulation provides an overhaul of the system, in order to harmonize the assessment of the submission and assessment of clinical trials conducted in EU Member States and to ensure greater consistency with the highest standards of patient safety in the EU. Specifically, the new legislation seeks to simplify and streamline approval of the clinical trials. Under the new coordinated procedure, the sponsor of a clinical trial is required to submit a single application to a reporting EU Member State. The reporting Member State will consult and coordinate with all other Member States in which the clinical trial is planned to be conducted. If the application is rejected, it can be amended and resubmitted through a central EU Portal. If an approval is issued, the sponsor can start the clinical trial in all Member States concerned. However, a Member State can in certain cases declare an "opt-out" from the approval. In such a case, the clinical trial cannot be conducted in such Member State(s). The Clinical Trials Regulation also aims to streamline and simplify the rules on safety reporting for clinical trials.

In order to obtain marketing authorization for a medicinal product in the EU, applicants are required to submit a MAA to either (a) the national competent authorities (through the decentralized, mutual recognition, or national procedures) or (b) the EMA (through the centralized authorization procedure). Applicants are required to demonstrate the quality, safety and efficacy of the medicinal product in the application for marketing authorization, which implies the requirement to conduct human clinical trials to generate the necessary clinical data. Furthermore, all applications for marketing authorization for new medicines have to include the results of studies as described in an agreed pediatric investigation plan ("PIP"). Regulation (EC) No 726/2004 of the European Parliament and of the Council lays down the rules applicable to the centralized procedure for the authorization of medicinal products; The centralized procedure allows pharmaceutical companies to submit s a single application to EMA, which is followed by a single evaluation and which results in a single approval to market the medicinal product throughout the European Economic Area (the "EEA"), on the basis of a single market authorization. Approval via the centralized procedure is a two-step process whereby the CHMP first evaluates the MAA and issues an opinion on whether the medicinal product may be authorized or not (step 1). The CHMP opinion is subsequently sent to the European Commission ("EC"), which takes a legally binding decision to grant a marketing authorization (step 2). The marketing authorization is valid throughout the EU and is automatically recognized in three of the four European Free Trade Association states (Iceland, Liechtenstein and Norway). This allows the marketing authorization holder to market the medicine and make it available throughout the EEA. The timeframe for the first step of the centralized procedure (evaluation by the CHMP) opinion is 210 days from receipt of a valid application. However, the actual time needed to complete this first step is generally longer than the 210 days, since procedural clock stops are required in order for the applicant to respond to additional requests for information by the CHMP. Following a positive CHMP opinion, the EC has 67 days to issue its decision to grant the marketing authorization or not.

Accelerated evaluation of the MAA is possible in exceptional cases, following a justified request from the applicant, when a medicinal product is of a major public health interest, particularly from the point of view of therapeutic innovation. The CHMP determines what constitutes a major public interest on a case-by-case basis. Justifications must include the major benefits expected and present the arguments to support the claim that the medicinal product introduces new methods of therapy or improves on existing methods, thereby addressing, to a significant extent, the greater unmet needs for maintaining and improving public health. In case of an accelerated assessment, the timeframe for review of a MAA by the EMA's CHMP is reduced to 150 days. The timeframe for the EC to issue its decision remains unaltered.

Article 3 of Regulation (EC) No 726/2004 defines in which cases the centralized application procedure *must* (mandatory scope) or *may* (optional scope) be followed. The centralized procedure is mandatory for medicinal products derived from biotechnological and other high-tech processes, orphan medicinal products, advanced therapy medicinal products and products indicated for the treatment of HIV/AIDS, cancer, diabetes, auto-immune and other immune dysfunctions, viral diseases and neurodegenerative diseases. For medicinal products that do not fall under any of the aforementioned categories, a submission via the centralized procedure is possible, provided that it concerns a new active substance or product that can demonstrate a significant therapeutic, scientific or technical innovation and for which approval would be in the interest of public health. Given the foregoing, our portfolio of innovative orphan products for neurodegenerative diseases is subject to the mandatory centralized procedure.

Innovative medicinal products which have been authorized in accordance with the centralized procedure, benefit from an eight-year period of data protection and a ten-year period of marketing protection. During the data exclusivity period, applicants for approval of generics of these innovative products cannot reference or rely upon data contained in the marketing authorization dossier submitted for the innovative medicinal product. Furthermore, the marketing protection entails that even if the generic product is approved, it cannot be placed on the market until the full ten-year period of market protection has elapsed from the initial authorization of the reference medicinal product. The marketing protection period can be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder for the innovative product obtains an authorization for new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies or as the result of significant pre-clinical or clinical trials.

Pharmaceutical companies can apply for the designation as an orphan medicine. In the EU, applications for orphan designation are evaluated by the EMA. In order to qualify as an orphan medicine, the medicinal product must be intended to diagnose, prevent or treat condition that is life-threatening or chronically debilitating, with a prevalence of no more than 5 in 10,000 people in the EU or for which it is unlikely that its sale would generate sufficient returns to justify the investment needed for its development. In addition, the sponsor is required to demonstrate that no satisfactory method of diagnosis, prevention or treatment of the condition can be authorized in the EU or, if such method exists, the medicinal product is of significant benefit to those affected by the condition as compared to approved methods. The benefits of being granted orphan designation are significant, including up to ten years of market exclusivity. During this ten-year period, the EMA may not accept a new marketing application for a similar medicinal product for the same therapeutic indication as the approved orphan medicinal product. Pursuant to Regulation (EC) 1901/2006 on medicinal products for pediatric use, the ten-year orphan market exclusivity can be extended to a maximum period of twelve years on the satisfactory completion of all the key elements of the agreed PIP. We have been granted orphan drug designation for eteplirsen in the EU.

Similar to the U.S., marketing authorization holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA and/or the national competent authorities of the EU Member States. This oversight applies both before and after the granting of manufacturing and marketing authorizations. It includes compliance with EU GMP and GDP rules in relation to such activities as distribution, importing and exporting of medicinal products, rules governing conduct of pharmacovigilance and requirements governing advertising, promotion and sale of medicinal products.

Failure to comply with the EU Member State laws implementing the EU Community Code on medicinal products, and EU rules governing the promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices, with the EU Member State laws that apply to the promotion of medicinal products, statutory health insurance, bribery and anti-corruption or with other applicable regulatory requirements can result in enforcement action by the relevant EU Member State authorities. This may include any of the following sanctions: fines, imprisonment, orders forfeiting products or prohibiting or suspending their supply to the market, orders to suspend, vary, or withdraw the marketing authorization or requiring the manufacturer to issue public warnings, or to conduct a product recall.

The approval process in other countries outside the U.S. and the EU varies from country to country, and the time may be longer or shorter than that required for the FDA approval. In addition, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement for market access vary greatly from country to country. In all cases, clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

Data and Market Exclusivities

In addition to patent exclusivities, the FDA and certain other foreign health authorities may grant data or market exclusivity for a newly approved chemical entity or biologic, which runs in parallel to any patent protection. Regulatory data protection or exclusivity prevents a potential generic competitor from relying on clinical trial data generated by the sponsor when establishing the safety and efficacy of its competing product. Market exclusivity prohibits any marketing of the same drug for the same indication.

In the U.S., the FDA will generally grant an NCE that is the subject of an NDA with five years of regulatory data exclusivity, during which time a competitor generally may not submit an application to the FDA based on a sponsor's clinical data. A competitor, however, may file an Abbreviated New Drug Application ("ANDA") seeking approval of a generic drug four years from the date of approval of the innovative product if it is accompanied by a so-called Paragraph IV certification. For a newly approved biologic that is the subject of a Biologics License Application ("BLA"), the FDA will generally grant 12 years of market exclusivity, during which time a competitor may not market the same drug for the same indication.

In addition, the FDA may provide six months of pediatric exclusivity to a sponsor of a marketing application, if the sponsor conducted a pediatric study or studies of a product. This process is applied to products developed for adult use and is initiated by the FDA as a written request for pediatric studies that applies to a sponsor's product. If the sponsor conducts qualifying studies and the studies are accepted by the FDA, then an additional six months of pediatric exclusivity will be added to previously granted exclusivity, such as orphan drug exclusivity and NCE exclusivity, as well as certain patent-based exclusivities.

Orphan Drug Designation and Exclusivity

In the U.S., the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the U.S., or more than 200,000 individuals in the U.S. for which there is no reasonable expectation that the cost of developing and making available in the U.S. a drug for this type of disease or condition will be recovered from sales in the U.S. for that drug. An orphan drug designation must be requested before submitting an application for marketing approval. An orphan drug designation does not shorten the duration of the regulatory review and approval process. The approval of an orphan designation request does not alter the regulatory requirements and process for obtaining marketing approval. Safety and efficacy of a compound must be established through adequate and well-controlled studies. If a product which has an orphan drug designation subsequently receives FDA approval for the indication for which it has such designation, the product is generally entitled to an orphan drug exclusivity period of seven years, which means the FDA may not grant approval to any other application to market the same chemical entity for the same indication for a period of seven years, except in limited circumstances, such as where an alternative product demonstrates clinical superiority to the product with orphan exclusivity. In addition, holders of exclusivity for orphan drugs are expected to assure the availability of sufficient quantities of their orphan drugs to meet the needs of patients. Failure to do so could result in the withdrawal of orphan exclusivity for the drug. Competitors may receive approval of different drugs or biologics for the indications for which a prior approved orphan drug has exclusivity.

In Europe, the EMA may grant orphan status to product candidates thereby providing such product candidates with up to ten years of marketing exclusivity, meaning that another application for marketing authorization of a later, similar medicinal product for the same therapeutic indication will generally not be approved in Europe during that time period.

Expanded / Early Access

In certain countries, drug products approved in the U.S. or the EU can be accessed by patients before the drug has obtained marketing approval in such country. There are various forms of this access including, but not limited to, the actual purchase of product by the purchaser, which is often times the government for patients, on a named patient basis, and providing the product free of charge on a named patient basis for compassionate use. Each country has its own laws and regulations that apply to these forms of access and the extent and nature of such laws and regulations vary by country. For example, in 2018, the so-called Right to Try Act became law in the U.S. The law, among other things, allows eligible patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to such eligible patients as a result of the Right to Try Act.

We have initiated an EAP for eteplirsen in select countries in Europe, North America, South America and Asia where it currently has not been approved. We are also in the process of initiating an EAP for golodirsen outside of the U.S. The EAP provides a mechanism through which physicians can prescribe our products, within their professional responsibility, to patients who meet pre-specified medical and other criteria and can secure funding. We have commenced shipments through the EAP and continue to expand the EAP to include more countries. In addition, we contracted with third party distributors and service providers to distribute our products in certain areas outside the U.S., such as Brazil and certain countries in the Middle East, on a named patient basis.

Other Regulatory Requirements

In addition to regulations enforced by the FDA and foreign authorities relating to the clinical development and marketing of products, we are or may become subject to regulation under the Occupational Safety and Health Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other present and potential future foreign, federal, state and local laws and regulations. Although we believe that we are in material compliance with applicable environmental laws that apply to us, we cannot predict whether new regulatory restrictions will be imposed by state or federal regulators and agencies or whether existing laws and regulations will adversely affect us in the future.

Healthcare Fraud and Abuse Laws

We are subject to various federal, state and local laws targeting fraud and abuse in the healthcare industry, including anti-kickback and false claims laws. Violations of fraud and abuse laws may be punishable by crime or civil sanctions, including fines and civil monetary penalties, and/or exclusion from federal health care programs (including Medicare and Medicaid). Federal and state authorities are paying increased attention to enforcement of these laws within the pharmaceutical industry, and private individuals have been active in alleging violations of the laws and bringing suits on behalf of the government under the federal False Claims Act ("FCA"). Violations of international fraud and abuse laws could result in similar penalties, including exclusion from participation in health programs outside the U.S. Given the broad scope of these laws, our activities could be subject to scrutiny under the laws. If we were subject to allegations concerning, or were convicted of violating, these laws, our business could be harmed.

The federal Anti-Kickback Statute generally prohibits, among other things, a pharmaceutical manufacturer from directly or indirectly soliciting, offering, receiving, or paying any remuneration in cash or in kind where one purpose is either to induce the referral of an individual for, or the purchase or prescription of a particular drug that is payable by a federal health care program, including Medicare or Medicaid. A person or entity does not need to have actual knowledge of the statute or a specific intent to violate the statute. Violations of the federal Anti-Kickback Statute can result in exclusion from Medicare, Medicaid or other governmental programs as well as civil and criminal fines and penalties of up to $102,522 per violation and three times the amount of the unlawful remuneration. A claim arising from a violation of the federal Anti-Kickback Statute also constitutes a false or fraudulent claim for purposes of the FCA. A new federal anti-kickback statute enacted in 2018 prohibits certain payments related to referrals of patients to certain providers (such as clinical laboratories) and applies to services reimbursed by private health plans as well as government health care programs.

Federal and state false claims laws generally prohibit anyone from knowingly and willfully, among other activities, presenting, or causing to be presented for payment to third party payors (including Medicare and Medicaid) claims for drugs or services that are false or fraudulent (which may include claims for services not provided as claimed or claims for medically unnecessary services). False or fraudulent claims for purposes of the FCA carry fines and civil penalties for violations ranging from $11,181 to $22,363 for each false claim, plus up to three times the amount of damages sustained by the federal government and, may provide the basis for exclusion from federally funded healthcare programs. There is also a criminal FCA statute by which individuals or entities that submit false claims can face criminal penalties. In addition, under the federal Civil Monetary Penalty Law, the Department of Health and Human Services Office of Inspector General has the authority to exclude from participation in federal health care programs or to impose civil penalties against any person who, among other things, knowingly presents, or causes to be presented, certain false or otherwise improper claims.

The majority of states also have anti-kickback, false claims, and similar fraud and abuse laws and although the specific provisions of these laws vary, their scope is generally broad, and there may not be regulations, guidance or court decisions that apply the laws to particular industry practices.

Laws and regulations have also been enacted by the federal government and various states to regulate the sales and marketing practices of pharmaceutical manufacturers. The laws and regulations generally limit financial interactions between manufacturers and health care providers; require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government; and/or require disclosure to the government and/or public of financial interactions (so-called "sunshine laws"). State laws may also require disclosure of pharmaceutical pricing information and marketing expenditures. Manufacturers must also submit information to the FDA on the identity and quantity of drug samples requested and distributed by a manufacturer during each year. Many of these laws and regulations contain ambiguous requirements or require administrative guidance for implementation. Given the lack of clarity in laws and their implementation, our activities could be subject to the penalty provisions of the pertinent federal and state laws and regulations.

Data Privacy and Security

We may be subject to privacy and security laws in the various jurisdictions in which we operate, obtain or store personally identifiable information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business.

Within the U.S., our operations may be affected by the Health Insurance Portability and Accountability Act of 1996 as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations (collectively, "HIPAA"), which impose obligations on certain "covered entities" (healthcare providers, health plans and healthcare clearinghouses) and certain of their "business associate" contractors with respect to safeguarding the privacy, security and transmission of individually identifiable health information. Although we believe that we currently are neither a "covered entity" nor a "business associate" under the legislation, a business associate relationship may be imputed from facts and circumstances even in the absence of an actual business associate agreement. In addition, HIPAA may affect our interactions with customers who are covered entities or their business associates because HIPAA affects the ability of these entities to disclose patient health information to us.

Various states also have laws that regulate the privacy and security of personal information and so may affect our business operations. For example, we are subject to the California Consumer Privacy Act ("CCPA"), that became effective on January 1, 2020. The CCPA gives California consumers (defined to include all California residents) certain rights, including the right to ask companies to disclose information regarding the collection, use and disclosure of their personal information. The CCPA also imposes several obligations on companies to provide notice to California consumers regarding a company's data processing activities. Additionally, the CCPA gives California consumers the right to ask companies to delete a consumer's personal information and it places limitations on a company's ability to sell personal information, including providing consumers a right to opt out of sales of their personal information. The compliance obligations imposed by the General Data Protection Regulation (the "GDPR") and the CCPA have required us to enhance our operations. The CCPA contains significant penalties for companies that violate its requirements and provides California residents a private right of action, including the ability to seek statutory damages, in the event of a data breach involving their data.

Outside the U.S., other laws regulating the privacy and security of personal information may apply. For example, the processing of personal data in the EEA, is subject to the GDPR, which took effect in May 2018. The GDPR increases obligations with respect to clinical trials conducted in the EEA, such as in relation to the provision of fair processing notices, exercising data subject rights and reporting certain data breaches to regulators and affected individuals, as well as how we document our relationships with third parties that process GDPR-covered personal data on our behalf. The GDPR also increases the scrutiny applied to transfers of personal data from the EEA (including from clinical trial sites in the EEA) to countries that are considered by the European Commission to lack an adequate level of data protection, such as the U.S. Fines for non-compliance with the GDPR have the potential to be significant—the greater of EUR 20.0 million or 4% of our global annual revenue in the previous financial year. The GDPR imposes a private right of action on data subjects and their representatives for breaches of certain data protection requirements.

Pharmaceutical Pricing and Reimbursement

We have an ongoing dialogue with payors globally with the goal of obtaining broad coverage for our products. To date, payors' policies on coverage for our products have varied widely, including policies that allow broad coverage per the respective product's prescribing information, policies that provide limited coverage and policies that have denied coverage. The majority of payors have policies that provide for case-by-case coverage or restricted coverage. Our revenue depends, in part, upon the extent to which payors provide coverage for our products and the amount that payors, including government authorities or programs, private health insurers and other organizations, reimburse patients and healthcare providers for the cost of our products.

Third Party Reimbursement and Pricing in the U.S.

Commercial Insurance. Coverage and reimbursement of our products vary from commercial payor to commercial payor. Many commercial payors, such as managed care plans, manage access to FDA approved products, and may use drug formularies and medical policies (which may include specific coverage requirements such as prior authorization, re-authorization and achieving performance metrics under value-based contracts) to control utilization. Exclusion from or restriction in coverage can reduce product usage.

Medicaid. Our products are eligible to be reimbursed by Medicaid. Medicaid is a joint federal and state program that is administered by the states for low income and disabled beneficiaries. Under the Medicaid Drug Rebate Program, participating manufacturers are required to pay a rebate for each unit of product reimbursed under the state Medicaid programs. The amount of the rebate for each product is set by law and may be subject to an additional discount if certain pricing increases more than inflation. State Medicaid programs and Medicaid managed care plans can seek additional "supplemental" rebates from manufacturers in connection with favorable positioning on formularies.

Medicare. Medicare is a federal program that is administered by the federal government that covers individuals age 65 and over as well as those with certain disabilities. Our products are eligible for reimbursement under Medicare Part B. Medicare Part B generally covers drugs that must be administered by physicians. Medicare Part B pays for such drugs under a payment methodology based on the average sales price ("ASP") of the drugs. Reimbursement levels and reimbursement methodologies have come under scrutiny and may be subject to change. The Centers for Medicare & Medicaid Services ("CMS") are also increasingly bundling drug reimbursement into procedure costs, which can severely decrease the reimbursement rates for some manufacturers' drugs.

Federal Purchasers. Drug products are subject to discounted pricing when purchased by federal agencies via the Federal Supply Schedule ("FSS"). FSS participation is required for a drug product to be covered and reimbursed by certain federal agencies and for coverage under Medicaid, Medicare Part B and the Public Health Service ("PHS") 340B drug pricing program. FSS pricing is negotiated periodically with the Department of Veterans Affairs. FSS pricing is intended not to exceed the price that a manufacturer charges its most-favored non-federal customer for its product. In addition, prices for drugs purchased by the Veterans Administration, Department of Defense (including drugs purchased by military personnel and dependents through the TRICARE retail pharmacy program), Coast Guard, and PHS are subject to a cap on pricing (known as the "federal ceiling price") and may be subject to an additional discount if pricing increases more than the rate of inflation.

PHS 340B Drug Pricing Program. To maintain coverage of drugs under the Medicaid Drug Rebate Program and Medicare Part B, manufacturers are required to extend discounts to certain purchasers under the PHS 340B drug pricing program. Purchasers eligible for discounts include hospitals that serve a disproportionate share of financially needy patients, community health clinics and other entities that receive health services grants from the PHS.

Healthcare and Other Reform. In the U.S., federal and state governments continue to propose and pass legislation designed to reform delivery of, or payment for, health care, which include initiatives to reduce the cost of healthcare. For example, in March 2010, the U.S. Congress enacted the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act (the "Healthcare Reform Act"), which expanded health care coverage through Medicaid expansion, implemented the "individual mandate" for health insurance coverage (by imposing a tax penalty on individuals who did not obtain insurance) and changed the coverage and reimbursement of drug products under government healthcare programs. Under the Trump administration, there have been ongoing efforts to modify or repeal all or certain provisions of the Healthcare Reform Act. Tax reform legislation was enacted at the end of 2017 that includes provisions that will affect healthcare insurance coverage and payment, such as the elimination of the tax penalty for individuals who do not maintain sufficient health insurance coverage. The Healthcare Reform Act has also been subject to judicial challenge. In December 2018, a federal district court judge, in a challenge brought by a number of state attorneys general, found the Healthcare Reform Act unconstitutional in its entirety because once Congress repealed the "individual mandate" provision, there was no longer a basis to rely on Congressional taxing authority to support enactment of the law. The court reasoned that the "individual mandate" was not severable from the rest of the Healthcare Reform Act and found the entire Healthcare Reform Act was an unconstitutional exercise of Congressional authority. In December 2019, a federal appeals court agreed that the individual mandate provision was unconstitutional, but remanded the case back to the district court to assess more carefully whether any provisions of the Healthcare Reform Act were severable and could survive. Pending action by the district court and resolution of any appeals, which could take some time, the Healthcare Reform Act is still operational in all respects.

There have been other reform initiatives under the Trump Administration. For example, in May 2018, President Trump and the Secretary of the Department of Health and Human Services released a "blueprint" to lower prescription drug prices and out-of-pocket costs. Certain proposals in the blueprint, and related drug pricing measures proposed since the blueprint, could cause significant operational and reimbursement changes for the pharmaceutical industry. As another example, in October 2018, the CMS solicited public comments on potential changes to payment for certain Medicare Part B drugs, including reducing the Medicare payment amount for selected Medicare Part B drugs to more closely align with international drug prices. As another example, legislation passed in 2019 revised how certain prices reported by manufacturers under the Medicaid Drug Rebate Program are calculated, a revision that the Congressional Budget Office has estimated will save the Medicaid program approximately $3.0 billion in the next ten years.

There have also been efforts by government officials or legislators to implement measures to regulate prices or payment for pharmaceutical products, including legislation on drug importation. Recently, there has been considerable public and government scrutiny of pharmaceutical pricing and proposals to address the perceived high cost of pharmaceuticals. There have also been recent state legislative efforts to address drug costs, which generally have focused on increasing transparency around drug costs or limiting drug prices. Certain state legislation has been subject to legal challenges. Adoption of new legislation regulating drug pricing at the federal or state level could further affect demand for, or pricing of, our products.

General legislative cost control measures may also affect reimbursement for our products. The Budget Control Act, as amended, resulted in the imposition of 2% reductions in Medicare (but not Medicaid) payments to providers in 2013 and will remain in effect through 2029 unless additional Congressional action is taken. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented and/or any significant taxes or fees that may be imposed on us could have an adverse impact on our results of operations.

Third Party Reimbursement and Pricing outside the U.S.

We currently have no products approved for marketing outside the U.S., other than a marketing authorization for EXONDYS 51 in Israel. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. In the EU and certain other territories, price controls and Health Technology Assessments for new, highly priced medicines are expected. Uncertainty exists about the pricing and reimbursement status of newly approved products in the EU. Criteria such as cost-effectiveness, cost per quality-adjusted life year, budget impact, or others, in addition to the clinical benefit, are often required to demonstrate added value or benefit of a drug and vary by country. Third party reimbursement limits may reduce the demand for our products. The pace of the application process in some countries could also delay commercial product launches. Gaining acceptance of our product pipeline and an economically viable reimbursement terms in the EU and other markets will require strong education and awareness efforts around DMD as well as strong data supporting its effectiveness and cost-effectiveness.

Competition

The pharmaceutical and biotechnology industries are intensely competitive, and any product candidate developed by us would likely compete with existing drugs and therapies. There are many pharmaceutical companies, biotechnology companies, public and private universities, government agencies and research organizations that compete with us in developing various approaches to the treatment of rare, neuromuscular and other diseases. Many of these organizations have substantially greater financial, technical, manufacturing and marketing resources than we have. Several of them have developed or are developing therapies that could be used for treatment of the same diseases that we are targeting. In addition, some of these competitors have significantly greater commercial infrastructures than we have. Our ability to compete successfully will depend largely on:

- our ability to complete clinical development and obtain regulatory approvals for our product candidates;
- the efficacy, safety and reliability of our product candidates;
- the timing and scope of regulatory approvals;
- product acceptance by physicians and other health-care providers;
- protection of our proprietary rights and the level of generic competition;
- the ability to have freedom to operate to commercialize our product candidates;
- the speed at which we develop product candidates;
- our ability to supply commercial quantities of a product to the market;
- obtaining reimbursement for product use in approved indications;
- our ability to recruit and retain skilled employees; and
- the availability of substantial capital resources to fund development and commercialization activities, including the availability of funding from the U.S. government.

DMD Program Competition. Currently, other than EXONDYS 51 and VYONDYS 53, no disease-modifying product has been approved for the treatment of DMD in the U.S. Other companies, however, have product candidates or other interests in development for the treatment of DMD.

Wave Life Sciences (“Wave”) until recently was developing an exon 51 skipping product candidate for DMD, suvodirsen (WVE-210201). Wave also reported its intent to develop an exon 53 skipping product candidate, WVE-N531. On December 16, 2019, Wave announced the discontinuation of suvodirsen development for DMD (exon 51 amenable patients) and the suspension of further development of WVE-N531 for DMD (exon 53 amenable patients).

Nippon Shinyaku Co. Ltd. (“Nippon”) has reported clinical data for its exon 53 skipping candidate, viltolarsen (NS-065/NCNP-01), from a Phase 1/2 study in Japan and a Phase 2 study in the U.S. Viltolarsen has been reported to have received an orphan drug designation in the U.S., was granted fast track designation by FDA and received a “SAKIGAKE designation” in Japan from the Japanese Ministry of Health, Labor, and Welfare (“MHLW”). Nippon reported in February 2019 that it had initiated a rolling NDA submission with the FDA. Nippon announced on February 7, 2020 that the FDA has filed its NDA for viltolarsen setting a target action date of the third calendar quarter of 2020. Nippon announced on September 26, 2019 that it submitted its NDA for viltolarsen in Japan to the MHLW.

Daiichi Sankyo (“Daiichi”) has reported a phase 1/2 clinical trial being underway in Japan for its exon 45 skipping candidate, DS-5141b. In April 2018, Daiichi announced top-line results of the Phase 1/2 clinical trial in Japan of DS-5141 and that Daiichi will continue to develop DS-5141b. Daiichi continues to sponsor an ongoing Phase 1/2 clinical trial of DS-5141b that is active and not recruiting.

Solid Biosciences, LLC (“Solid”) has reported that its micro-dystrophin gene transfer product candidate for DMD, SGT-001 began a Phase 2 clinical study in December 2017. SGT-001 was granted fast track designation by the FDA in October 2018, orphan drug designation in August 2016, and rare pediatric disease designation in 2017. In Europe, orphan designation was granted in September 2016. In February 2019, Solid reported micro-dystrophin expression data for the first three patients in its clinical trial and announced plans to continue the study at a higher dose pending FDA and IRB approval. Solid announced on January 9, 2020 that in response to the FDA placing the SGT-001 IGNITE DMD trial on clinical hold, previously announced in November 2019, it is conducting its analyses of SGT-001 to determine how to address the clinical hold and resume dosing.

Pfizer Inc. (“Pfizer”), following its acquisition of Bamboo Therapeutics, Inc., has initiated a Phase 1 clinical trial in January 2018 to test the safety and tolerability of its AAV-9 / micro-dystrophin gene transfer product candidate for DMD, PF-06939926/BMB-D001. The related orphan designation was granted in Europe in August 2016, and in the U.S. in May 2017. Rare pediatric disease designation was granted by the FDA in April 2018. In June 2019, Pfizer presented initial Phase 1b clinical data on PF-06939926, and on January 28, 2020, it announced that it expects proof-of-concept readouts for PF-06939926 in the first half of 2020.

Other companies continue to pursue approval of products for the treatment of DMD and their products may or may not prove to be safer and/or more efficacious than the products and product candidates in our DMD pipeline. Regarding any of these competitors, it is unknown if further clinical development of these or other exon-skipping compounds is planned.

Additionally, companies such as Santhera, PTC Therapeutics, Catabasis, Fibrogen, ReveraGen, Capricor, BioPhytis, Mallinckrodt, Astellas Pharma, and Tivorsan have product candidates with mechanisms of action distinct from ours in different stages of development or approval in DMD which we believe could be seen as complementary to exon skipping and not a direct replacement of our products or product candidates at this time.

In addition, several companies and institutions have recently entered into collaborations or other agreements for the development of product candidates, including mRNA, gene (CRISPR, AAV, etc.) or small molecule therapies that are potential competitors for therapies being developed in the muscular dystrophy, neuromuscular, CNS and rare disease space, including but not limited to Audentes (now Astella), 4D Molecular Therapeutics, Biogen Inc., Ionis, Synthena AG, Alexion Pharmaceuticals, Inc., Sanofi, Takeda, Roche, Novartis, Eli Lilly, Alnylam Pharmaceuticals, Inc., Moderna Therapeutics, Inc., Akashi, Oxford University, Exonics Therapeutics (acquired by Vertex Pharmaceuticals), CRISPR Therapeutics and Editas Medicine.

Platform Technology Competition. We believe that other biotechnology and pharmaceutical companies share a focus on RNA-targeted drug discovery and development. Competitors with respect to our RNA-targeted technologies include, but are not limited to, Alnylam, Tekmira Pharmaceuticals Corp., Deciphera Pharmaceuticals, Ionis, BioMarin, Sanofi, Synthena AG, Roche Innovation Center Copenhagen (formerly Santaris Pharma A/S), Shire plc (now Takeda), Nippon, Daiichi Sankyo, Moderna Therapeutics, Avidity, Dyne Therapeutics, Stoke Therapeutics and Wave.

Employees

As of December 31, 2019, we had 743 employees, 387 of whom hold advanced degrees. Of these employees, 397 are engaged directly in research and development activities and 346 are in selling, general and administration including 71 in the sales force. None of our employees are covered by collective bargaining agreements and we consider relations with our employees to be good.

General Corporate Information

We were originally incorporated in the State of Oregon on July 22, 1980, and on June 6, 2013, we reincorporated in the State of Delaware. Our principal executive offices are located at 215 First Street, Suite 415, Cambridge, MA 02142 and our telephone number is (617) 274-4000. Our common stock is quoted on the Nasdaq Global Select Market under the symbol “SRPT”.

While we achieve revenue from EXONDYS 51 and VYONDYS 53 in the U.S. and through distribution of eteplirsen on a named patient basis or through our EAP outside the U.S., we are likely to continue to incur operating losses in the near term associated with our ongoing operations, research and development activities and potential business development activities. For more information about our revenues and operating losses, see *Item 7, Management’s Discussion and Analysis of Financial Condition and Results of Operations*.

As of December 31, 2019, we had approximately $1,134.4 million of cash, cash equivalents and investments, consisting of $835.1 million of cash and cash equivalents, $289.7 million of short-term investments and $9.6 million of long-term restricted cash investments. We believe that our balance of cash, cash equivalents and investments is sufficient to fund our current operational plan for at least the next twelve months. In addition to pursuing additional cash resources through public or private financings, we may also seek to enter into contracts, including collaborations or licensing agreements with respect to our technologies, with third parties, including government entities.

Where You Can Find Additional Information

We make available free of charge through our corporate website, www.sarepta.com, our annual reports, quarterly reports, current reports, proxy statements and all amendments to those reports as soon as reasonably practicable after such material is electronically filed or furnished with the SEC. These reports may also be obtained without charge by submitting a written request via mail to Investor Relations, Sarepta Therapeutics, Inc., 215 First Street, Suite 415, Cambridge, MA 02142 or by e-mail to investorrelations@sarepta.com. Our internet website and the information contained therein or incorporated therein are not intended to be incorporated into this Annual Report on Form 10-K. In addition, the Securities and Exchange Commission (the "SEC") maintains an Internet site that contains reports, proxy and information statements, and other information regarding reports that we file or furnish electronically with the SEC at www.sec.gov.

We have adopted a Code of Business Conduct and Ethics and written charters for our Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee. Each of the foregoing is available on our website at www.sarepta.com under "For Investors—Corporate Governance." In accordance with SEC rules, we intend to disclose any amendment (other than any technical, administrative, or other non-substantive amendment) to the above code, or any waiver of any provision thereof with respect to any of our executive officers, on our website within four business days following such amendment or waiver. In addition, we may use our website as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation Fair Disclosure promulgated by the SEC. These disclosures will be included on our website under the "For Investors" section.

Item 1A. Risk Factors.

Set forth below and elsewhere in this report and in other documents we file with the SEC are descriptions of risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements contained in this report. Because of the following factors, as well as other variables affecting our operating results, past financial performance should not be considered a reliable indicator of future performance and investors should not use historical trends to anticipate results or trends in future periods. The risks and uncertainties described below are not the only ones facing us. Other events that we do not currently anticipate or that we currently deem immaterial also affect our results of operations and financial condition.

Risks Related to Our Business

We are highly dependent on the commercial success of our products in the U.S. We may not be able to meet expectations with respect to sales of our products or attain profitability and positive cash-flow from operations.

On September 19, 2016 and December 12, 2019, the FDA granted accelerated approval for EXONDYS 51 and VYONDYS 53, respectively, as therapeutic treatments for DMD in patients who have a confirmed mutation in the DMD gene that is amenable to exon 51 and exon 53 skipping, respectively. EXONDYS 51 is currently commercially available in the U.S. and Israel only, and VYONDYS 53 is currently commercially available in the U.S. only, although they are available in additional countries through our EAP. The commercial success of our products continues to depend on a number of factors, including, but not limited to:

- the effectiveness of our sales, managed markets, marketing efforts and support for our products;
- the generation and dissemination of new data analyses and the consistency of any new data with prior results, whether they support a favorable safety, efficacy and effectiveness profile of our products and any potential impact on our FDA accelerated approval status and/or FDA package insert for our products;
- the effectiveness of our ongoing commercialization activities, including negotiating and entering into any additional commercial, supply and distribution contracts, ongoing manufacturing efforts and hiring any additional personnel as needed to support commercial efforts;
- our ability to comply with FDA post-marketing requirements and commitments, including through successfully conducting additional studies that confirm clinical efficacy, effectiveness and safety of our products and acceptance of the same by the FDA and medical community since continued approval may be contingent upon verification of a clinical benefit in confirmatory trials;

- the occurrence of any side effects, adverse reactions or misuse, or any unfavorable publicity in these areas;
- the generation of evidence describing payers, patients and/or societal value of our products;
- whether we can consistently manufacture our products and product candidates at acceptable costs;
- the rate and consistency with which our products are prescribed by physicians, which depends on physicians' views on the safety, effectiveness and efficacy of our products;
- our ability to secure and maintain adequate reimbursement for our products, including the duration of the prior-authorization as well as the number and duration of re-authorization processes required for patients who initially obtained coverage by third parties, including by government payors, managed care organizations and private health insurers;
- our ability to obtain and maintain patent protection for our products, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights and to operate without infringing on the proprietary rights of third parties;
- the development, commercialization or pricing of competing products or therapies for the treatment of DMD, or its symptoms, and the existence of competing clinical trials;
- our ability to increase awareness of the importance of genetic testing and knowing/understanding DMD mutations, and identifying and addressing procedural barriers to obtaining therapy;
- our ability to remain compliant with laws and regulations that apply to us and our commercial activities;
- the actual market-size, ability to identify patients and the demographics of patients eligible for our products, which may be different than expected;
- the sufficiency of our drug supply to meet commercial and clinical demands and standards, which are negatively impacted by various factors, including when our projections on the potential number of amenable patients and their average weight are inaccurate; if regulatory requirements increase our drug supply needs; if our current drug supply is destroyed or negatively impacted at our manufacturing sites, storage sites or in transit; failure to meet cGMP requirements; or if we encounter delays expanding the number of patients on our products and portions of our products' supply expire before sale;
- our ability to obtain regulatory approvals to commercialize our product candidates, and to commercialize our products in markets outside of the U.S.;
- the process leading to a patient's first infusion of our products may be slower for certain patients. For example, the time to first infusion may take longer if a patient chooses to put in an intravenous port, which eases access to the vein. Delays in the process prior to first infusion could negatively impact the sales of our products; and
- the exercise by Roche of its option to obtain an exclusive license to commercialize one or more of our products outside of the U.S. and Roche's subsequent commercialization efforts.

We experience significant fluctuations in sales of our products from period to period and, ultimately, we may never generate sufficient revenues from our products to reach or maintain profitability or sustain our anticipated levels of operations.

Even though EXONDYS 51 and VYONDYS 53 have received accelerated approval by the FDA, they face future post-approval development and regulatory requirements, which will present additional challenges we will need to successfully navigate.

The accelerated approvals for EXONDYS 51 and VYONDYS 53 granted by the FDA were based on an increase in the surrogate biomarker of dystrophin in skeletal muscles observed in some patients treated with EXONDYS 51 and VYONDYS 53. These products will be subject to ongoing FDA requirements governing labeling, packaging, storage, advertising, promotion and recordkeeping, and we are required to submit additional safety, efficacy and other post-marketing information to the FDA.

Under the accelerated approval pathway, continued approval may be contingent upon verification of a clinical benefit in confirmatory trials. These post-approval requirements and commitments may not be feasible and/or could impose significant burdens and costs on us; could negatively impact our development, manufacturing and supply of our products; and could negatively impact our financial results. Failure to meet post-approval commitments and requirements, including completion of enrollment and in particular, any failure to obtain positive safety and efficacy data from our ongoing and planned studies of our products, would lead to negative regulatory action from the FDA and/or withdrawal of regulatory approval of EXONDYS 51 or VYONDYS 53.

Manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. Drug product manufacturers are required to continuously monitor and report adverse events from clinical trials and commercial use of the product. If we or a regulatory agency discover previously unknown adverse events or events of unanticipated severity or frequency, a regulatory agency may require labeling changes, implementation of risk evaluation and mitigation strategy program, or additional post-marketing studies or clinical trials. If we or a regulatory agency discover previously unknown problems with a product, such as problems with a facility where the API or drug product is manufactured or tested, a regulatory agency may impose restrictions on that product and/or the manufacturer, including removal of specific product lots from the market, withdrawal of the product from the market, or suspension of manufacturing. Sponsors of drugs approved under FDA accelerated approval provisions also are required to submit to the FDA, at least 30 days before initial use, all promotional materials intended for use after the first 120 days following marketing approval. If we or the manufacturing facilities for our products fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw or alter the conditions of our marketing approval;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- suspend any ongoing clinical trials;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- refuse to approve pending applications or supplements to applications submitted by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements;
- seize or detain products, refuse to permit the import or export of products or require us to initiate a product recall; or
- refuse to allow us to enter into supply contracts, including government contracts.

We are subject to uncertainty relating to reimbursement policies which, if not favorable, could hinder or prevent the commercial success of our products and/or product candidates.

Our ability to successfully maintain and/or increase sales of our products in the U.S. depends in part on the coverage and reimbursement levels set by governmental authorities, private health insurers and other third-party payors. Third party payors are increasingly challenging the effectiveness of and prices charged for medical products and services. We may not be able to obtain or maintain adequate third-party coverage or reimbursement for our products, and/or we may be required to provide discounts or rebates on our products in order to obtain or maintain adequate coverage.

We expect that private insurers will continue to consider the efficacy, effectiveness, cost-effectiveness and safety of our products, including any new data and analyses that we are able to collect and make available in a compliant manner, in determining whether to approve reimbursement for our products and at what levels. If there are considerable delays in the generation of new evidence or if any new data and information we collect is not favorable, third party insurers may make coverage decisions that negatively impact sales of our products. We continue to have discussions with payors, some of which may eventually deny coverage. We may not receive approval for reimbursement of our products from additional insurers on a satisfactory rate or basis, in which case our business would be materially adversely affected. In addition, obtaining these approvals can be a time consuming and expensive process. Our business would be materially adversely affected if we are not able to maintain favorable coverage decisions and/or fail to receive additional favorable coverage decisions from third party insurers, in particular during re-authorization processes for patients that have already initiated therapy. Our business could also be adversely affected if government health programs, private health insurers, including managed care organizations, or other reimbursement bodies or payors limit the indications for which our products will be reimbursed or fail to recognize accelerated approval and surrogate endpoints as clinically meaningful.

In some foreign countries, particularly Canada and the countries of Europe, Latin America and Asia Pacific, the pricing of prescription pharmaceuticals is subject to strict governmental control. In these countries, pricing negotiations with governmental authorities can take 12 to 24 months or longer after the receipt of regulatory approval and product launch. In order to obtain favorable reimbursement for the indications sought or pricing approval in some countries, we may be required to collect additional data, including conducting additional studies. Furthermore, several European countries have implemented government measures to either freeze or reduce pricing of pharmaceutical products. If reimbursement for our products is unavailable in any country in which reimbursement is sought, limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed. In addition, many foreign countries are referencing to other countries' official public list price, hence an unsatisfactory price level in one country could consequently impinge negatively upon overall revenue.

We expect to experience pricing pressures in connection with the sale of our current and future products due to a number of factors, including current and future healthcare reforms and initiatives by government health programs and private insurers (including managed care plans) to reduce healthcare costs, the scrutiny of pharmaceutical pricing, the ongoing debates on reducing government spending and additional legislative proposals. These healthcare reform efforts or any future legislation or regulatory actions aimed at controlling and reducing healthcare costs, including through measures designed to limit reimbursement, restrict access or impose unfavorable pricing modifications on pharmaceutical products, could impact our and our partners' ability to obtain or maintain reimbursement for our products at satisfactory levels, or at all, which could materially harm our business and financial results.

Additionally, our gene therapy product candidates represent novel approaches to treatment that will call for new levels of innovation in both pricing, reimbursement, payment and drug access strategies. Current reimbursement models may not accommodate the unique factors of our gene therapy product candidates, including high up-front costs, lack of long-term efficacy and safety data and fees associated with complex administration, dosing and patient monitoring requirements. Hence, it may be necessary to restructure approaches to payment, pricing strategies and traditional payment models to support these therapies.

The downward pressure on healthcare costs in general has become intense. As a result, increasingly high barriers are being erected to the entry of new products. If we are unable to obtain adequate levels of reimbursement, our ability to successfully market and sell our products and product candidates will be harmed. The manner and level at which reimbursement is provided for services related to our products and product candidates (e.g., for administration of our products to patients) is also important. Inadequate reimbursement for such services may lead to physician resistance and limit our ability to market or sell our products.

Healthcare reform and other governmental and private payor initiatives may have an adverse effect upon, and could prevent commercial success of our products and product candidates.

The U.S. government and individual states have aggressively pursued healthcare reform, as evidenced by the passing of the Healthcare Reform Act and the ongoing efforts to modify or repeal that legislation. The Healthcare Reform Act substantially changed the way healthcare is financed by both governmental and private insurers and contains a number of provisions that affect coverage and reimbursement of drug products and/or that could potentially reduce the demand for pharmaceutical products such as increasing drug rebates under state Medicaid programs for brand name prescription drugs and extending those rebates to Medicaid managed care and assessing a fee on manufacturers and importers of brand name prescription drugs reimbursed under certain government programs, including Medicare and Medicaid. Other aspects of healthcare reform, such as expanded government enforcement authority and heightened standards that could increase compliance-related costs, could also affect our business. Modifications have been implemented under the Trump Administration and additional modifications or repeal may occur. There are, and may continue to be, judicial challenges. We cannot predict the ultimate content, timing or effect of any changes to the Healthcare Reform Act or other federal and state reform efforts. There is no assurance that federal or state health care reform will not adversely affect our future business and financial results, and we cannot predict how future federal or state legislative, judicial or administrative changes relating to healthcare reform will affect our business.

The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, waiver from Medicaid drug rebate law requirements, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs and the introduction of international reference pricing in the U.S. We anticipate that the U.S. Congress, state legislatures and the private sector will continue to consider and may adopt healthcare policies intended to curb rising healthcare costs. These cost containment measures may include implementation or modification of:

- controls on government funded reimbursement for drugs;
- caps or mandatory discounts under certain government sponsored programs;
- controls on healthcare providers;
- challenges to the pricing of drugs or limits or prohibitions on reimbursement for specific products through other means;
- reform of drug importation laws;
- delegation of decision making to state Medicaid agencies and waiver of reimbursement requirements;
- expansion of use of managed care systems in which healthcare providers contract to provide comprehensive healthcare for a fixed cost per person; and
- prohibition on direct-to-consumer advertising or drug marketing practices.

We are unable to predict what additional legislation, regulations or policies, if any, relating to the healthcare industry or third party coverage and reimbursement may be enacted in the future or what effect such legislation, regulations or policies would have on our business. Any cost containment measures, including those listed above, or other healthcare system reforms that are adopted, could significantly decrease the available coverage and the price we might establish for our products and product candidates, which would have an adverse effect on our net revenues and operating results.

Our products may not be widely adopted by patients, payors or healthcare providers, which would adversely impact our potential profitability and future business prospects.

The commercial success of our products, particularly in the near term in the U.S., depends upon the level of market adoption by patients, payors and healthcare providers. If our products do not achieve an adequate level of market adoption for any reason, or if market adoption does not persist, our potential profitability and our future business prospects will be severely adversely impacted. The degree of market acceptance of our products depends on a number of factors, including:

- our ability to demonstrate to the medical and payor community, including specialists who may purchase or prescribe our products, the clinical efficacy, effectiveness and safety of our products as the prescription products of choice for their respective indications;
- the effectiveness of our sales and marketing organizations and distribution networks;
- the ability of patients or providers to be adequately reimbursed for our products in a timely manner from government and private payors;
- the ability to timely demonstrate to the satisfaction of payors real world effectiveness and the economic, humanistic and societal benefits of our products;
- the actual and perceived efficacy and safety profile of our products, particularly if unanticipated adverse events related to our products' treatment arise and create safety concerns among potential patients or prescribers or if new data and analyses we obtain for our products do not support, or are interpreted by some parties to not support, the efficacy of our products; and
- the efficacy and safety of our other exon-skipping product candidates, including our exon 45 product candidate (casimersen), and third parties' competitive therapies.

We may not be able to expand the global footprint of our products outside of the U.S.

Even though EXONDYS 51 was approved for marketing in the U.S. and in Israel, and VYONDYS 53 was approved for marketing in the U.S., we may not receive approval to commercialize these products in additional countries. In November 2016, we submitted a MAA for eteplirsen to the EMA and the application was validated in December 2016. As we announced on June 1, 2018, the CHMP of the EMA adopted a negative opinion for eteplirsen. In September 2018, the CHMP of the EMA confirmed its negative opinion for eteplirsen, and the European Commission adopted the CHMP opinion in December 2018. During 2019, we sought follow-up EMA scientific advice for eteplirsen. Once data from our ongoing studies is available, we plan to evaluate future engagement with the EMA on potential next steps.

In order to market any product in a country outside of the U.S., we must comply with numerous and varying regulatory requirements for approval in those countries regarding demonstration of evidence of the product's safety and efficacy and governing, among other things, labeling, distribution, advertising, and promotion, as well as pricing and reimbursement of the product. Obtaining marketing approval in a country outside of the U.S. is an extensive, lengthy, expensive and uncertain process, and the regulatory authority may reject an application or delay, limit or deny approval of any of our products for many reasons, including:

- we may not be able to demonstrate to the satisfaction of regulatory authorities outside the U.S. the risk benefit of our products;
- the results of clinical trials may not meet the level of statistical or clinical significance required for approval by regulatory authorities outside the U.S.;
- regulatory authorities outside the U.S. may disagree with the adequacy (number, design, size, controls, conduct or implementation) of our clinical trials prior to granting approval, and we may not be able to generate the required data on a timely basis, or at all;
- regulatory authorities outside the U.S. may conclude that data we submit to them fail to demonstrate an appropriate level of safety or efficacy of our products, or that our products' respective clinical benefits outweigh their safety risks;
- regulatory authorities outside the U.S. may not accept data generated at our clinical trial sites or require us to generate additional data or information;
- regulatory authorities outside the U.S. may impose limitations or restrictions on the approved labeling of our products, thus limiting intended users or providing an additional hurdle for market acceptance of the product;
- regulatory authorities outside the U.S. may identify deficiencies in the manufacturing processes, or may require us to change our manufacturing process or specifications; and
- regulatory authorities outside the U.S. may adopt new or revised approval policies and regulations.

Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ significantly from that required to obtain approval in the U.S. In particular, in many foreign countries, it is required that a product receives pricing and reimbursement approval before the product can be distributed commercially. Many foreign countries undertake cost-containment measures that could affect pricing or reimbursement of our products. This can result in substantial delays, and the price that is ultimately approved in some countries may be lower than the price for which we expect to offer our products.

Marketing approval in one country does not ensure marketing approval in another, but a failure or delay in obtaining marketing approval in one country may have a negative effect on the approval process in others. Failure to obtain marketing approval in other countries or any delay or setback in obtaining such approval would impair our ability to develop foreign markets for our products and could adversely affect our business and financial condition. In addition, failure to obtain approval in one country or area may affect sales under the EAP in other countries or areas. Even if we are successful in obtaining regulatory approval of our products in additional countries, our revenue earning capacity will depend on commercial and medical infrastructure, pricing and reimbursement negotiations and decisions with third party payors, including government payors.

In addition, we have granted Roche an exclusive option to obtain an exclusive license to commercialize certain products, including eteplirsen and golodirsen, outside of the U.S. If this option is exercised, Roche will have sole control over and decision-making authority with respect to the commercialization of such products outside the U.S.

We cannot predict whether historical revenues from eteplirsen through our EAP outside the U.S. will continue or whether we will be able to continue to distribute eteplirsen through our EAP.

We have initiated an EAP for eteplirsen in select countries in Europe, North America, South America and Asia where it currently has not been approved. We are also in the process of initiating an EAP for golodirsen outside of the U.S. While we generate revenue from the distribution of eteplirsen through our EAP, we cannot predict whether historical revenues from this program will continue, whether we will be able to continue to distribute our products through our EAP, or whether commercial revenues will exceed revenues historically generated from sales through our EAP. Reimbursement through national EAPs may cease to be available if authorization for an EAP expires or is terminated. For example, healthcare providers in EAP jurisdictions may not be convinced that their patients benefit from our products or may prefer to wait until such time as our products are approved by a regulatory authority in their country before prescribing any of our products. Even if a healthcare provider is interested in obtaining access to our products for its patient through the EAP, the patient will not be able to obtain access to our products if payment for the drug is not secured.

Any failure to maintain revenues from sales of eteplirsen through our EAP and/or to generate revenues from commercial sales of eteplirsen exceeding historical sales through our EAP could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

If we are unable to successfully maintain and further develop internal commercialization capabilities, sales of our products may be negatively impacted.

We have hired and trained a commercial team and put in the organizational infrastructure we believe we need to support the commercial success of our products in the U.S. Factors that may inhibit our efforts to maintain and further develop commercial capabilities include:

- an inability to retain an adequate number of effective commercial personnel;
- an inability to train sales personnel, who may have limited experience with our company or our products, to deliver a consistent message regarding our products and be effective in educating physicians on how to prescribe our products;
- an inability to equip sales personnel with compliant and effective materials, including medical and sales literature to help them educate physicians and our healthcare providers regarding our products and their proper administration and educate payors on the safety, efficacy and effectiveness profile of our products to support favorable coverage decisions; and
- unforeseen costs and expenses associated with maintaining and further developing an independent sales and marketing organization.

If we are not successful in maintaining an effective commercial, sales and marketing infrastructure, we will encounter difficulty in achieving, maintaining or increasing projected sales of our products in the U.S., which would adversely affect our business and financial condition.

If we are unable to execute effectively our sales and marketing activities outside the U.S., we may be unable to generate sufficient product revenue.

EXONDYS 51 and VYONDYS 53 are our first and second commercial products, respectively. As a result, our sales, marketing, managerial and other non-technical capabilities are relatively new in the U.S. We have built a commercial sales force in Europe and we are currently in the process of building commercial infrastructure in other key countries in order to be ready to launch our products with a relatively small specialty sales force in the event our products are ultimately approved in those jurisdictions. The establishment and development of our commercial infrastructure will continue to be expensive and time consuming, and we may not be able to successfully develop this capability in a timely manner or at all. We anticipate building sales, medical, marketing, managerial, distribution and other capabilities across multiple jurisdictions to prepare for potential approvals ex-U.S. Doing so will require a high degree of coordination and compliance with laws and regulations in such jurisdictions. If we are unable to effectively coordinate such activities or comply with such laws and regulations, our ability to commercialize our products in such jurisdictions will be adversely affected. Even if we are able to effectively hire a sales force and develop marketing and sales capabilities, our sales force may not be successful in commercializing our products or any product candidate that we develop. If we are unable to establish adequate manufacturing, sales, marketing, supply and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenue and may not become profitable outside of the U.S. Furthermore, we have granted Roche an exclusive option to obtain an exclusive license to commercialize certain products, including eteplirsen and golodirsen, outside of the U.S. If this option is exercised, Roche will have sole control over and decision-making authority with respect to the commercialization of such products outside the U.S.

If we fail to obtain or maintain regulatory exclusivity for our products, then we may not be able to protect our products from competition and our business may be adversely impacted. If a competitor obtains an authorization to market the same or substantially same product before a product of ours is authorized in a given country and is granted regulatory exclusivity, then our product may not be authorized for sale as a result of the competitor's regulatory exclusivity and as a result, our investment in the development of that product may not be returned.

In addition to any patent protection, we rely on various forms of regulatory exclusivity to protect our products. During the development of our products, we anticipate regulatory exclusivities available upon approval of our products. Implementation and enforcement of regulatory exclusivity, which may consist of regulatory data protection and market protection, varies widely from country to country. Failure to qualify for regulatory exclusivity, or failure to obtain or maintain the extent or duration of such protections that we expect in each of the markets for our products due to challenges, changes or interpretations in the law or otherwise, could affect our revenues for our products or our decision on whether to market our products in a particular country or countries or could otherwise have an adverse impact on our results of operations. We are not guaranteed to receive or maintain regulatory exclusivity for our current or future products, and if our products that are granted orphan status were to lose their status as orphan drugs or the data or marketing exclusivity provided for orphan drugs, our business and operations could be adversely affected.

Due to the nature of our products and product candidate pipeline, in addition to new chemical entity exclusivity and new biologic exclusivity, orphan drug exclusivity is especially important for our products that are eligible for orphan drug designation. For eligible products, we plan to rely on orphan drug exclusivity to maintain a competitive position. If we do not have adequate patent protection for our products, then the relative importance of obtaining regulatory exclusivity is even greater. While orphan status for any of our products, if granted or maintained, would provide market exclusivity for the time periods specified above upon approval, we would not be able to exclude other companies from obtaining regulatory approval of products using the same or similar active ingredient for the same indication during or beyond the exclusivity period applicable to our product on the basis of orphan drug status (e.g., seven years in the U.S.). Orphan drug designation neither shortens the development time or regulatory review time of a drug, nor gives the drug any advantage in the regulatory review or approval process.

In addition, we may face risks with maintaining regulatory exclusivities for our products, and our protection may be circumvented, even if maintained. For instance, orphan drug exclusivity in the U.S. may be rescinded if (i) an alternative, competing product demonstrates clinical superiority to our product with orphan exclusivity; or (ii) we are unable to assure the availability of sufficient quantities of our orphan products to meet the needs of patients. Moreover, competitors may receive approval of different drugs or biologics for indications for which our prior approved orphan products have exclusivity. Orphan drug exclusivity in Europe may be modified for several reasons, including a significant change to the orphan medicinal product designations or status criteria after-market authorization of the orphan product (*e.g.*, product profitability exceeds the criteria for orphan drug designation), problems with the production or supply of the orphan drug, or a competitor drug, although similar, is safer, more effective or otherwise clinically superior than the initial orphan drug. Thus, we cannot guarantee that another company will not receive approval to market a product candidate that is granted orphan drug exclusivity for the same drug or similar drug and same orphan indication as any of our product candidates for which we plan to file an NDA, BLA or MAA. If that were to happen, our prior approved orphan products may face competition and any pending NDA, BLA or MAA for our product candidate for that indication may not be approved until the competing company's period of exclusivity has expired in the U.S. or the EU, as applicable. For example, in January 2020, the FDA issued a draft guidance to clarify its position on when gene therapy products would be considered the "same" or "different" for purposes of orphan drug exclusivity. The draft guidance notes that if the gene therapy products differ in either the gene transferred by the products ("transgene") or the vector used to deliver the transgene, then the two gene therapy products are different and could both be approved for same indication. If the transgene and the vector are the same, then the products are likely the "same," such that the first product approved would gain regulatory exclusivity over the second product. If there are other, lesser differences in the products, FDA would make a case-by-case determination as how to apply orphan exclusivity to the competing product. As illustrated by this draft guidance, orphan drug exclusivity as applied to gene therapy products is an evolving area subject to change and interpretation by the FDA and therefore we cannot be certain as to how the FDA will apply those rules to our products.

Even though we have obtained orphan drug designation for certain of our product candidates and even if we obtain orphan drug designation for these or our future product candidates, due to the uncertainties associated with developing biopharmaceutical products, we may not be the first to obtain marketing approval for any particular orphan indication, which means that we may not obtain orphan drug exclusivity and could also potentially be blocked from approval of certain product candidates until the competitor's orphan drug exclusivity period on its product expires (e.g., seven years in the U.S.). Moreover, with respect to antisense oligonucleotides and gene therapies, it is uncertain how similarity between product candidates designed to treat the same rare disease or condition may be determined on a country-by-country basis and whether the orphan drug exclusivity of a previously approved product can block the approval of a chemically distinct product candidate under regulatory review.

The patient population suffering from DMD, LGMDs, Pompe disease, CMT 1A and MPS IIIA is small and has not been established with precision. If the actual number of patients is smaller than we estimate, our revenue and ability to achieve profitability may be adversely affected.

DMD, LGMD, Pompe disease, CMT 1A and MPS IIIA are rare, fatal genetic disorders. DMD affects an estimated one in approximately every 3,500 to 5,000 males born worldwide, of which up to 13% are estimated to be amenable to exon 51 skipping and up to 8% are estimated to be amenable to exon 53. LGMDs as a class affect an estimated range of approximately one in every 14,500 to one in every 123,000 individuals. Pompe disease affects an estimated one in approximately every 40,000 individuals. CMT is a group of peripheral nerve disorders affecting approximately one in every 2,500 individuals. CMT type 1A affects approximately 50,000 patients in the U.S. MPS IIIA affects approximately 1 in 100,000 newborns. Our estimates of the size of these patient populations are based on limited number of published studies as well as internal analyses. Various factors may decrease the market size of our products and product candidates, including the severity of the disease, patient demographics and the response of patients' immune systems to our products and product candidates. If the results of these studies or our analysis of them do not accurately reflect the relevant patient population, our assessment of the market may be inaccurate, making it difficult or impossible for us to meet our revenue goals, or to obtain and maintain profitability.

We face intense competition and rapid technological change, which may result in other companies discovering, developing or commercializing competitive products.

The biotechnology and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. We are aware of many pharmaceutical and biotechnology companies that are actively engaged in research and development in areas in which our products and product candidates are aimed. Some of these competitors are developing or testing product candidates that now, or may in the future, compete directly with our products or product candidates. For example, we face competition in the field of DMD by third parties who are developing or who had once developed: (i) exon skipping product candidates, such as Wave Life Sciences (notably for exons 51 and 53), Nippon Shinyaku (notably for exon 53), Daiichi Sankyo (notably for exon 45) and Audentes Therapeutics, Inc. (notably for exons 2, 51 and 53); (ii) gene therapies that express microdystrophin or mini-dystrophin, such as Pfizer and Solid Biosciences; (iii) CRISPR/Cas 9 approaches, such as Exonics Therapeutics (acquired by Vertex Pharmaceuticals), CRISPR Therapeutics and Editas Medicine; (iv) other disease modifying approaches, such as PTC Therapeutics, which has a small molecule candidate, ataluren, that targets nonsense mutations; and (v) other approaches that may be palliative in nature or potentially complementary with our products and product candidates and that are being developed by Santhera, Catabasis, Fibrogen, ReveraGen, Capricor, BioPhytis, Mallinckrodt, Astellas Pharma, and Tivorsan . Although BioMarin announced on May 31, 2016 its intent to discontinue clinical and regulatory development of drisapersen as well as its other clinical stage candidates, BMN 044, BMN 045 and BMN 053, then-currently in Phase 2 studies for distinct forms of DMD, it further announced its intent to continue to explore the development of next generation oligonucleotides for the treatment of DMD. In addition, while Wave announced its intention to discontinue development of suvodirsen and suspend development of WVE-N531, continued development of one or both of these candidates is possible.

In addition, we are aware of many pharmaceutical and biotechnology companies that are actively engaged in research and development using platform technologies that may be viewed as competing with ours beyond and including those companies mentioned immediately above, such as Alnylam Pharmaceuticals, Inc., Tekmira Pharmaceuticals Corp., Deciphera Pharmaceuticals, Ionis Pharmaceuticals, Inc., Roche Innovation Center Copenhagen (formerly Santaris Pharma A/S), Shire plc (now Takeda), Biogen, Moderna Therapeutics, Avidity, Dyne Therapeutics, Stoke Therapeutics and Sanofi. Additionally, several companies and institutions have entered into collaborations or other agreements for the development of product candidates, including mRNA, gene therapy and gene editing (CRIPSR and AAV, among others) and small molecule therapies that are potential competitors for therapies being developed in the muscular dystrophy, neuromuscular and rare disease space, including, but not limited to, Astellas Pharma, Biogen Inc., Ionis, Alexion Pharmaceuticals, Inc., Sanofi, Shire (now Takeda), Eli Lilly, Alnylam Pharmaceuticals, Inc., Moderna Therapeutics, Inc., Akashi, Catabasis, Capricor Therapeutics, Oxford University, Exonics Therapeutics (acquired by Vertex Pharmaceuticals), and Editas Medicine.

If any of our competitors are successful in obtaining regulatory approval for any of their product candidates, it may limit our ability to enter into the market, gain market share or maintain market share in the DMD space or other diseases targeted by our platform technologies, products and product candidate pipeline.

It is possible that our competitors will succeed in developing technologies that limit the market size for our products or product candidates, impact the regulatory approval and post-marketing process for our products and product candidates, are more effective than our products or product candidates or would render our technologies obsolete or noncompetitive. Our competitors may, among other things:

- develop safer or more effective products;
- implement more effective approaches to sales and marketing;
- develop less costly products;
- obtain regulatory approval more quickly;
- have access to more manufacturing capacity;
- develop products that are more convenient and easier to administer;
- form more advantageous strategic alliances; or
- establish superior intellectual property positions.

We have entered into multiple collaborations, including our collaboration with Roche, and may seek or engage in future collaborations, strategic alliances, acquisitions or licensing agreements that complement or expand our business. We may not be able to complete such transactions, and such transactions, if executed, may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

In order to achieve our long-term business objectives, we actively evaluate various strategic transactions on an ongoing basis, including licensing or acquiring products, technologies or businesses. We may face competition from other companies in pursuing acquisitions and similar transactions in the biotechnology industry. This competition is most intense for approved drugs and late-stage drug candidates, which have the lowest risk and would have the most immediate effect on our financial performance. Our ability to complete transactions may also be limited by applicable antitrust and trade regulation laws and regulations in the U.S. and foreign jurisdictions in which we or the operations or assets we seek to acquire carry on business.

We have entered into multiple collaborations, including with Roche, Nationwide, Lysogene, Lacerta, Duke University, Genethon and StrideBio. We may not realize the anticipated benefits of such collaborations, and the anticipated benefits of any future collaborations or acquisitions, each of which involves numerous risks, including:

- collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our products or product candidates based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our products or product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product or product candidate;
- failure to successfully develop the acquired or licensed drugs or technology or to achieve strategic objectives, including successfully developing and commercializing the drugs, drug candidates or technologies that we acquire or license;
- entry into markets in which we have no or limited direct prior experience or where competitors in such markets have stronger market positions;

- disruption of our ongoing business, distraction of our management and employees from other opportunities and challenges and retention of key employees;
- potential failure of the due diligence processes to identify significant problems, liabilities or other shortcomings or challenges of an acquired company, or acquired or licensed product or technology, including but not limited to, problems, liabilities or other shortcomings or challenges with respect to intellectual property, product quality, safety, accounting practices, employee, customer or third-party relations and other known and unknown liabilities;
- liability for activities of the acquired company or licensor before the acquisition or license, including intellectual property infringement claims, violations of laws, commercial disputes, tax liabilities, and other known and unknown liabilities;
- exposure to litigation or other claims in connection with, or inheritance of claims or litigation risk as a result of an acquisition or license, including but not limited to, claims from terminated employees, customers, former equity holders or other third-parties;
- difficulty in integrating the products, product candidates, technologies, business operations and personnel of an acquired asset or company; and
- difficulties in the integration of the acquired company's departments, systems, including accounting, human resource and other administrative systems, technologies, books and records, and procedures, as well as in maintaining uniform standards, controls, including internal control over financial reporting required by the Sarbanes-Oxley Act of 2002 and related procedures and policies.

For example, we will have limited influence and control over the development and commercialization activities of Roche in the territories in which it leads development and commercialization of SRP-9001, and if the exclusive option is exercised, in the territories in which it leads commercialization of certain other products or product candidates. Roche's development and commercialization activities in the territories where it is the lead party may adversely impact our own efforts in the U.S. Failure by Roche to meet its obligations under the collaboration agreement, to apply sufficient efforts at developing and commercializing collaboration products, or to comply with applicable legal or regulatory requirements, may materially adversely affect our business and our results of operations. In addition, to the extent we rely on Roche to commercialize any products for which we obtain regulatory approval, we may receive less revenues than if we commercialized these products ourselves, which could materially harm our prospects.

Even if we achieve the long-term benefits associated with strategic transactions, our expenses and short-term costs may increase materially and adversely affect our liquidity and short-term net income (loss). Future licenses or acquisitions could result in potentially dilutive issuances of equity securities, the incurrence of debt, the creation of contingent liabilities, impairment expenses related to goodwill, and impairment or amortization expenses related to other intangible assets, which could harm our financial condition. For example, in February 2020, we issued and sold 2,522,227 shares of common stock to Roche Finance in connection with the entry into the collaboration agreement with Roche.

Risks Related to the Development of our Product Candidates

We may find it difficult to enroll patients in our clinical trials, which could delay or prevent clinical trials of our product candidates.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit eligible patients to participate in testing our product candidates. We have experienced delays in some of our clinical trials, and we may experience similar delays in the future. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology or termination of the clinical trials altogether.

We may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics to achieve diversity in a study, to complete our clinical trials in a timely manner. Patient enrollment is affected by factors including:

- design of the study protocol;
- size of the patient population;
- eligibility criteria for the study in question;
- manufacturing of product candidates;

- perceived risks and benefits of the product candidate under study, including as a result of adverse effects observed in similar or competing therapies;
- proximity and availability of clinical trial sites for prospective patients;
- availability of competing therapies and clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- activities of patient advocacy groups;
- ability to monitor patients adequately during and after treatment; and
- severity of the disease under investigation.

In particular, each of the conditions for which we plan to evaluate our product candidates are rare genetic diseases with limited patient pools from which to draw for clinical trials. Further, because newborn screening for these diseases is not widely adopted, and it can be difficult to diagnose these diseases in the absence of a genetic screen, we may have difficulty finding patients who are eligible to participate in our studies. The eligibility criteria of our clinical trials will further limit the pool of available study participants. Additionally, the process of finding and diagnosing patients may prove costly. The treating physicians in our clinical trials may also use their medical discretion in advising patients enrolled in our clinical trials to withdraw from our studies to try alternative therapies.

We may not be able to initiate or continue clinical trials if we cannot enroll a sufficient number of eligible patients to participate in the clinical trials required by the FDA or the EMA or other regulatory agencies. Our ability to successfully initiate, enroll and complete a clinical trial in any foreign country is subject to numerous risks unique to conducting business in foreign countries, including:

- difficulty in establishing or managing relationships with contract research organizations (“CROs”) and physicians;
- different standards for the conduct of clinical trials;
- our inability to locate qualified local consultants, physicians and partners; and
- the potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatment.

If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit or terminate ongoing or planned clinical trials, any of which would have an adverse effect on our business.

Failures or delays in the commencement or completion of ongoing and planned clinical trials of our product candidates negatively impact commercialization efforts; result in increased costs; and delay, prevent or limit our ability to gain regulatory approval of product candidates and to generate revenues and continue our business.

Successful completion of clinical trials at each applicable stage of development is a prerequisite to submitting a marketing application to the regulatory agencies and, consequently, the ultimate approval and commercial marketing of any of our product candidates for the indications in which we develop them. We do not know whether any of our clinical trials will begin or be completed, and results announced, as planned or expected, if at all, as the commencement and completion of clinical trials and announcement of results is often delayed or prevented for a number of reasons, including, among others:

- denial by the regulatory agencies of permission to proceed with our planned clinical trials or any other clinical trials we may initiate, or placement of a clinical trial on hold;
- delays in filing or receiving approvals of additional INDs that may be required;
- negative results from our ongoing non-clinical trials or clinical trials;
- challenges in identifying, recruiting, enrolling and retaining patients to participate in clinical trials
- timely and effectively contract with (under reasonable terms), manage and work with investigators, institutions, hospitals and the CROs involved in the clinical trial;

- negotiate contracts and other related documents with clinical trial parties and institutional review boards, such as informed consents, CRO agreements and site agreements, which can be subject to extensive negotiations that could cause significant delays in the clinical trial process, with terms possibly varying significantly among different trial sites and CROs and possibly subjecting the Company to various risks;
- inadequate quantity or quality of supplies of a product candidate or other materials necessary to conduct clinical trials, for example as a result of delays in defining and implementing the manufacturing process for materials used in pivotal trials or for the manufacture of larger quantities or other delays or issues arising in the manufacturing of sufficient supply of finished drug product;
- difficulties obtaining institutional review board ("IRB") approval, and equivalent approval for sites outside the U.S., to conduct a clinical trial at a prospective site or sites;
- ensure adherence to trial designs and protocols agreed upon and approved by regulatory authorities and applicable legal and regulatory guidelines;
- delays or problems in analyzing data, or the need for additional analysis or data or the need to enroll additional patients;
- the occurrence of serious adverse events or unexpected drug-related side effects experienced by patients in a clinical trial or unexpected results in ongoing non-clinical trials;
- delays in validating endpoints utilized in a clinical trial;
- our inability to satisfy the requirements of the regulatory agencies to commence clinical trials, including CMC requirements, or other regulatory requirements prior to the initiation of a clinical trial;
- the regulatory agencies disagreeing with our clinical trial design and our interpretation of data from clinical trials, or changing the requirements for approval even after the regulatory authority has reviewed and commented on the design for our clinical trials;
- reports from non-clinical or clinical testing of competing therapies that raise safety or efficacy concerns; and
- the recruitment and retention of employees, consultants or contractors with the required level of expertise.

Any inability to complete successfully pre-clinical and clinical development could result in additional costs to us or impair our ability to generate revenues from product sales, regulatory and commercialization milestones and royalties. In addition, manufacturing or formulation changes to our product candidates often require additional studies to demonstrate comparability of the modified product candidates to earlier versions. Clinical study delays also shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which impairs our ability to successfully commercialize our product candidates and harms our business and results of operations.

Results from pre-clinical and early-stage clinical trials may not be indicative of efficacy in late-stage clinical trials, and pre-clinical and clinical trials may fail to demonstrate acceptable levels of safety, efficacy, and quality of our product candidates, which could prevent or significantly delay their regulatory approval.

To obtain the requisite regulatory approvals to market and sell any of our product candidates, we must demonstrate, through extensive pre-clinical and clinical trials, that the product candidate is safe and effective in humans. Ongoing and future pre-clinical and clinical trials of our product candidates may not show sufficient safety, efficacy or adequate quality to obtain or maintain regulatory approvals. For example, although we believe the pre-clinical data for PPMO SRP-5051 collected to date is positive, the additional data we collect, including in the clinic, may not be consistent with the pre-clinical data or show a safe benefit that warrants further development or pursuit of a regulatory approval for PPMO product candidates.

Furthermore, success in pre-clinical and early clinical trials does not ensure that the subsequent trials will be successful, nor does it predict final results of a confirmatory trial. Some of our clinical trials were conducted with small patient populations and were not blinded or placebo-controlled, making it difficult to predict whether the favorable results that we observed in such trials will be repeated in larger and more advanced clinical trials. For example, on October 3, 2018, Nationwide presented positive results from a Phase 1/2a micro-dystrophin gene therapy clinical trial in four individuals with DMD enrolled in the trial and, on March 25, 2019, we presented nine-month functional and CK data from baseline from these four individuals, and twelve-month CK data from baseline from one of these individuals. In addition, on February 27, 2019, we announced positive expression and biomarker data from the first three-patient cohort dosed in the SRP-9003 gene therapy trial to treat LGMD type 2E, or beta-sarcoglycanopathy and, on October 4, 2019, we announced positive nine-month functional data from these three patients. The data is based on small patient samples and therefore may not be predictive of future results. In addition, we cannot assure that the results of additional data or data from any future trial will yield results that are consistent with the data presented, that we will be able to demonstrate the safety and efficacy of

these product candidates, that later trial results will support further development, or even if such later results are favorable, that we will be able to successfully complete the development of, obtain accelerated, conditional or standard regulatory approval for, or successfully commercialize any of such product candidates. Similarly, we cannot provide assurances that data from our ongoing and planned studies with respect to our commercially approved products and product candidates will be positive and consistent or that the interpretation by regulators, such as the FDA or EMA, of the data we collect for our products or product candidates will be consistent with our interpretations.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent regulatory approval of product candidates, limit the commercial potential or result in significant negative consequences following any potential marketing approval.

Our product candidates may cause undesirable side effects. In addition to side effects caused by our product candidates, the administration process or related procedures also can cause adverse side effects. If any such adverse events occur in our trials, we may decide, or the FDA, the EMA or other regulatory authorities could order us, to halt, delay or amend pre-clinical development or clinical development of our product candidates or we may be unable to receive regulatory approval of our product candidates for any or all targeted indications. Even if we are able to demonstrate that all future serious adverse events are not product-related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the trial. Moreover, if we elect, or are required, to delay, suspend or terminate any clinical trial of any of our product candidates, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to develop other product candidates and may harm our business, financial condition and prospects significantly.

Our gene therapy product candidates may be perceived as unsafe or may result in unforeseen adverse events. Failure of other gene therapy programs, negative public opinion and increased regulatory scrutiny of gene therapy may damage public perception of the safety of our gene therapy product candidates and harm our ability to conduct our business or obtain regulatory approvals for our gene therapy product candidates.

Gene therapy remains a newly applied technology, with only a few gene therapy products approved to date in the U.S., the EU or elsewhere. Public perception may be influenced by claims that gene therapy is unsafe, and gene therapy may not gain the acceptance of the public or the medical community. In particular, our success will depend upon physicians who specialize in the treatment of genetic diseases targeted by our product candidates, prescribing treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments with which they are familiar and for which greater clinical data may be available.

In addition, ethical, social and legal concerns about gene therapy, genetic testing and genetic research could result in additional regulations or prohibiting the processes we may use. Federal and state agencies, congressional committees and foreign governments have expressed their intentions to further regulate biotechnology. More restrictive regulations or claims that our product candidates are unsafe or pose a hazard could prevent us from commercializing any products. New government requirements may be established that could delay or prevent regulatory approval of our product candidates under development. It is impossible to predict whether legislative changes will be enacted, regulations, policies or guidance changed, or interpretations by agencies or courts changed, or what the impact of such changes, if any, may be.

More restrictive government regulations or negative public opinion would harm our business, financial condition, results of operations and prospects and may delay or impair the development and commercialization of our gene therapy product candidates or demand for any products we may develop. For example, earlier gene therapy trials led to several well-publicized adverse events, including death. Lack of efficacy and/or serious adverse events related to clinical trials we, our strategic partners or other companies conduct, even if such adverse events are not ultimately attributable to the relevant product candidates or products, and/or failed commercialization of gene therapy products may result in increased government regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates.

If there are significant delays in obtaining or we are unable to obtain or maintain required regulatory approvals, we will not be able to commercialize our product candidates in a timely manner or at all, which could impair our ability to generate sufficient revenue and have a successful business.

The research, testing, manufacturing, labeling, approval, commercialization, marketing, selling and distribution of drug products are subject to extensive regulation by applicable local, regional and national regulatory authorities and regulations may differ from jurisdiction to jurisdiction. In the U.S., approvals and oversight from federal (e.g., FDA), state and other regulatory authorities are required for these activities. Sale and marketing of our product candidates in the U.S. or other countries is not permitted until we obtain the required approvals from the applicable regulatory authorities. Of the large number of drugs in development in the biopharmaceutical industry, only a small percentage result in the submission of a marketing application to the FDA or an MAA to the EMA and even fewer are approved for commercialization.

Our ability to obtain the government or regulatory approvals required to commercialize any of our product candidates in any jurisdiction, including in the U.S. or the EU, cannot be assured, may be significantly delayed or may never be achieved for various reasons including the following:

- Our non-clinical, clinical, chemistry, manufacturing and controls and other data and analyses from past, current and future studies for any of our product candidates may not be sufficient to meet regulatory requirements for marketing application approvals. The regulatory authorities could disagree with our interpretations and conclusions regarding data we provide in connection with NDA, BLA or MAA submissions for one or more of our product candidates, and may delay, reject or refuse to accept for review, or approve any submission we make or identify additional requirements for product approval to be submitted upon completion, if ever. In addition, in the U.S., an FDA advisory committee could determine that our data are insufficient to provide a positive recommendation for approval of any NDA or BLA we submit to the FDA. Even if we meet FDA requirements and an advisory committee votes to recommend approval of an NDA or BLA submission, the FDA could still disagree with the advisory committee's recommendation and deny approval of a product candidate based on their review.
- The regulatory approval process for product candidates targeting orphan diseases, such as DMD, that use new technologies and processes, such as antisense oligonucleotide therapies, gene therapy and other alternative approaches or endpoints for the determination of efficacy is uncertain due to, among other factors, evolving interpretations of a new therapeutic class, the broad discretion of regulatory authorities, lack of precedent, small safety databases, varying levels of applicable expertise of regulators or their advisory committees, scientific developments, changes in the competitor landscape, shifting political priorities and changes in applicable laws, rules or regulations and interpretations of the same. As a result of uncertainty in the approval process for products intended to treat serious rare diseases, we may not be able to anticipate, prepare for or satisfy requests or requirements from regulatory authorities, including completing and submitting planned NDAs, BLAs and MAAs for our product candidates, in a timely manner, or at all. Examples of such requests or requirements could include, but are not limited to, conducting additional or redesigned trials and procedures (e.g., additional safety data, patient muscle biopsies, dystrophin analyses and the use of assays), repeating or completing additional analysis of our data, or providing additional supportive data. In addition, in the U.S., an FDA advisory committee or regulators may disagree with our data analysis, interpretations and conclusions at any point in the approval process, which could negatively impact the approval of our NDA or BLA or result in a decision by the Company not to proceed with an NDA or BLA submission for a product candidate based on feedback from regulators.
- We may not have the resources required to meet regulatory requirements and successfully navigate what is generally a lengthy, expensive and extensive approval process for commercialization of drug product candidates.

Any failure on our part to respond to these requirements in a timely and satisfactory manner could significantly delay or negatively impact confirmatory study timelines and/or the development plans we have for PMO, PPMO, gene therapy-based product candidates or other product candidates. Responding to requests from regulators and meeting requirements for clinical trials, submissions and approvals may require substantial personnel, financial or other resources, which, as a small biopharmaceutical company, we may not be able to obtain in a timely manner or at all. In addition, our ability to respond to requests from regulatory authorities that involve our agents, third party vendors and associates may be complicated by our own limitations and those of the parties we work with. It may be difficult or impossible for us to conform to regulatory guidance or successfully execute our product development plans in response to regulatory guidance, including guidance related to clinical trial design with respect to any NDA, BLA or MAA submissions.

Even if our product candidates demonstrate safety and efficacy in clinical studies, the regulatory agencies may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Additional delays may result if an FDA Advisory Committee or other regulatory advisory group or authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical studies and the review process. Regulatory agencies also may approve a treatment candidate for fewer or more limited indications than requested or may grant approval subject to the performance of post-marketing studies. Finally, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our treatment candidates. Even after approval and commercialization of a product candidate, we remain subject to ongoing regulatory compliance and oversight to maintain our approval. Conducting our confirmatory studies could take years to complete, could yield negative or uninterpretable results or could result in an FDA determination that the studies do not provide the safety and efficacy requirements to maintain regulatory approval. If we or any of our strategic partners are unable to develop, or obtain regulatory approval for, or, if approved, maintain regulatory compliance and successfully commercialize, our product candidates, our business will be materially harmed.

We are investing significant resources in the development of novel gene therapy product candidates. Only a few gene therapy products have been approved in the U.S. and EU. If we are unable to show the safety and efficacy of these product candidates, experience delays in doing so or are unable to successfully commercialize at least one of these drugs, our business would be materially harmed.

We are investing significant resources in the development of our gene therapy product candidates. We believe that a significant portion of the long-term value attributed to our company by investors is based on the commercial potential of these product candidates. There can be no assurance that any development problems we experience in the future related to our gene therapy programs will not cause significant delays or unanticipated costs, or that such development problems can be solved. Initial results from ongoing clinical trials may differ materially from final results from such clinical trials. The results from pre-clinical and early clinical studies do not always accurately predict results in later, large-scale clinical trials. We may also experience delays in developing a sustainable, reproducible and commercial-scale manufacturing process or transferring that process to commercial partners, which may prevent us from completing our clinical trials or commercializing our products on a timely or profitable basis, if at all.

In addition, the clinical trial requirements of the FDA, the EMA, and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known or more extensively studied pharmaceutical or other product candidates. Currently, only a few gene therapy products have been approved in the Western world. Given the few precedents of approved gene therapy products, it is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our gene therapy product candidates in the U.S., the EU or other jurisdictions. Approvals by the EMA and the European Commission may not be indicative of what the FDA may require for approval.

Regulatory requirements governing gene therapy products have evolved and may continue to change in the future. Within the FDA, the Center for Biologics Evaluation and Research ("CBER") regulates gene therapy products. Within the CBER, the review of gene therapy and related products is consolidated in the Office of Cellular, Tissue and Gene Therapies, and the FDA has established the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its reviews. The CBER works closely with the National Institutes of Health (the "NIH"). The FDA and the NIH have published guidance documents with respect to the development and submission of gene therapy protocols. For example, on January 28, 2020, the FDA issued final guidance documents that updated draft guidance documents that were originally released in July 2018 to reflect recent advances in the field, and to set forth the framework for the development, review and approval of gene therapies. These final guidance documents pertain to the development of gene therapies for the treatment of specific disease categories, including rare diseases, and to manufacturing and long-term follow up issues relevant to gene therapy, among other topics. At the same time the FDA issued a new draft guidance document describing the FDA's approach for determining whether two gene therapy products were the same or different for the purpose of assessing orphan drug exclusivity. In addition, the FDA can put an IND, on clinical hold if the information in an IND is not sufficient to assess the risks in pediatric patients.

These regulatory review agencies, committees and advisory groups and the new requirements and guidelines they promulgate may lengthen the regulatory review process, require us to perform additional or larger studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these treatment candidates or lead to significant post-approval studies, limitations or restrictions. As we advance our product candidates, we will be required to consult with these regulatory and advisory groups and comply with applicable requirements and guidelines. If we fail to do so, we may be required to delay or discontinue development of our product candidates.

If the anticipated or actual timing of marketing approvals for our gene therapy product candidates, or the market acceptance of these product candidates, if approved, including treatment reimbursement levels agreed to by third-party payors, do not meet the expectations of investors or public market analysts, the market price of our common stock would likely decline.

Because we are developing product candidates for the treatment of certain diseases in which there is little clinical experience and we are using new endpoints or methodologies, there is increased risk that the FDA, the EMA or other regulatory authorities may not consider the endpoints of our clinical trials to provide clinically meaningful results and that these results may be difficult to analyze.

During the FDA review process, we will need to identify success criteria and endpoints such that the FDA will be able to determine the clinical efficacy and safety profile of our product candidates. As we are developing novel treatments for diseases in which there is little clinical experience with new endpoints and methodologies, such as gene therapy, there is heightened risk that the FDA, the EMA or other regulatory bodies may not consider the clinical trial endpoints to provide clinically meaningful results (reflecting a tangible benefit to patients). In addition, the resulting clinical data and results may be difficult to analyze. Even if the FDA does find our success criteria to be sufficiently validated and clinically meaningful, we may not achieve the pre-specified endpoints to a degree of statistical significance. Different methodologies, assumptions and applications we utilize to assess particular safety or efficacy parameters may yield different statistical results. Even if we believe the data collected from clinical trials of our product candidates are promising, these data may not be sufficient to support approval by the FDA or foreign regulatory authorities. Pre-clinical and clinical data can be interpreted in different ways. Accordingly, the FDA or foreign regulatory authorities could interpret these data in different ways from us or our partners, which could delay, limit or prevent full or accelerated regulatory approval.

If our study data do not consistently or sufficiently demonstrate the safety or efficacy of any of our product candidates, the regulatory approvals for such product candidates could be significantly delayed as we work to meet approval requirements, or, if we are not able to meet these requirements, such approvals could be withheld or withdrawn.

Fast track product, breakthrough therapy, priority review, or Regenerative Medicine Advanced Therapy ("RMAT") designation by the FDA, or access to the PRIME scheme by the EMA, for our product candidates may not lead to faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek fast track, breakthrough therapy designation, RMAT designation, PRIME scheme access or priority review designation for our product candidates if supported by the results of clinical trials. A fast track product designation is designed to facilitate the clinical development and expedite the review of drugs intended to treat a serious or life-threatening condition which demonstrate the potential to address an unmet medical need. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. A RMAT designation is designed to accelerate approval for regenerative advanced therapies such as our gene therapy product candidates. Priority review designation is intended to speed the FDA marketing application review timeframe for drugs that treat a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. PRIME is a scheme provided by the EMA to enhance support for the development of medicines that target an unmet medical need.

For drugs and biologics that have been designated as fast track products or breakthrough therapies, or granted access to the PRIME schema, interaction and communication between the regulatory agency and the sponsor of the trial can help to identify the most efficient path for clinical development. Sponsors of drugs with fast track products or breakthrough therapies may also be able to submit marketing applications on a rolling basis, meaning that the FDA may review portions of a marketing application before the sponsor submits the complete application to the FDA, if the sponsor pays the user fee upon submission of the first portion of the marketing application. For products that receive a priority review designation, the FDA's marketing application review goal is shortened to six months, as opposed to ten months under standard review. This review goal is based on the date the FDA accepts the marketing application for review, this application validation period typically adds approximately two months to the timeline for review and decision from the date of submission. RMAT designations will accelerate approval but the exact mechanisms have not yet been announced by FDA.

Designation as a fast track product, breakthrough therapy, RMAT, PRIME, or priority review product is within the discretion of the regulatory agency. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a fast track product, breakthrough therapy, RMAT, PRIME, or priority review product, the agency may disagree and instead determine not to make such designation. In any event, the receipt of such a designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional regulatory procedures and does not assure ultimate marketing approval by the agency. In addition, regarding fast track products and breakthrough therapies, the FDA may later decide that the products no longer meet the conditions for qualification as either a fast track product, RMAT, or a breakthrough therapy or, for priority review products, decide that period for FDA review or approval will not be shortened.

We may not be able to advance all of our programs, and we may use our financial and human resources to pursue particular programs and fail to capitalize on programs that may be more profitable or for which there is a greater likelihood of success.

Our pipeline includes more than 40 programs in various stages of development for a broad range of diseases and disorders. We plan to expand our pipeline through internal research and development and through strategic transactions. Because we have limited resources, we may not be able to advance all of our programs. We may also forego or delay pursuit of opportunities with certain programs or for indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for product candidates may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate, or we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

Risks Related to Third Parties

If we are unable to maintain our agreements with third parties to distribute our products to patients, our results of operations and business could be adversely affected.

We rely on third parties to commercially distribute our products to patients in the U.S. We have contracted with a third-party logistics company to warehouse our products and with distributors and specialty pharmacies to sell and distribute our products to patients. A specialty pharmacy is a pharmacy that specializes in the dispensing of medications for complex or chronic conditions that require a high level of patient education and ongoing management.

This distribution network requires significant coordination with our sales and marketing and finance organizations. In addition, failure to coordinate financial systems could negatively impact our ability to accurately report product revenue from our products. If we are unable to effectively manage the distribution process, the sales of our products, as well as any future products we may commercialize, could be delayed or severely compromised and our results of operations may be harmed.

In addition, the use of third parties involves certain risks, including, but not limited to, risks that these organizations will:

- not provide us with accurate or timely information regarding their inventories, the number of patients who are using our products or serious adverse events and/or product complaints regarding our products;
- not effectively sell or support our products;
- reduce or discontinue their efforts to sell or support our products;
- not devote the resources necessary to sell our products in the volumes and within the time frame we expect;
- be unable to satisfy financial obligations to us or others; or
- cease operations.

Any such events may result in decreased product sales, lower product revenue, loss of revenue, and/or reputational damage, which would harm our results of operations and business.

With respect to the pre-commercial distribution of our products to patients outside of the U.S., we have contracted with third party distributors and service providers to distribute our products in certain countries through our EAP. We will need to continue building out our network for commercial distribution in jurisdictions in which our products are approved, which will also require third party contracts. The use of distributors and service providers involves certain risks, including, but not limited to, risks that these organizations will not comply with applicable laws and regulations, or not provide us with accurate or timely information regarding serious adverse events and/or product complaints regarding our products. Any such events may result in regulatory actions that may include suspension or termination of the distribution and sale of our products in a certain country, loss of revenue, and/or reputational damage, which could harm our results of operations and business.

We rely on third parties to conduct some aspects of our early stage research and pre-clinical and clinical development. The inadequate performance by or loss of any of these third parties could affect the development and commercialization of our product candidate development.

We have relied upon, and plan to continue to rely upon, third parties to conduct some aspects of our early stage research and pre-clinical and clinical development with respect to certain of our product candidates, including our follow-on exon-skipping product candidates, PPMO, gene therapy and gene editing product candidates. Our third-party collaborators may not commit sufficient resources or adequately develop our programs for these candidates. If our third-party collaborators fail to commit sufficient resources to any of our product candidates or to carry out their contractual duties or obligations, our programs related to any particular product candidate could be delayed, terminated, or unsuccessful. Furthermore, if we fail to make required payments to these third-party collaborators, including up-front, milestone, reimbursement or royalty payments, or to observe other obligations in our agreements with them, these third parties may not be required to perform their obligations under our respective agreements with them and may have the right to terminate such agreements.

We also have relied upon and plan to continue to rely upon third-party CROs to monitor and manage data for our ongoing pre-clinical and clinical programs. We rely on these parties for execution of our pre-clinical and clinical trials, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on collaborators and CROs does not relieve us of our regulatory responsibilities.

The individuals at our third-party collaborators and CROs who conduct work on our behalf, including their sub-contractors, are not always our employees, and although we participate in the planning of our early stage research and pre-clinical and clinical programs, we cannot control whether or not they devote sufficient time and resources or exercise appropriate oversight of these programs, except for remedies available to us under our agreements with such third parties. If our collaborators and CROs do not successfully carry out their contractual duties or obligations or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our pre-clinical and clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Our reliance on third parties requires us to share our proprietary information, which increases the possibility that a competitor will discover them or that our proprietary information will be misappropriated or inadvertently disclosed.

Our reliance on third-party collaborators requires us to disclose our proprietary information to these parties, which could increase the risk that a competitor will discover this information or that this information will be misappropriated or disclosed without our intent to do so. Furthermore, if these third parties cease to continue operations and we are not able to quickly find a replacement provider or we lose information or items associated with our products or product candidates, our development programs may be delayed. Although we carefully manage our relationships with our third-party collaborators and CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

Risks Related to Manufacturing

We currently rely on third parties to manufacture our products and to produce our product candidates; our dependence on these parties, including failure on our part to accurately anticipate product demand and timely secure manufacturing capacity to meet commercial, EAP, clinical and pre-clinical product demand may impair the availability of product to successfully support various programs, including research and development and the potential commercialization of our product candidates.

We currently do not have the internal ability to undertake the manufacturing process for our products or product candidates in the quantities needed to meet commercial, clinical or EAPs demand for our products, or to conduct our research and development programs and conduct clinical trials. Therefore, we rely on, and expect to continue relying on for the foreseeable future, a limited number of third parties to manufacture and supply materials (including raw materials and subunits), API and drug product, as well as to perform additional steps in the manufacturing process, such as labeling and packaging of vials and storage of our products and product candidates. The limited number of third parties with facilities and capabilities suited for the manufacturing process of our products and product candidates creates a heightened risk that we may not be able to obtain materials and APIs in the quantity and purity that we require.

In addition, the process for adding new manufacturing capacity is lengthy and often causes delays in development efforts. Any interruption of the development or operation of those facilities due to, among other reasons, events such as order delays for equipment or materials, equipment malfunctions, quality control and quality assurance issues, regulatory delays and possible negative effects of such delays on supply chains and expected timelines for product availability, production yield issues, shortages of qualified personnel, discontinuation of a facility or business or failure or damage to a facility by natural disasters, such as earthquakes or fires, could result in the cancellation of shipments, loss of product in the manufacturing process or a shortfall in supply of our products, product candidates or materials.

If these third parties cease providing quality manufacturing and related services to us, and we are not able to engage appropriate replacements in a timely manner, our ability to manufacture our products or product candidates in sufficient quality and quantity required for our planned commercial, pre-clinical and clinical or EAPs, our various product research, development and commercialization efforts would be adversely affected.

Furthermore, any problems in our manufacturing process or the facilities with which we contract make us a less attractive collaborator for potential partners, including larger pharmaceutical companies and academic research institutions, which could limit our access to additional attractive development programs. Problems in third-party manufacturing processes or facilities also restrict our ability to meet market demand.

We, through our third-party manufacturers, seek to produce or produce supply of our products and product candidates. In light of the limited number of third parties with the expertise to produce our products and product candidates, the lead time needed to manufacture them, and the availability of underlying materials, we may not be able to, in a timely manner or at all, establish or maintain sufficient commercial and other manufacturing arrangements on the commercially reasonable terms necessary to provide adequate supply of our products and product candidates. Furthermore, we may not be able to obtain the significant financial capital that may be required in connection with such arrangements. Even after successfully engaging third parties to execute the manufacturing process for our products and product candidates, such parties may not comply with the terms and timelines they have agreed to for various reasons, some of which may be out of their or our control, which impacts our ability to execute our business plans on expected or required timelines in connection with the commercialization of our products and the continued development of our product candidates. When we enter into long-term manufacturing agreements that contain exclusivity provisions and /or substantial termination penalties, we constrain our operational flexibility.

The third parties we use in the manufacturing process for our products and product candidates may fail to comply with cGMP regulations.

Our contract manufacturers are required to produce our materials, APIs and drug products under cGMP. We and our contract manufacturers are subject to periodic inspections by the FDA, EMA and corresponding state and foreign authorities to ensure strict compliance with cGMP and other applicable government regulations. In addition, before we can begin to commercially manufacture our product candidates in third-party or our own facilities, we must obtain regulatory approval from the FDA, which includes a review of the manufacturing process and facility. A manufacturing authorization also must be obtained from the appropriate EU regulatory authorities and may be required by other foreign regulatory authorities. The timeframe required to obtain such approval or authorization is uncertain. In order to obtain approval, we need to demonstrate that all of our processes, methods and equipment are compliant with cGMP, and perform extensive audits of vendors, contract laboratories and suppliers. In complying with cGMP, we are obligated to expend time, money and effort in production, record keeping and quality control to seek to assure that the product meets applicable specifications and other requirements.

We do not have direct operational control over a third-party manufacturer's compliance with regulations and requirements. In addition, changes in cGMP could negatively impact the ability of our contract manufacturers to complete the manufacturing process of our products and product candidates in a compliant manner on the schedule we require for commercial and clinical trial use, respectively. Failure to achieve and maintain compliance with cGMP and other applicable government regulations, including failure to detect or control anticipated or unanticipated manufacturing errors, results in product recalls, clinical holds, delayed or withheld approvals, patient injury or death.

This risk is particularly heightened as we optimize manufacturing for our product candidates. For example, we were notified by the Research Institute at Nationwide that they received a letter from the FDA on July 24, 2018, stating that their Phase 1/2a DMD micro-dystrophin gene therapy trial had been placed on clinical hold due to the presence of a trace amount of DNA fragment in research-grade third-party supplied plasmid (the "Clinical Hold"). The Research Institute, working with us, developed an action plan with immediate plans to submit for review by the FDA, which included the use of cGMP plasmid for the program. On September 24, 2018, we announced that the FDA had lifted the Clinical Hold.

Failure by our contract manufacturers to adhere to applicable cGMP and other applicable government regulations, or our contract manufacturers experiencing manufacturing problems, may result in significant negative consequences, including product seizures or recalls, postponement or cancellation of clinical trials, loss or delay of product approval, fines and sanctions, loss of revenue, termination of the development of a product candidate, reputational damage, shipment delays, inventory shortages, inventory write-offs and other product-related charges and increased manufacturing costs. If we experience any of these consequences, the success of our commercialization of our products and/or our development efforts for our product candidates could be significantly delayed, fail or otherwise be negatively impacted.

We may not be able to successfully scale up manufacturing of our products or product candidates in sufficient quality and quantity or within targeted timelines, or be able to secure ownership of intellectual property rights developed in this process, which could negatively impact the commercial success of our products and/or the development of our product candidates.

We are working to increase manufacturing capacity and scale up production of some of the components of our drug products. Our focus remains on (i) achieving larger-scale manufacturing capacity for our products and product candidates throughout the manufacturing supply chain, (ii) continuing to increase material and API production capacity to provide the anticipated amounts of drug product needed for our planned studies for our product candidates and (iii) optimizing manufacturing for our follow-on exon skipping product candidates and other programs, including PPMO and gene therapy. We may not be able to successfully increase manufacturing capacity or scale up the production of materials, APIs and drug products, whether in collaboration with third party manufacturers or on our own, in a manner that is safe, compliant with cGMP conditions or other applicable legal or regulatory requirements, in a cost-effective manner, in a time frame required to meet our timeline for commercialization, clinical trials and other business plans, or at all.

Challenges complying with cGMP requirements and other quality issues arise during efforts to increase manufacturing capacity and scale up production. We experience such issues in connection with manufacturing, packaging and storage of our products and product candidates, and during shipping and storage of the APIs or finished drug product. In addition, in order to release our products for commercial use and demonstrate stability of product candidates for use in clinical trials (and any subsequent drug products for commercial use), our manufacturing processes and analytical methods must be validated in accordance with regulatory guidelines. Failure to successfully validate, or maintain validation of, our manufacturing processes and analytical methods or demonstrate adequate purity, stability or comparability of our products or product candidates in a timely or cost-effective manner, or at all, may undermine our commercial efforts. Failure to successfully validate our manufacturing processes and analytical methods or to demonstrate adequate purity, stability or comparability, will negatively impact the commercial availability of our products and the continued development and/or regulatory approval of our product candidates, which could significantly harm our business.

During our work with our third-party manufacturers to increase and optimize manufacturing capacity and scale up production, they may make proprietary improvements in the manufacturing and scale-up processes for our products or product candidates. We may not own or be able to secure ownership of such improvements or may have to share the intellectual property rights to those improvements. Additionally, we may need additional processes, technologies and validation studies, which could be costly and which we may not be able to develop or acquire from third parties. Failure to secure the intellectual property rights required for the manufacturing process needed for large-scale clinical trials or commercialization of our products or the continued development of our product candidates could cause significant delays in our business plans or otherwise negatively impact the commercialization of our products or the continued development of our product candidates.

Products intended for use in gene therapies are novel, complex and difficult to manufacture. We could experience production problems that result in delays in our development or commercialization of gene therapy programs, limit the supply of our products or otherwise harm our business.

We currently have development, manufacturing and testing agreements with third parties to manufacture supplies of our gene therapy product candidates. Several factors could cause production interruptions, including equipment malfunctions, facility contamination, raw material shortages or contamination, natural disasters, disruption in utility services, human error or disruptions in the operations of suppliers.

The physical and chemical properties of biologics such as ours generally cannot be fully characterized. As a result, assays of the finished product may not be sufficient to ensure that the product will perform in the intended manner. Accordingly, we employ multiple steps to control our manufacturing process to assure that the process works and the product candidate is made strictly and consistently in compliance with the process. Problems with the manufacturing process, even minor deviations from the normal process, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims or insufficient inventory. We may encounter problems achieving adequate quantities and quality of clinical and/or commercial-grade materials that meet FDA, EMA or other applicable foreign standards or specifications with consistent and acceptable production yields and costs.

In addition, the FDA, the EMA and other foreign regulatory authorities may require us to submit samples of any lot of any approved product together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA, the EMA or other foreign regulatory authorities may require that we not distribute a lot until the competent authority authorizes its release. Slight deviations in the manufacturing process, including those affecting quality attributes and stability and deviations among different sites, may result in unacceptable changes in the product that could result in lot failures or product recalls. Lot failures or product recalls could cause us to delay clinical trials or product launches which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects.

As our product candidates advance to later stage clinical trials, it is customary that various aspects of the development program, such as manufacturing, formulation and other processes, and methods of administration, may be altered to optimize the candidates and processes for scale-up necessary for later stage clinical trials and potential approval and commercialization. These changes may not produce the intended optimization, including production of drug substance and drug product of a quality and in a quantity sufficient for Phase 3 clinical stage development or for commercialization, which may cause delays in the initiation or completion of clinical trials and greater costs. We may also need to conduct additional studies to demonstrate comparability between newly manufactured drug substance and/or drug product for commercialization relative to previously manufactured drug substance and/or drug product for clinical trials. Demonstrating comparability may require us to incur additional costs or delay initiation or completion of clinical trials and, if unsuccessful, could require us to complete additional preclinical studies or clinical trials.

We also may encounter problems hiring and retaining the experienced scientific, quality control and manufacturing personnel needed to operate our manufacturing process which could result in delays in our production or difficulties in maintaining compliance with applicable regulatory requirements.

Furthermore, no manufacturer currently has the experience or ability to produce our vectors or gene therapy product candidates at commercial levels. Even if we timely develop a manufacturing process and successfully transfer it to the third-party vector and product manufacturers or successfully and timely develop our internal capacity, if we or such third-party manufacturers are unable to produce the necessary quantities of viral vectors and our product candidates, or in compliance with GMP or other pertinent regulatory requirements, and within our planned time frame and cost parameters, it may result in delays in our development plans or increased capital expenditures, and the development and sales of our products, if approved, may be materially harmed.

Risks Related to our Intellectual Property

Our success, competitive position and future revenue depend in part on our ability and the abilities of our licensors and other collaborators to obtain, maintain and defend the patent protection for our products, product candidates, and platform technologies, to preserve our trade secrets, and to prevent third parties from infringing on our proprietary rights.

We currently directly hold various issued patents and patent applications, or have exclusive license or option rights to issued patents and patent applications, in each case in the U.S. as well as other countries that protect our products, product candidates and platform technologies. We anticipate filing additional patent applications both in the U.S. and in other countries. Our success will depend, in significant part, on our ability to obtain, maintain and defend our U.S. and foreign patents covering our products, product candidates and platform technologies as well as preserving our trade secrets for these assets. The patent process is subject to numerous risks and uncertainties, and we can provide no assurance that we will be successful in obtaining, maintaining, or defending our patents. Even when our patent claims are allowed, the claims may not issue, or in the event of issuance, may not be sufficient to protect our products, product candidates or platform technologies.

The patent positions of pharmaceutical, biotechnology and other life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. This uncertainty is heightened for our PMO-based products and product candidates and gene therapy-based product candidates for which there has been little patent litigation involving such technologies. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date in the U.S. and tests used for determining the patentability of patent claims in all technologies are in flux. The USPTO and patent offices in other jurisdictions have often required that patent applications concerning pharmaceutical and/or biotechnology-related inventions be limited or narrowed substantially to cover only the specific innovations exemplified in the patent application, thereby limiting the scope of protection against competitive challenges. Accordingly, even if we or our licensors are able to obtain patents, the patents might be substantially narrower than anticipated. Thus, there is no assurance as to the degree and range of protections any of our patents, if issued, may afford us or whether patents will be issued. Patents which may be issued to us may be subjected to further governmental review that may ultimately result in the reduction of their scope of protection, and pending patent applications may have their requested breadth of protection significantly limited before being issued, if issued at all. The pharmaceutical, biotechnology and other life sciences patent situation outside the U.S. can be even more uncertain.

As a matter of public policy, there might be significant pressure on governmental bodies to limit the scope of patent protection or impose compulsory licenses for disease treatments that prove successful, particularly as a tactic to impose a price control. Additionally, competitors may leverage such pressure to enhance their ability to exploit these laws to create, develop and market competing products.

We may be able to assert that certain activities engaged in by our competitors infringe on our current or future patent rights. To the extent that we enforce our patents, an alleged infringer may deny infringement and/or counter-claim that our patents are not valid, and if successful, could negatively impact our patent estate. We may not be able to successfully defend patents necessary to prevent competitors from commercializing competing product candidates. Our patent rights might be challenged, invalidated, circumvented or otherwise not provide any competitive advantage. Defending our patent positions may require significant financial resources and could negatively impact other Company objectives.

Under the Hatch-Waxman Act, one or more motivated third parties may file an ANDA, seeking approval of a generic copy of an innovator product approved under the NDA pathway such as our PMO products, or a NDA under Section 505(b)(2), which may be for a new or improved version of the original innovator products. The third parties are allowed to rely on the safety and efficacy data of the innovator’s product, may not need to conduct clinical trials and can market a competing version of a product after the expiration or loss of patent exclusivity or the expiration or loss of regulatory exclusivity and often charge significantly lower prices. Upon the expiration or loss of patent protection or the expiration or loss of regulatory exclusivity for a product, the major portion of revenues for that product may be dramatically reduced in a very short period of time. If we are not successful in defending our patents and regulatory exclusivities, we will not derive the expected benefit from them. As such, a third party could be positioned to market an ANDA or Section 505(b)(2) product that competes with one of our products prior to the expiry of our patents if the third party successfully challenged the validity of our patents protecting the product.

The DMD patent landscape is continually evolving, and we may be able to assert that certain activities engaged in by third parties infringe our current or future patent rights. There has been, and we believe that there will continue to be, significant litigation in the biopharmaceutical and pharmaceutical industries regarding patent and other intellectual property rights. As such, the patents and patent applications that we own, license, have optioned, and rely on for exclusivity for our product candidates may be challenged.

Uncertainty over intellectual property in the pharmaceutical and biotechnology industry has been the source of litigation and other disputes, which is inherently costly and unpredictable.

Litigation, interferences, oppositions, inter partes reviews, administrative challenges or other similar types of proceedings are, have been and may in the future be necessary in some instances to determine the validity and scope of certain of our proprietary rights, and in other instances to determine the validity, scope or non-infringement of certain patent rights claimed by third parties to be pertinent to the manufacture, use or sale of our products. We may also face challenges to our patent and regulatory exclusivities covering our products by third parties, including manufacturers of generics and biosimilars that may choose to launch or attempt to launch their products before the expiration of our patent or regulatory exclusivity. Litigation, interferences, oppositions, inter partes reviews, administrative challenges or other similar types of proceedings are unpredictable and may be protracted, expensive and distracting to management. The outcomes of such proceedings could adversely affect the validity and scope of our patents or other proprietary rights, hinder our ability to manufacture and market our products, require us to seek a license for the infringed products or technology or result in the assessment of significant monetary damages against us that may exceed amounts, if any, accrued in our financial statements. An adverse determination in a judicial or administrative proceeding or a failure to obtain necessary licenses could prevent us from manufacturing or selling our products. Furthermore, payments under any licenses that we are able to obtain would reduce our profits derived from our products. Any of these circumstances could result in financial, business or reputational harm to us or could cause a decline or volatility in our stock price.

On September 16, 2011, the Leahy-Smith America Invents Act (the "Leahy-Smith Act"), was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted, and may also affect patent litigation. The USPTO has issued regulations and procedures to govern administration of the Leahy-Smith Act. In view of the long timelines for interpreting legal provisions in the court system and the evolving nature of our laws, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition. For instance, a third party may petition the Patent Trial and Appeal Board ("PTAB") seeking to challenge the validity of some or all of the claims in any of our patents through an inter partes review or other post-grant proceeding. Should the PTAB institute an inter partes review or other proceeding and decide that some or all of the claims in the challenged patent are invalid, such a decision, if upheld on appeal, could have a material adverse effect on our business and financial condition.

Our business prospects will be impaired if third parties successfully assert that our products, product candidates, or platform technologies infringe proprietary rights of such third parties.

Similar to us, competitors continually seek intellectual property protection for their technology. Several of our development programs, particularly gene therapy programs, focus on therapeutic areas that have been the subject of extensive research and development by third parties for many years and have been protected with third party patent rights. Due to the amount of intellectual property in our various fields of technology, we cannot be certain that we do not infringe intellectual property rights of competitors or other third parties or that we will not infringe intellectual property rights of competitors or other third parties granted or created in the future. Our competitors or other third parties might have obtained, or could obtain in the future, patents that limit, interfere with or eliminate our ability to make, use and sell our products, product candidates or platform technologies in important commercial markets.

In order to maintain or obtain freedom to operate for our products and product candidates, we may incur significant expenses, including those associated with entering into agreements with third parties that require milestone and royalty payments. Additionally, if we were to challenge the patent rights of our competitors, we could incur substantial costs and ultimately might not be successful.

If our products, product candidates, or platform technologies are alleged to infringe or are determined to infringe enforceable proprietary rights of others, we could incur substantial costs and may have to:

- obtain rights or licenses from others, which might not be available on commercially reasonable terms or at all;
- abandon development of an infringing product candidate, or cease commercialization of an infringing product;
- redesign our products, product candidates or processes to avoid infringement;
- pay damages; and/or
- defend litigation or administrative proceedings which might be costly whether we win or lose, and which could result in a substantial diversion of financial and management resources.

Any of these events could result in product and product candidate development delays or cessation, and as such substantially harm our potential earnings, financial condition and operations. The patent landscape of our product candidates is continually evolving and multiple parties, including both commercial entities and academic institutions, may have rights to claims or may be pursuing additional claims that could provide these parties a basis to assert that our products, product candidates or platform technologies infringe on the intellectual property rights of such parties. There has been, and we believe that there will continue to be, significant litigation in the biopharmaceutical and pharmaceutical industries regarding patent and other intellectual property rights.

Risks Related to our Business Operations

If we fail to comply with healthcare and other regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

As a manufacturer of pharmaceuticals, within the U.S., certain federal and state healthcare laws and regulations will apply to or affect our business. The laws and regulations include:

- federal healthcare program anti-kickback laws, which prohibit, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, information or claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent;
- the Federal Food, Drug and Cosmetic Act, which among other things, strictly regulates drug product and medical device marketing, prohibits manufacturers from marketing such products for off-label use and regulates the distribution of samples;
- federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;
- the so-called “federal sunshine” law, which requires pharmaceutical and medical device companies to monitor and report certain financial interactions with physicians and teaching hospitals to the federal government for re-disclosure to the public; and
- state law equivalents of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third party payor, including commercial insurers, state laws regulating interactions between pharmaceutical manufactures and health care providers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

The number and complexity of both federal and state laws continues to increase, and additional governmental resources are being used to enforce these laws and to prosecute companies and individuals who are believed to be violating them. We anticipate that government scrutiny of pharmaceutical sales and marketing practices will continue for the foreseeable future and subject us to the risk of government investigations and enforcement actions.

In connection with the commercial launch of our products, we have enhanced our compliance program, which is based on industry best practices and is designed to ensure that the commercialization of our products complies with all applicable laws, regulations and industry standards. As the requirements in this area are constantly evolving, we cannot be certain that our program will eliminate all areas of potential exposure. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. If our operations are found to be in violation of any of the laws described above or any other laws, rules or regulations that apply to us, we will be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. Responding to government investigations, defending any claims raised, and any resulting fines, restitution, damages and penalties, settlement payments or administrative actions, as well as any related actions brought by stockholders or other third parties, could have a material impact on our reputation, business and financial condition and divert the attention of our management from operating our business. Even if we successfully defend against an action against us for violation of a law, the action and our defense could nonetheless cause us to incur significant legal expenses and divert our management’s attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security, fraud and reporting laws may prove costly.

We may be subject to product liability claims and our insurance may not be adequate to cover damages.

The current and future use of our product candidates by us and our collaborators in clinical trials, expanded access programs, the sale of our products, or the use of our products under emergency use vehicles may expose us to liability claims inherent to the manufacture, clinical testing, marketing and sale of medical products. These claims might be made directly by consumers or healthcare providers or indirectly by pharmaceutical companies, our collaborators or others selling such products. Regardless of merit or eventual outcome, we may experience financial losses in the future due to such product liability claims. We have obtained commercial general liability insurance coverage for our clinical trials and the sale of commercial products. However, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against all losses. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

If we, our collaborators, or any third-party manufacturers engaged by us or our collaborators fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We, our collaborators, and any third-party manufacturers we engage are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the generation, handling, use, storage, treatment, manufacture, transportation and disposal of, and exposure to, hazardous materials and wastes, as well as laws and regulations relating to occupational health and safety, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of bio-hazardous materials. Our operations involve the use of hazardous materials, including organic and inorganic solvents and reagents. Although we believe that our activities conform in all material respects with such environmental laws, there can be no assurance that violations of these laws will not occur in the future as a result of human error, accident, equipment failure or other causes. Liability under environmental, health and safety laws can be joint and several and without regard to fault or negligence. The failure to comply with past, present or future laws could result in the imposition of substantial fines and penalties, remediation costs, property damage and personal injury claims, loss of permits or a cessation of operations, and any of these events could harm our business and financial condition. We expect that our operations will be affected by other new environmental, health and workplace safety laws on an ongoing basis, and although we cannot predict the ultimate impact of any such new laws, they may impose greater compliance costs or result in increased risks or penalties, which could harm our business.

Further, with respect to the operations of any current or future collaborators or third party contract manufacturers, it is possible that if they fail to operate in compliance with applicable environmental, health and safety laws and regulations or properly dispose of wastes associated with our product or product candidates, we could be held liable for any resulting damages, suffer reputational harm or experience a disruption in the manufacture and supply of our product or product candidates.

Violation of the General Data Protection Regulation could subject us to significant fines.

The GDPR increases our obligations with respect to clinical trials conducted in the member states of the EEA by expanding the definition of personal data to include coded data and requiring changes to informed consent practices and more detailed notices for clinical trial subjects and investigators. In addition, the GDPR increases the scrutiny that clinical trial sites located in the EEA should apply to transfers of personal data from such sites to countries that are considered to lack an adequate level of data protection, such as the U.S. The GDPR imposes substantial fines for breaches of data protection requirements, which can be up to four percent of global revenue or 20 million Euros, whichever is greater, and it also confers a private right of action on data subjects for breaches of data protection requirements. Compliance with these directives will be a rigorous and time-intensive process that may increase our cost of doing business, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation and reputational harm in connection with our European activities.

If we fail to retain our key personnel or are unable to attract and retain additional qualified personnel, our future growth and our ability to compete would suffer.

We are highly dependent on the efforts and abilities of the principal members of our senior management. Additionally, we have scientific personnel with significant and unique expertise in RNA-targeted therapeutics and gene therapy technologies. The loss of the services of any one of the principal members of our managerial team or staff may prevent us from achieving our business objectives.

The competition for qualified personnel in the biotechnology field is intense, and our future success depends upon our ability to attract, retain and motivate such personnel. In order to develop and commercialize our products successfully, we will be required to retain key management and scientific employees. In certain instances, we may also need to expand or replace our workforce and our management ranks. In addition, we rely on certain consultants and advisors, including scientific and clinical advisors, to assist us in the formulation and advancement of our research and development programs. Our consultants and advisors may be employed by other entities or have commitments under consulting or advisory contracts with third parties that limit their availability to us, or both. If we are unable to attract, assimilate or retain such key personnel, our ability to advance our programs would be adversely affected.

We expect to expand our organization and may experience difficulties in managing this growth, which could disrupt our operations.

As our business activities expand, we expect to expand our full-time employee base and to hire more consultants and contractors. Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Our ability to manage our growth properly and maintain compliance with all applicable rules and regulations will require us to continue to improve our operational, legal, financial and management controls, as well as our reporting systems and procedures. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy.

Our sales and operations are subject to the risks of doing business internationally.

We are increasing our presence in international markets, including emerging markets, subjecting us to many risks that could adversely affect our business and revenues, such as:

- the inability to obtain necessary foreign regulatory or pricing approvals of products in a timely manner;
- uncertainties regarding the collectability of accounts receivable;
- fluctuations in foreign currency exchange rates that may adversely impact our revenues, net income and value of certain of our investments;
- difficulties in staffing and managing international operations;
- the imposition of governmental controls;
- less favorable intellectual property or other applicable laws;
- increasingly complex standards for complying with foreign laws and regulations that may differ substantially from country to country and may conflict with corresponding U.S. laws and regulations;
- the far-reaching anti-bribery and anti-corruption legislation in the U.K., including the U.K. Bribery Act 2010, and elsewhere and escalation of investigations and prosecutions pursuant to such laws;
- compliance with complex import and export control laws;
- restrictions on direct investments by foreign entities and trade restrictions; and
- changes in tax laws and tariffs.

In addition, our international operations are subject to regulation under U.S. law. For example, the Foreign Corrupt Practices Act (“FCPA”) prohibits U.S. companies and their representatives from paying, offering to pay, promising to pay or authorizing the payment of anything of value to any foreign government official, government staff member, political party or political candidate for the purpose of obtaining or retaining business or to otherwise obtain favorable treatment or influence a person working in an official capacity. In many countries, the health care professionals we regularly interact with may meet the FCPA's definition of a foreign government official. Failure to comply with domestic or foreign laws could result in various adverse consequences, including: possible delay in approval or refusal to approve a product, recalls, seizures or withdrawal of an approved product from the market, disruption in the supply or availability of our products or suspension of export or import privileges, the imposition of civil or criminal sanctions, the prosecution of executives overseeing our international operations and damage to our reputation. Any significant impairment of our ability to sell products outside of the U.S. could adversely impact our business and financial results.

Unfavorable global economic conditions could harm our business, financial condition or results of operations.

Our results of operations could be harmed by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could strain our manufacturers, possibly resulting in manufacturing disruption, or cause delays in payments for our services by third-party payors or our future collaborators. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could harm our business.

Additionally, in June 2016, a majority of United Kingdom ("UK") voters voted for the UK to exit the EU (Brexit) and, on January 31, 2020, the UK's withdrawal became effective. A transition period will apply until the end of 2020 (or later, if extended) during which the pre-Brexit legal regime will continue to apply with the UK and the EU negotiate rules that will apply to their future relationship. The economic effects of Brexit will depend on any agreements the UK makes to retain access to EU markets either during a transitional period or more permanently. Brexit could adversely affect European and worldwide economic or market conditions and could contribute to instability in global financial markets. Brexit is likely to lead to legal uncertainty and potentially divergent national laws and regulations as the UK determines which EU laws to replace or replicate. Any of these effects of Brexit, and any other effects we cannot anticipate, could adversely affect our business, business opportunities, results of operations, financial condition and cash flows.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cyber security incidents, could harm our ability to operate our business effectively.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our suppliers, as well as personally identifiable information of the patients using our commercially approved products, clinical trial participants and employees. Similarly, our third-party providers possess certain of our sensitive data. The secure maintenance of this information is critical to our operations and business strategy. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information, including our data being breached at third party providers, could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, disrupt our operations and damage our reputation, which could adversely affect our business.

We may incur substantial costs in connection with litigation and other disputes.

In the ordinary course of business we may, and in some cases have, become involved in lawsuits and other disputes such as securities claims, intellectual property challenges, including interferences declared by the USPTO, and employee matters. It is possible that we may not prevail in claims made against us in such disputes even after expending significant amounts of money and company resources in defending our positions in such lawsuits and disputes. The outcome of such lawsuits and disputes is inherently uncertain and may have a negative impact on our business, financial condition and results of operations.

Comprehensive tax reform in the U.S. and future guidance could adversely affect our business and financial condition.

The Tax Cuts and Jobs Act (the "TCJA") was enacted on December 22, 2017 in the U.S. The TCJA contains significant changes to corporate taxation, including reduction of the U.S. corporate tax rate from 35% to 21%, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, limitation of the tax deduction for interest expense, immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits.

We continue to monitor for legislative developments, issuance of regulations and technical memorandum to provide further clarification and/or interpretations of the TCJA.

Our ability to use net operating loss carryforwards and other tax attributes to offset future taxable income may be limited as a result of future transactions involving our common stock.

In general, under Section 382 of the Internal Revenue Code, a corporation that undergoes an ''ownership change'' is subject to limitations on its ability to utilize its pre-change net operating losses and certain other tax assets to offset future taxable income. In general, an ownership change occurs if the aggregate stock ownership of certain stockholders increases by more than 50 percentage points over such stockholders' lowest percentage ownership during the testing period, which is generally three years. An ownership change could limit our ability to utilize our net operating loss and tax credit carryforwards for taxable years including or following such "ownership change." Limitations imposed on the ability to use net operating losses and tax credits to offset future taxable income could require us to pay U.S. federal income taxes earlier than we estimated or than would have otherwise been required if such limitations were not in effect and could cause such net operating losses and tax credits to expire unused, in each case reducing or eliminating the benefit of such net operating losses and tax credits and potentially adversely affecting our financial position. Similar rules and limitations may apply for state income tax purposes.

We are winding down our expired U.S. government contracts, and the U.S. government may deny payment of some or all of the currently outstanding amounts owed to us. In addition, further development of our infectious disease programs may be limited by the intellectual property and other rights retained by the U.S. government.

We have historically relied on U.S. government contracts and awards to fund and support certain infectious disease development programs. These contracts are expired and we are currently involved in contract close-out activities. The U.S. government has the right to perform additional audits prior to making final payment of costs and fees. If we are not able to adequately support costs incurred or other government requirements, the government may deny payment of some or all of the currently outstanding amounts owed to us. In addition, the U.S. government may have the right to develop all or some parts of product candidates that we have developed under a U.S. government contract after such contract has terminated or expired.

Our employees, principal investigators, consultants and strategic partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and strategic partners. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA and non-U.S. regulators, provide accurate information to the FDA and non-U.S. regulators, comply with healthcare fraud and abuse laws and regulations in the U.S. and abroad, report financial information or data accurately or disclose unauthorized activities to us. We adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our products, technologies and programs, and the diseases our product and product candidates are designed to treat. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media channels to comment on the effectiveness of a product or to report an alleged adverse event. When such disclosures occur, there is a risk that we fail to monitor and comply with applicable adverse event reporting obligations or we may not be able to defend ourselves or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our product and/or product candidates. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face overly restrictive regulatory actions or incur other harm to our business.

We or the third parties upon whom we depend may be adversely affected by natural disasters and/or health epidemics, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage, health epidemics or other event occurred that prevented us from using all or a significant portion of our office, manufacturing and/or lab spaces, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time.

Our business could be adversely impacted by the effects of the coronavirus (COVID-19) outbreak originating in China, or by other epidemics. Although we do not currently source APIs or drug product from China, our supply chain for other raw materials and critical components is worldwide and accordingly could be subject to disruption. In addition, certain of our research and development efforts are conducted globally. A health epidemic or other outbreak, including the current coronavirus outbreak, may materially and adversely affect our business, financial condition and results of operations.

The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business.

Risks Related to our Financial Condition and Capital Requirements

We have incurred operating losses since our inception and we may not achieve or sustain profitability.

We incurred an operating loss of $705.6 million for the year ended December 31, 2019. Our accumulated deficit was $2.3 billion as of December 31, 2019. Although we currently have two commercially approved products in the U.S., we believe that it will take us some time to attain profitability and positive cash flow from operations. Since our products and product candidates target small patient populations, the per-patient drug pricing must be high in order to recover our development and manufacturing costs, fund adequate patient support programs, fund additional research and achieve profitability. We may be unable to maintain or obtain sufficient sales volumes at a price high enough to justify our product development efforts and our sales, marketing and manufacturing expenses.

We have generally incurred expenses related to research and development of our technologies and product candidates and from general and administrative expenses that we have incurred while building our business infrastructure. We anticipate that our expenses will increase substantially if and/or as we:

- continue the commercialization of our products in the U.S.;
- expand the global footprint of our products outside of the U.S.;
- establish our sales, marketing and distribution capabilities;
- continue our research, pre-clinical and clinical development of our product candidates;
- respond to and satisfy requests and requirements from regulatory authorities in connection with development and potential approval of our product candidates;
- initiate additional clinical trials for our product candidates;
- seek marketing approvals for our product candidates that successfully complete clinical trials;
- acquire or in-license other product candidates;
- maintain, expand and protect our intellectual property portfolio;
- increase manufacturing capabilities, including capital expenditures related to our real estate facilities and entering into manufacturing agreements;
- hire additional clinical, quality control and scientific personnel; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts.

As a result, we expect to continue to incur significant operating losses at least through 2020. Because of the numerous risks and uncertainties associated with developing biopharmaceutical products, we are unable to predict the extent of any future losses or when, or if, we will become profitable.

We will need to raise additional funding, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.

We will likely require additional capital from time to time in the future in order to meet FDA post-marketing approval requirements and market and sell our products as well as to continue the development of product candidates in our pipeline, to prepare for potential commercialization of our product candidates, to expand our product portfolio and to continue or enhance our business development efforts. The actual amount of funds that we may need and the sufficiency of the capital we have or are able to raise will be determined by many factors, some of which are in our control and others that are beyond our control.

While we are currently well capitalized, we may use available capital resources sooner than we expect under our current operating plan. In addition, our operating plan may change. We may need or choose to seek additional funds sooner than planned, through equity or debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or a combination of these approaches. In any event, we expect to require additional capital to expand future development efforts, obtain regulatory approval for, and to commercialize, our product candidates. Raising funds in the current economic environment may present additional challenges. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or in light of specific strategic considerations.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. In the event we receive negative data from our key clinical programs or encounter other major setbacks in our development, manufacturing or regulatory activities or in our commercialization efforts, our stock price is likely to decline, which would make a future financing more difficult. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders. The issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product, if approved, or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights.

We may seek additional capital through a combination of private and public equity offerings, debt financings, collaborations and strategic and licensing arrangements. To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, the ownership interest of our stockholders in our company will be diluted. In addition, the terms of any such securities may include liquidation or other preferences that materially adversely affect the rights of our stockholders. Debt financing, if available, would increase our fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration, strategic partnerships and licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, our intellectual property, future revenue streams or grant licenses on terms that are not favorable to us.

The estimates and judgments we make, or the assumptions on which we rely, in preparing our consolidated financial statements could prove inaccurate.

Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses, the amounts of charges accrued by us and related disclosure of contingent assets and liabilities. Such estimates and judgments include revenue recognition, inventory, valuation of stock-based awards, research and development expenses and income tax. We base our estimates on historical experience, facts and circumstances known to us and on various other assumptions that we believe to be reasonable under the circumstances. We cannot provide assurances, however, that our estimates, or the assumptions underlying them, will not change over time or otherwise prove inaccurate. If this is the case, we may be required to restate our consolidated financial statements, which could, in turn, subject us to securities class action litigation. Defending against such potential litigation relating to a restatement of our consolidated financial statements would be expensive and would require significant attention and resources of our management. Moreover, our insurance to cover our obligations with respect to the ultimate resolution of any such litigation may be inadequate. As a result of these factors, any such potential litigation could have a material adverse effect on our financial results and cause our stock price to decline, which could in turn subject us to securities class action litigation.

Risks Related to Our Common Stock

Our stock price is volatile and may fluctuate due to factors beyond our control.

The market prices for and trading volumes of securities of biotechnology companies, including our securities, has historically been volatile. Our stock has had significant swings in trading prices, in particular in connection with our public communications regarding feedback received from regulatory authorities. For example, over the last thirty-six months, our stock has increased as much as 37% in a single day or decreased as much as 15% in a single day. The market has from time to time experienced significant price and volume fluctuations unrelated to the operating performance of particular companies. The market price of our common stock may fluctuate significantly due to a variety of factors, including but not limited to:

- the commercial performance of our products in the U.S.;
- the timing of our submissions to regulatory authorities and regulatory decisions and developments;
- positive or negative clinical trial results or regulatory interpretations of data collected in clinical trials conducted by us, our strategic partners, our competitors or other companies with investigational drugs targeting the same, similar or related diseases to those targeted by us;
- delays in beginning and completing pre-clinical and clinical trials for potential product candidates;
- delays in entering or failing to enter into strategic relationships with respect to development and/or commercialization of our products or product candidates or entry into strategic relationships on terms that are not deemed to be favorable to us;
- technological innovations, product development or additional commercial product introductions by ourselves or competitors;
- changes in applicable government regulations or regulatory requirements in the approval process;
- developments concerning proprietary rights, including patents and patent litigation matters, such as developments in the interferences declared by the USPTO, including in the near term any outcomes of ongoing interference proceedings and over the longer term the outcomes from any related appeals;
- public concern relating to the commercial value, efficacy or safety of any of our products;
- our ability to obtain funds, through the issuance of equity or equity linked securities or incurrence of debt, or other corporate transactions;
- comments by securities analysts;
- developments in litigation against us;
- changes in senior management; or
- general market conditions in our industry or in the economy as a whole.

Broad market and industry factors may seriously affect the market price of a company’s stock, including ours, regardless of actual operating performance. In addition, in the past, following periods of volatility in the overall market and the market price of a particular company’s securities, securities class action litigation has often been instituted against these companies. Such litigation could result in substantial costs and a diversion of our management’s attention and resources.

Our revenues and operating results could fluctuate significantly, which may adversely affect our stock price.

Our revenues and operating results may vary significantly from year-to-year and quarter-to-quarter as well as in comparison to the corresponding quarter of the preceding year. Variations my result from one or more factors, including, without limitation:

- timing of purchase orders;
- changes in coverage and reimbursement policies of health plans and other health insurers, especially in relation to those products that are currently manufactured, under development or identified for future development by us;
- re-authorizations processes that may be required for patients who initially obtained coverage by third parties, including government payors, managed care organizations and private health insurers;
- transition from temporary billing codes established by the CMS to permanent medical codes;
- timing of approval of applications filed with the FDA;

- timing of product launches and market acceptance of products launched;
- changes in the amounts spent to research, develop, acquire, license or promote new and existing products;
- results of clinical trial programs;
- serious or unexpected health or safety concerns with our product or product candidates and any resulting clinical holds;
- introduction of new products by others that render one or more of our products obsolete or noncompetitive;
- the ability to maintain selling prices and gross margins on our products;
- increases in the cost of raw materials contained within our products and product candidates;
- manufacturing and supply interruptions, including product rejections or recalls due to failure to comply with manufacturing specifications;
- timing of revenue recognition relating to our distribution agreements;
- the ability to protect our intellectual property from being acquired by other entities;
- the ability to avoid infringing the intellectual property of others; and
- the addition or loss of customers.

In addition, in one or more future periods, our results of operations may fall below the expectations of securities analysts and investors. In that event, the market price of our common stock could decline.

Provisions of our certificate of incorporation, bylaws and Delaware law might deter acquisition bids for us that might be considered favorable and prevent or frustrate any attempt to replace or remove the then-current management and board of directors.

Certain provisions of our certificate of incorporation and bylaws may make it more difficult for a third party to acquire control of us or effect a change in our board of directors and management. These provisions include:

- when the board is comprised of six or more directors, classification of our board of directors into two classes, with one class elected each year;
- directors may only be removed for cause by the affirmative vote of a majority of the voting power of all the then-outstanding shares of voting stock;
- prohibition of cumulative voting of shares in the election of directors;
- right of the board of directors to elect directors to fill a vacancy created by the expansion of the board of directors or the resignation, death, disqualification or removal of a director;
- express authorization of the board of directors to make, alter or repeal our bylaws;
- prohibition on stockholder action by written consent;
- advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at stockholder meetings;
- the ability of our board of directors to authorize the issuance of undesignated preferred stock, the terms and rights of which may be established and shares of which may be issued without stockholder approval, including rights superior to the rights of the holders of common stock; and
- a super-majority (66 2/3%) of the voting power of all of the then-outstanding shares of capital stock are required to amend, rescind, alter or repeal our bylaws and certain provisions of our certificate of incorporation.

In addition, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These and other provisions in our certificate of incorporation and our bylaws and in the Delaware General Corporation Law could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors.

A significant number of shares of our common stock are issuable pursuant to outstanding stock awards, and we expect to issue additional stock awards and shares of common stock to attract and retain employees, directors and consultants. We may also

issue shares of common stock to finance our operations and in connection with our strategic goals. Exercise of these awards and sales of shares will dilute the interests of existing security holders and may depress the price of our common stock.

Currently, our Amended and Restated Certificate of Incorporation authorizes the issuance of up to 99.0 million shares of common stock. As of December 31, 2019, there were approximately 75.2 million shares of common stock outstanding and outstanding awards to purchase 9.1 million shares of common stock under various incentive stock plans. Additionally, as of December 31, 2019, there were approximately 3.4 million shares of common stock available for future issuance under our 2018 Equity Incentive Plan, approximately 0.6 million shares of common stock available for issuance under our Amended and Restated 2013 Employee Stock Purchase Plan, and approximately 0.6 million shares of common stock available for issuance under our 2014 Employment Commencement Incentive Plan.

We may issue additional shares to grant equity awards to our employees, officers, directors and consultants under our 2018 Equity Incentive Plan, our 2013 Employee Stock Purchase Plan or our 2014 Employment Commencement Incentive Plan. We may also issue additional common stock and warrants from time to time to finance our operations and in connection with strategic transactions, such as acquisitions and licensing. For example, in February 2020, we issued and sold 2,522,227 shares of common stock to Roche Finance in connection with the entry into the collaboration agreement with Roche. We will need to increase our authorized shares of common stock under our Amended and Restated Certificate of Incorporation to support these strategic goals. There can be no assurance that we will be able to obtain shareholder approval to increase the number of authorized shares.

The issuance of additional shares of common stock or warrants to purchase common stock and the perception that such issuances may occur or exercise of outstanding warrants or stock options may have a dilutive impact on other stockholders and could have a material negative effect on the market price of our common stock.

Future sales of our common stock in the public market could cause our share price to fall.

Sales of a substantial number of our common stock in the public market, including sales by members of our management or board of directors, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity or equity-related securities.

Risks Related to Our Credit Agreement and Convertible Senior Notes

Our indebtedness resulting from our credit agreement could adversely affect our financial condition or restrict our future operations.

On December 13, 2019, we entered into a loan agreement (the "Credit Agreement") with BioPharma Credit PLC, as the collateral agent and a lender ("BioPharma"), and BioPharma Credit Investments V (Master) LP, as a lender (together with BioPharma in its capacity as a lender, and each of their respective successors and assigns at any time party to the Credit Agreement, the "Lenders" and each a "Lender") that provides for a senior secured term loan facility of up to $500.0 million to be funded in two tranches: (i) a Tranche A Loan in an aggregate principal amount of $250.0 million (the "Tranche A Loan"), which was funded on December 20, 2019; and (ii) a Tranche B Loan in an aggregate principal amount of up to $250.0 million (the "Tranche B Loan", and together with the Tranche A Loan, the "Term Loans"), to be funded at our option in increments of $50.0 million, which proposed funding date shall be 75 days following the delivery of notice and in no event later than December 31, 2020. There is no assurance that the Lenders will fund the Tranche B Loan if and when requested.

All obligations under the Credit Agreement are secured pursuant to the terms of a security agreement and subject to certain exceptions, by security interests in certain collateral (collectively, the "Collateral"), which includes the following: (1) any and all U.S. intellectual property owned by, and rights to U.S. intellectual property licensed to, us relating to any pharmaceutical composition in which eteplirsen or golodirsen is indicated to be administered for use in the treatment of DMD in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 or 53 skipping, respectively, or for any other use approved by the FDA (the "Loan Products"), (2) 100% of the equity interests directly held by us in certain wholly owned domestic subsidiaries and 65% of the equity interests in certain other wholly owned domestic subsidiaries, and (3) all of our personal property, including, without limitation, cash held in all our deposit accounts. Any non-U.S. intellectual property related to the Loan Products and intellectual property unrelated in any way to the Loan Products anywhere are not part of the Collateral.

The Credit Agreement contains negative covenants that, among other things and subject to certain exceptions, restrict our ability to:

- sell or dispose of assets, including certain intellectual property;
- amend, modify or waive certain material agreements or organizational documents;
- consolidate or merge;
- incur additional indebtedness;
- incur additional liens on the Collateral;
- pay dividends or make any distribution or payment on or redeem, retire or purchase any equity interests; and

- make payments of certain subordinated indebtedness.

The Credit Agreement requires us to have consolidated liquidity of at least $100.0 million as of the last day of each month. Additionally, the Credit Agreement contains certain representations and warranties, affirmative covenants and provisions relating to events of default, which include, but are not limited to, the following: (i) nonpayment of principal, interest and other amounts; (ii) failure to comply with covenants; (iii) the occurrence of a material adverse change in (A) our ability to fulfill the payment or performance obligations under the Credit Agreement and related documents or (B) the binding nature of the Credit Agreement and related documents; (iv) the rendering of judgments or orders or the acceleration or payment default by us in respect of other indebtedness in excess of $10.0 million; and (v) certain insolvency and ERISA events. A change of control triggers a mandatory prepayment of the Term Loans, and we may not have sufficient funds or the ability to raise the funds necessary to prepay them.

Servicing our Credit Agreement and 1.50% notes due 2024 (the "Notes") requires a significant amount of cash, and we may not have sufficient cash flow to pay our debt.

In 2017, we issued $570.0 million aggregate principal amount of Notes, pursuant to that certain indenture, dated as of November 14, 2019, between us, as issuer, and U.S. Bank National Association, as trustee. Our ability to make scheduled payments of the principal of, to pay interest on, or to refinance our indebtedness, including the Credit Agreement and the Notes, depends on our future performance, which is subject to many factors, including, economic, financial, competitive and other, beyond our control. We do not expect our business to be able to generate cash flow from operations in the foreseeable future, sufficient to service our debt and make necessary capital expenditures and we may therefore be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance the Credit Agreement, which matures in 2023, and the Notes, which are non-callable and mature in 2024, will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations, and limit our flexibility in planning for and reacting to changes in our business.

We may not have the ability to raise the funds necessary to repurchase the Notes as required upon a fundamental change, and our future debt may contain limitations on our ability to repurchase the Notes.

Holders of the Notes will have the right to require us to repurchase their Notes for cash upon the occurrence of a fundamental change at a fundamental change repurchase price equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest, if any. A fundamental change may also constitute an event of default or prepayment under, and result in the acceleration of the maturity of, our then-existing indebtedness. We cannot assure you that we will have sufficient financial resources, or will be able to arrange financing, to pay the fundamental change repurchase price in cash with respect to any Notes surrendered by holders for repurchase upon a fundamental change. In addition, restrictions under our then existing credit facilities or other indebtedness, if any, may not allow us to repurchase the Notes upon a fundamental change. Our failure to repurchase the Notes upon a fundamental change when required would result in an event of default with respect to the Notes which could, in turn, constitute a default under the terms of our other indebtedness, if any. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the Notes.

Capped call transactions entered into in connection with the Notes may impact the value of our common stock.

In connection with the Notes, we entered into capped call transactions (the "Capped Call Transactions") with certain financial institutions. The Capped Call Transactions are expected to generally reduce the potential dilution upon conversion of the Notes into shares of our common stock.

In connection with establishing their initial hedges of the Capped Call Transactions, these financial institutions or their respective affiliates entered into various derivative transactions with respect to our common stock and/or to purchase our common stock. The financial institutions, or their respective affiliates, may modify their hedge positions by entering into or unwinding various derivatives with respect to our common stock and/or purchasing or selling our common stock or other securities of ours in secondary market transactions prior to the maturity of the Notes. This activity could also cause or avoid an increase or a decrease in the market price of our common stock or the Notes, which could affect the value of our common stock.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

A description of the facilities we own and/or occupy is included in the following table. We believe that our current facilities in Cambridge, Andover and Burlington, Massachusetts and Columbus, Ohio are suitable and will provide sufficient capacity to meet

the projected needs of our business for the next 12 months. Except as noted below, all of our properties are currently being used in the operation of our business.

Location of Property	Square Footage	Lease Expiration Date	Purpose	Other Information
215 First Street, Cambridge, MA	170,929	September 2025	Laboratory and office space	Corporate headquarters
100 Federal Street, Andover, MA	65,589	N/A- facility is owned	Laboratory and office space	Primarily laboratory space
300 Federal Street, Andover, MA	23,102	December 2020	Office space	Office space
55 Network Drive, Burlington, MA	44,740	January 2022	Laboratory and office space	Primarily laboratory space
3435 Stelzer Road, Columbus, OH	77,679	June 2026	Laboratory and office space	Primarily laboratory space

Item 3. Legal Proceedings.

For material legal proceedings, please read *Note 21, Commitments and Contingencies - Litigation* to our consolidated financial statements included in this Annual Report.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock is quoted on the NASDAQ Global Select Market under the same symbol "SRPT".

Holders

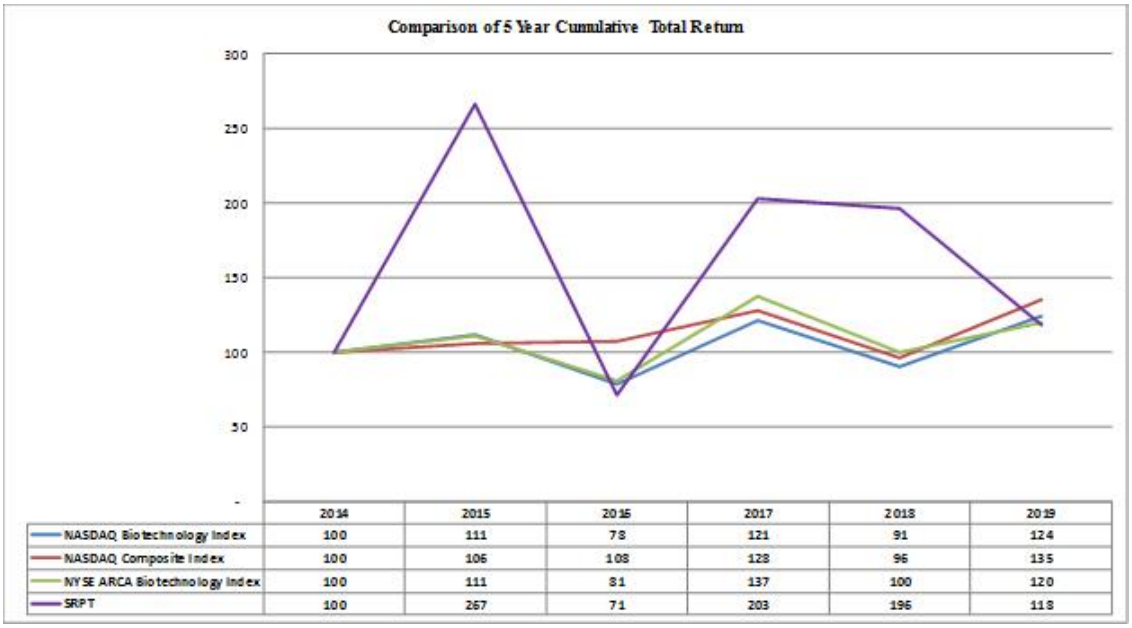
As of February 21, 2020, we had 196 stockholders of record of our common stock.

Dividends

We did not declare or pay cash dividends on our common stock in 2019, 2018 or 2017. We currently expect to retain future earnings, if any, to finance the operation and expansion of our business, and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors.

Performance Graph

The following graph compares the performance of our Common Stock for the periods indicated with the performance of the NASDAQ Composite Index, NASDAQ Biotechnology Index and the NYSE ARCA Biotechnology Index. This graph assumes an investment of $100 after the market closed December 31, 2014 in each of our common stock, the NASDAQ Composite Index, NASDAQ Biotechnology Index and the NYSE ARCA Biotechnology Index, and assumes reinvestment of dividends, if any. The stock price performance shown on the graph below is not necessarily indicative of future stock price performance. This graph is not "soliciting material," is not deemed "filed" with the SEC and is not to be incorporated by reference into any of our filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.



	2014	2015	2016	2017	2018	2019
NASDAQ Biotechnology Index	100	111	78	121	91	124
NASDAQ Composite Index	100	106	108	128	96	135
NYSE ARCA Biotechnology Index	100	111	81	137	100	120
SRPT	100	267	71	203	196	118

Recent Sales of Unregistered Securities.

On November 13, 2019, pursuant to a Stock Purchase Agreement, dated as of November 13, 2019, between Sarepta and StrideBio, we issued and sold 301,980 shares (the "StrideBio Shares") of common stock to StrideBio for an aggregate purchase price of approximately $30.5 million, or $101.00 per share. The price was equal to the closing sales price of our common stock on November 13, 2019. We agreed to file a registration statement with the U.S. Securities and Exchange Commission covering the resale by StrideBio of the StrideBio Shares. We relied on the exemption from the registration requirements of the Securities Act under Section 4(a)(2) thereof, for a transaction by an issuer not involving any public offering.

On February 14, 2020, pursuant to a Stock Purchase Agreement, dated as of December 23, 2019, between Sarepta and Roche Finance, we issued and sold 2,522,227 shares (the "Roche Shares") of common stock to Roche Finance for an aggregate purchase price of approximately $400.0 million, or $158.59 per share. We relied on the exemption from the registration requirements of the Securities Act under Section 4(a)(2) thereof, for a transaction by an issuer not involving any public offering.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers.

None.

Item 6. Selected Financial Data.

The following selected financial data are derived from our consolidated financial statements and should be read in conjunction with, and is qualified in its entirety by, *Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations*, and *Item 8, Financial Statements and Supplementary Data.*

	For the Year Ended December 31,				
	2019	2018	2017	2016	2015
	(in thousands, except per share amounts)				
Operations data:					
Revenues	$ 380,833	$ 301,034	$ 154,584	$ 5,421	$ 1,253
Cost of sales (excluding amortization of in licensed rights)	56,586	34,193	7,353	101	—
Research and development	560,909	401,843	166,707	188,272	146,394
Selling, general and administrative	284,812	207,761	122,682	83,749	75,043
Settlement and license charges	10,000	—	28,427	—	—
Acquired in-process research and development	173,240	—	—	—	—
Amortization of in-licensed rights	849	865	1,053	29	—
Operating loss	(705,563)	(343,628)	(171,638)	(266,730)	(220,184)
Other (expense) income, net	(8,317)	(18,982)	(1,990)	(535)	154
Gain from sale of Priority Review Voucher	—	—	125,000	—	—
Loss before income tax expense (benefit)	(713,880)	(362,610)	(48,628)	(267,265)	(220,030)
Income tax expense (benefit)	1,195	(692)	2,060	—	—
Net loss	$ (715,075)	$ (361,918)	$ (50,688)	$ (267,265)	$ (220,030)
Net loss per share—basic and diluted	$ (9.71)	$ (5.46)	$ (0.86)	$ (5.49)	$ (5.20)
Balance sheet data:					
Cash and cash equivalents	$ 835,080	$ 370,829	$ 599,691	$ 122,420	$ 80,304
Short-term investments	289,668	803,083	489,349	195,425	112,189
Working capital	1,204,146	1,252,493	1,140,312	298,054	162,249
Total assets	1,822,822	1,642,075	1,307,964	424,104	273,782
Long-term debt	681,900	420,554	431,051	16,150	20,905
Stockholders' equity	818,187	1,032,276	789,217	336,691	190,347

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements that involve risks and uncertainties. Please review our legend titled "Forward-Looking Information" at the beginning of this Annual Report on Form 10-K which is incorporated herein by reference. Our actual results could differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled "Risk Factors" included elsewhere in this Annual Report on Form 10-K. Throughout this discussion, unless the context specifies or implies otherwise, the terms "Sarepta", "we", "us" and "our" refer to Sarepta Therapeutics, Inc. and its subsidiaries.

This section discusses 2019 and 2018 items and year-to-year comparisons between 2019 and 2018. Discussions of 2017 items and year-to-year comparisons between 2018 and 2017 have been excluded from this Form 10-K and can be found in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7 of our Annual Report on Form 10-K for the fiscal year ended December 31, 2018.

Overview

We are a commercial-stage biopharmaceutical company focused on helping patients through the discovery and development of unique RNA-targeted therapeutics, gene therapy and other genetic therapeutic modalities for the treatment of rare diseases. Applying our proprietary, highly-differentiated and innovative technologies, and through collaborations with our strategic partners, we are developing potential therapeutic candidates for a broad range of diseases and disorders, including DMD, LGMDs, MPS IIIA and other CNS related disorders.

Our first commercial product, EXONDYS 51, was granted accelerated approval by the FDA on September 19, 2016. EXONDYS 51 is indicated for the treatment of DMD in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping. EXONDYS 51 uses our PMO chemistry and exon-skipping technology to skip exon 51 of the dystrophin gene.

Our second commercial product, VYONDYS 53, was granted accelerated approval by the FDA on December 12, 2019. VYONDYS 53 is indicated for the treatment of DMD in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. VYONDYS 53 uses our PMO chemistry and exon-skipping technology to skip exon 53 of the dystrophin gene.

A summary description of our key product candidates, including those in collaboration with our strategic partners, is as follows:

- *Casimersen* (SRP-4045) uses our PMO chemistry and exon-skipping technology to skip exon 45 of the DMD gene. Casimersen is designed to bind to exon 45 of dystrophin pre-mRNA, resulting in exclusion, or "skipping", of this exon during mRNA processing in patients with genetic mutations that are amenable to exon 45 skipping. We are enrolling and dosing patients in ESSENCE (4045-301), our Phase 3 placebo controlled confirmatory trial in patients who have a confirmed mutation of the DMD gene that is amenable to exon 45 or 53 skipping using casimersen and golodirsen, respectively. On March 28, 2019, we announced results from our interim analysis of muscle biopsy endpoints comparing casimersen treatment to placebo in the ESSENCE study. In January 2020, we commenced a rolling submission of an NDA to the FDA seeking accelerated approval for casimersen.
- *SRP-5051* uses our next-generation chemistry platform, PPMO, and our exon-skipping technology to skip exon 51 of the dystrophin gene. SRP-5051, a peptide conjugated PMO, is designed to bind to exon 51 of dystrophin pre-mRNA, resulting in exclusion of this exon during mRNA processing in patients with genetic mutations that are amenable to exon 51 skipping. Exon skipping is intended to promote the production of an internally truncated but functional dystrophin protein. In the fourth quarter of 2017, we commenced a first-in-human, single ascending dose, study for the treatment of DMD in patients who are amenable to exon 51 skipping. In 2019, we commenced a multiple ascending dose, study for the treatment of DMD with SRP-5051 in patients who are amenable to exon 51 skipping, and we expect to have safety and dosing insights in the middle of 2020.
- *SRP-9001 (DMD, micro-dystrophin gene therapy program)*, aims to express micro-dystrophin – a smaller but still functional version of dystrophin. A unique, engineered micro-dystrophin is used because naturally-occurring dystrophin is too large to fit in an AAV vector. In the fourth quarter of 2017, an IND application for the micro-dystrophin gene therapy program was cleared by the FDA, and a Phase 1/2a clinical trial in individuals with DMD was initiated. On October 3, 2018, Nationwide presented what we believe to be positive results from the Phase 1/2a clinical trial in four individuals with DMD enrolled in the trial. On March 25, 2019, we presented nine-month functional and CK data from baseline from these four individuals, and twelve-month CK data from baseline from one of these individuals. In the fourth quarter of 2018, we commenced a randomized, double-blind, placebo-controlled trial of SRP-9001 with the goal to establish the functional benefits of micro-dystrophin expressions. We have dosed all 41 participants in that trial and have begun dosing participants in the crossover phase of the study. We plan to commence a trial evaluating SRP-9001 using commercial supply in the middle of 2020, pending regulatory feedback.

- *SRP-9003 (LGMD, gene therapy program)*. We are developing gene therapy programs for various forms of LGMDs. The most advanced of our LGMD product candidates, SRP-9003, is designed to transfer a gene that codes for and restores beta-sarcoglycan protein with the goal of restoring the dystrophin associated protein complex. It utilizes the AAVrh.74 vector system, the same vector used in the micro-dystrophin gene therapy program we are developing with Nationwide. A Phase 1/2a trial of SRP-9003 was commenced in the fourth quarter of 2018. On February 27, 2019, we announced positive two-month biopsy data from the first three-patient cohort dosed in the SRP-9003 trial, and on October 4, 2019, we announced positive nine-month functional data from these three patients. We have recently dosed one additional cohort of three patients at a higher dose per the study protocol. We expect to have the results from the second cohort and make a dose selection in the third quarter of 2020.
- *LYS-SAF 302*. We are collaborating with Lysogene to develop a gene therapy, LYS-SAF302, to treat MPS IIIA. Lysogene is conducting a global Phase 2/3 clinical trial of LYS-SAF302 (AAVance) to evaluate the effectiveness of a one-time delivery of an AAVrh.10 virus carrying the N-SGSH gene. We expect to complete dosing in this trial in the first half of 2020.

Our pipeline includes more than 40 programs in various stages of pre-clinical and clinical development, reflecting our aspiration to apply our multifaceted approach and expertise in precision genetic medicine to make a profound difference in the lives of patients suffering from rare diseases.

We have developed proprietary state-of-the-art CMC and manufacturing capabilities that allow synthesis and purification of our products and product candidates to support both clinical development as well as commercialization. Our current main focus in manufacturing is to continue scaling up production of our PMO-based therapies and optimizing manufacturing for PPMO and gene therapy-based product candidates. We have entered into certain manufacturing and supply arrangements with third-party suppliers which will in part utilize these capabilities to support production of certain of our products and product candidates and their components. In 2017, we opened a facility in Andover, Massachusetts, which significantly enhanced our research and development manufacturing capabilities. However, we currently do not have internal large scale GMP manufacturing capabilities to produce our products and product candidates for commercial and/or clinical use.

As of December 31, 2019, we had approximately $1,134.4 million of cash, cash equivalents and investments, consisting of $835.1 million of cash and cash equivalents, $289.7 million of short-term investments and $9.6 million of long-term restricted cash and investments. We believe that our balance of cash, cash equivalents and investments is sufficient to fund our current operational plan for at least the next twelve months.

The likelihood of our long-term success must be considered in light of the expenses, difficulties and delays frequently encountered in the development and commercialization of new pharmaceutical products, competitive factors in the marketplace and the complex regulatory environment in which we operate. We may never achieve significant revenue or profitable operations.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements included elsewhere in this Annual Report on Form 10-K. The preparation of our consolidated financial statements in accordance with accounting principles generally accepted in the U.S. requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities for the periods presented. Some of these judgments can be subjective and complex, and, consequently, actual results may differ from these estimates. We believe that the estimates and judgments upon which we rely are reasonable based upon historical experience and information available to us at the time that we make these estimates and judgments. To the extent there are material differences between these estimates and actual results, our consolidated financial statements will be affected. Although we believe that our judgments and estimates are appropriate, actual results may differ from these estimates. We believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our consolidated financial statements:

- revenue recognition;
- inventory; and
- income tax.

Revenue Recognition

To determine revenue recognition for arrangements within the scope of ASC 606, we perform the following five steps: (1) identify the contracts with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when or as we satisfy a performance obligation.

Variable Consideration

Product revenues are recorded at the net sales price (transaction price) which includes estimated reserves for variable consideration, such as Medicaid rebates, governmental chargebacks, including PHS chargebacks, prompt payment discounts, co-pay assistance and distribution fees. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if no payment is required by us) or a current liability (if a payment is required by us). These reserves reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the contracts. Additional details relating to variable consideration follows:

- Medicaid rebates relate to our estimated obligations to states under established reimbursement arrangements. Rebate reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a liability which is included in accrued expenses.
- Governmental chargebacks, including PHS chargebacks, relate to our estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices that we charge to wholesalers. The wholesaler charges us for the difference between what the wholesaler pays for the products and the ultimate selling price to the qualified healthcare providers. Chargeback reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable. Chargeback amounts are generally determined at the time of resale to the qualified healthcare provider from the wholesaler, and we generally issue credits for such amounts within a few weeks of receiving notification of resale from the wholesaler.
- Prompt payment discounts relate to our estimated obligations for credits to be granted to specialty pharmacies for remitting payment on their purchases within established incentive periods. Reserves for prompt payment discounts are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable.
- Co-pay assistance relates to financial assistance provided to qualified patients, whereby we may assist them with prescription drug co-payments required by the patient's insurance provider. Reserves for co-pay assistance are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a liability which is included in accrued expenses.
- Distribution fees relate to fees paid to customers in the distribution channel that provide us with inventory management, data and distribution services and are generally accounted for as a reduction of revenue. To the extent that the services received are distinct from our sale of products to the customer, these payments are accounted for as selling, general and administrative expenses. Reserves for distribution fees result in an increase in a liability if payments are required of us or a reduction of accounts receivable if no payments are required of us.

Please read *Note 7, Accounts Receivable and Reserves for Product Sales* to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K for a further discussion of revenue recognition.

Inventory Valuation

Inventories are stated at the lower of cost and net realizable value with cost determined on a first-in, first-out basis. We capitalize inventory costs associated with products following regulatory approval when future commercialization is considered probable and the future economic benefit is expected to be realized. EXONDYS 51 and VYONDYS 53 inventory that may be used in clinical development programs is charged to research and development expense when the product enters the research and development process and no longer can be used for commercial purposes.

We periodically review our inventories for excess amounts or obsolescence and write down obsolete or otherwise unmarketable inventory to its estimated net realizable value. Additionally, though our products are subject to strict quality control and monitoring, which we perform throughout the manufacturing processes, certain batches or units of product may not meet quality specifications resulting in a charge to cost of sales.

Income Tax

We recognize the effect of income tax positions only if those positions are more likely than not of being sustained upon an examination. The calculation of our tax liabilities resulting from uncertain tax positions can involve significant judgment. Further, the calculation may involve the application of complex tax regulations in a foreign jurisdiction. Although we believe that we have adequately provided for tax liabilities resulting from uncertain tax positions, the actual amounts paid, if any, could have a material impact on our results of operations. Interest and penalties associated with uncertain tax positions are classified as a component of income tax expense.

Please read *Note 2, Summary of Significant Accounting Policies and Recent Accounting Pronouncements* to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K for a further discussion of our critical accounting policies and estimates.

The following table sets forth selected consolidated statements of operations data for each of the periods indicated:

	For the Year Ended December 31,			
	2019	2018	Change	Change
	(in thousands, except per share amounts)		$	%
Revenues:				
Product, net	$ 380,833	$ 301,034	$ 79,799	27%
Total revenues	380,833	301,034	79,799	27%
Cost and expenses:				
Cost of sales (excluding amortization of in-licensed rights)	56,586	34,193	22,393	65%
Research and development	560,909	401,843	159,066	40%
Selling, general and administrative	284,812	207,761	77,051	37%
Acquired in-process research and development	173,240	—	173,240	NM*
Settlement and license charges	10,000	—	10,000	NM*
Amortization of in-licensed rights	849	865	(16)	(2)%
Total cost and expenses	1,086,396	644,662	441,734	69%
Operating loss	(705,563)	(343,628)	(361,935)	105%
Other loss:				
Other expense, net	(8,317)	(18,982)	10,665	(56)%
Loss before income tax expense (benefit)	(713,880)	(362,610)	(351,270)	97%
Income tax expense (benefit)	1,195	(692)	1,887	(273)%
Net loss	$ (715,075)	$ (361,918)	$ (353,157)	98%
Net loss per share — basic and diluted	$ (9.71)	$ (5.46)	$ (4.25)	78%

* NM: not meaningful

Revenues

Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established and which result from Medicaid rebates, governmental chargebacks, including PHS chargebacks, prompt pay discounts, co-pay assistance and distribution fees. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if no payments are required of us) or a current liability (if a payment is required of us). These reserves are based on estimates of the amounts earned or to be claimed on the related sales. Our estimates take into consideration current contractual and statutory requirements. The amount of variable consideration that is included in the transaction price may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received or paid may differ from our estimates. If actual results in the future vary from our estimates, we will adjust these estimates, which would affect net product revenue and net loss in the period such variances become known.

Net product revenues for our products for 2019 increased by $79.8 million compared with 2018. The increase primarily reflects the continuing increase in demand for EXONDYS 51 in the U.S.

Cost of sales (excluding amortization of in-licensed rights)

Our cost of sales (excluding amortization of in-licensed rights) primarily consists of inventory costs that relate to sales of our products following their commercial launches in the U.S., royalty payments, and other inventory costs. Prior to receiving regulatory approval for EXONDYS 51 and VYONDYS 53 by the FDA in September 2016 and December 2019, respectively, we expensed such manufacturing and material costs as research and development expenses. For VYONDYS 53 sold in 2019, the majority of related manufacturing costs incurred had previously been expensed as research and development expenses, as such costs were incurred prior to the FDA approval of the products. For EXONDYS 51 sold in 2018 and 2019, only part of the related manufacturing costs incurred had previously been expensed as research and development expenses. If product related costs had not previously been expensed as research and development expenses prior to receiving FDA approval, the incremental inventory costs related to our products sold in 2019 and 2018 would have been approximately $12.4 million and $12.6 million, respectively.

In addition to royalty payments to BioMarin Pharmaceuticals, Inc. ("BioMarin"), during the second quarter of 2019, we began to pay the University of Western Australia ("UWA") a low-single-digit percentage royalty on net sales of products covered by issued patents licensed from UWA.

The following table summarizes the components of our cost of sales for the periods indicated:

	For the Year Ended December 31,		Change	Change
	2019	2018		
	(in thousands)		$	%
Inventory costs related to products sold	$ 28,891	$ 13,370	$ 15,521	116%
Royalty payments	22,923	15,065	7,858	52%
Other inventory costs	4,772	5,758	(986)	(17)%
Total cost of sales	$ 56,586	$ 34,193	$ 22,393	65%

The cost of sales for 2019 increased $22.4 million, or 65%, compared with 2018. The increase was primarily driven by the following:

- $15.5 million and $7.9 million increases in inventory costs related to products sold and royalty payments to BioMarin and UWA, respectively, primarily as a result of the increasing demand for EXONDYS 51 during 2019; and
- $1.0 million decrease in other inventory costs as a result of a reduction in write-offs of certain batches of EXONDYS 51 not meeting our quality specifications.

Research and Development Expenses

Research and development expenses consist of costs associated with research activities as well as costs associated with our product development efforts, conducting pre-clinical trials, clinical trials and manufacturing activities. Direct research and development expenses associated with our programs include clinical trial site costs, clinical manufacturing costs, costs incurred for consultants, up-front fees and milestones paid to third parties in connection with technologies that have not reached technological feasibility and do not have an alternative future use, and other external services, such as data management and statistical analysis support, and materials and supplies used in support of clinical programs. Indirect costs of our clinical programs include salaries, stock-based compensation and allocation of our facility and technology costs.

Research and development expenses represent a substantial percentage of our total operating expenses. We do not maintain or evaluate and, therefore, do not allocate internal research and development costs on a project-by-project basis. As a result, a significant portion of our research and development expenses are not tracked on a project-by-project basis, as the costs may benefit multiple projects.

The following table summarizes our research and development expenses by project for each of the periods indicated:

	For the Year Ended December 31,		Change	Change
	2019	2018		
	(in thousands)		$	%
Gene therapies	$ 123,210	$ 8,880	$ 114,330	NM*
Up-front, milestone, and other expenses	103,162	142,413	(39,251)	(28)%
Eteplirsen (exon 51)	47,042	32,056	14,986	47%
Casimersen (exon 45)	27,095	26,758	337	1%
Golodirsen (exon 53)	21,390	25,875	(4,485)	(17)%
PPMO platform	19,082	23,911	(4,829)	(20)%
Collaboration cost-sharing	9,416	8,599	817	10%
Other projects	3,262	2,135	1,127	53%
Internal research and development expenses	207,250	131,216	76,034	58%
Total research and development expenses	$ 560,909	$ 401,843	$ 159,066	40%

* NM: not meaningful

The following table summarizes our research and development expenses by category for each of the periods indicated:

	For the Year Ended December 31,			
	2019	2018	Change	Change
	(in thousands)		$	%
Clinical and manufacturing expenses	$ 222,178	$ 111,101	$ 111,077	100%
Up-front, milestone, and other expenses	103,162	142,413	(39,251)	(28)%
Compensation and other personnel expenses	89,639	49,701	39,938	80%
Facility- and technology-related expenses	46,556	16,555	30,001	181%
Stock-based compensation	27,681	14,214	13,467	95%
Professional services	22,965	17,926	5,039	28%
Pre-clinical expenses	11,729	22,992	(11,263)	(49)%
Collaboration cost-sharing	9,416	8,599	817	10%
Research and other	27,583	18,342	9,241	50%
Total research and development expenses	$ 560,909	$ 401,843	$ 159,066	40%

Research and development expenses for 2019 increased by $159.1 million, or 40%, compared with 2018. The increase was primarily driven by the following:

- $111.1 million increase in clinical and manufacturing expenses primarily due to a ramp-up of manufacturing activities for our gene therapy programs (including our micro-dystrophin program), increased patient enrollment in our ESSENCE trial, and initiation of certain post-market studies for EXONDYS 51. These increases were partially offset by a ramp-down of clinical trials in EXONDYS 51, including the PROMOVI trial and the Phase 1/2 trial in VYONDYS 53;
- $39.3 million decrease in up-front, milestone, and other expenses, primarily due to $46.9 million of up-front cash and equity payments to StrideBio as a result of the execution of a license and collaboration agreement in November 2019, a $28.0 million up-front payment to Genethon as a result of the execution of a license and collaboration agreement in November 2019, and $25.6 million of up-front and milestone payments made to various academic institutions throughout 2019, as compared with $85.0 million up-front and milestone payments to Myonexus as a result of the execution of a warrant agreement in May 2018 as well as certain development milestones being achieved, $44.8 million up-front and milestone payments to Lysogene as a result of the execution of a collaboration and license agreement in October 2018 as well as certain development milestones becoming probable of being achieved, and $8.0 million related to the purchase of a license to develop, manufacture and commercialize a pre-clinical Pompe product candidate under a license agreement with Lacerta in August 2018;
- $39.9 million increase in compensation and other personnel expenses primarily due to a net increase in headcount;
- $30.0 million increase in facility- and technology-related expenses due to our continuing global expansion efforts as well as a change in methodology in allocation of technology expense;
- $13.5 million increase in stock-based compensation expense primarily driven by increases in headcount and stock price;
- $5.0 million increase in professional services primarily due to continuing accelerated company growth as a result of expansion of our research and development pipeline;
- $11.3 million decrease in pre-clinical expenses primarily due to the completion of certain toxicology studies in our PPMO platform;
- $0.8 million increase in collaboration cost-sharing driven by collaboration cost-sharing with Genethon on its microdystrophin platform, offset by a decrease in collaboration cost-sharing with Summit (Oxford) Ltd. as it wound down activities on its Utrophin platform; and
- $9.2 million increase in research and other primarily driven by a $7.1 million increase in lab supplies as a result of an increase in headcount as well as a $3.0 million increase in sponsored research with academic institutions, partially offset by a reduction of $3.8 million in loss due to impairment of certain patents from 2018.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist of salaries, benefits, stock-based compensation and related costs for personnel in our executive, finance, legal, information technology, business development, human resources, commercial and other general and administrative functions. Other general and administrative expenses include an allocation of our facility and technology costs and professional fees for legal, consulting and accounting services.

The following table summarizes our selling, general and administrative expenses by category for each of the periods indicated:

	For the Year Ended December 31,			
	2019	2018	Change	Change
	(in thousands)		$	%
Compensation and other personnel expenses	$ 105,998	$ 72,042	$ 33,956	47%
Professional services	91,384	78,856	12,528	16%
Stock-based compensation	50,921	35,913	15,008	42%
Facility- and technology-related expenses	27,249	10,729	16,520	154%
Restructuring expenses	—	(2,222)	2,222	(100)%
Other	9,260	12,443	(3,183)	(26)%
Total selling, general and administrative expenses	$ 284,812	$ 207,761	$ 77,051	37%

Selling, general and administrative expenses for 2019 increased by $77.1 million, or 37%, compared with 2018. This was primarily driven by the following:

- $34.0 million increase in compensation and other personnel expenses primarily due to a net increase in headcount;
- $12.5 million increase in professional services primarily due to continuing global expansion;
- $15.0 million increase in stock-based compensation primarily due to increases in headcount and stock price;
- $16.5 million increase in facility- and technology-related expense primarily due to continuing global expansion offset by a decrease in technology expense due to a change in allocation methodology; and
- $2.2 million decrease in restructuring credits due to the relief of cease-use liabilities as a result of the termination of the rental agreement for our Corvallis facility recorded during the second quarter of 2018.

Acquired In-process Research and Development

As a result of the Myonexus acquisition, we recorded acquired in-process research and development expense of approximately $173.2 million during the second quarter of 2019. There was no such transaction during the same period of 2018.

Settlement and License Charges

In December 2019, we recognized a $10.0 million settlement charge related to contingent settlement payments to BioMarin as a result of the approval of VYONDYS 53. This was a result of a settlement and license agreement with BioMarin in July 2017. There was no such expense recognized during the same period of 2018.

Amortization of In-licensed Rights

Amortization of in-licensed rights relate to the agreements we entered into with BioMarin and UWA in July 2017 and April 2011, respectively. We recorded an in-licensed right asset of approximately $6.6 million in 2017 as a result of the settlement and license agreements with BioMarin. Additionally, following the first sale of EXONDYS 51 in September 2016 and VYONDYS 53 in December 2019, we recorded an in-licensed right asset of $1.0 million and $0.5 million, respectively, related to the license agreement with UWA. Each in-licensed right is being amortized on a straight-line basis over the life of the patent from the first commercial sale of each product. For the years ended December 31, 2019 and 2018, we recorded amortization of in-licensed rights of approximately $0.8 million and $0.9 million, respectively.

Other expense, net

Other expense, net, primarily consists of interest income on our cash, cash equivalents and investments, interest expense on our debt facilities, amortization of investment discount, gain from our investment in Lysogene, and rental income and loss. Our cash equivalents and investments consist of money market funds, commercial paper, government and government agency debt securities, corporate debt securities and certificates of deposit. Interest expense primarily includes interest accrued on our convertible notes, term loan, revolving line of credit and a mortgage loan related to our Corvallis, Oregon property. Rental income and loss is from leasing excess space in some of our facilities.

Other expense, net, for 2019 decreased by $10.7 million compared with 2018. The decrease primarily reflected decreases in term loan termination expense and an increase in amortization of investment discount as a result of an increase in interest rates.

Income tax expense (benefit)

Income tax expense for 2019 was approximately $1.2 million, which primarily reflected adjustments to estimated foreign and current state income taxes in 2019. Income tax benefit for 2018 was approximately $0.7 million, which primarily reflected adjustments to estimated state income taxes in 2017.

Liquidity and Capital Resources

The following table summarizes our financial condition for each of the periods indicated:

	For the Year Ended December 31,		Change	Change
	2019	2018		
	(in thousands)		$	%
Financial assets:				
Cash and cash equivalents	$ 835,080	$ 370,829	$ 464,251	125%
Short-term investments	289,668	803,083	(513,415)	(64)%
Restricted cash and investments	9,566	1,001	8,565	NM*
Total cash, cash equivalents and investments	$ 1,134,314	$ 1,174,913	$ (40,599)	(3)%
Borrowings:				
Long-term debt	$ 240,004	$ —	$ 240,004	NM*
Convertible debt	441,896	420,554	21,342	5%
Total borrowings	$ 681,900	$ 420,554	$ 261,346	62%
Working capital				
Current assets	1,468,913	1,426,183	42,730	3%
Current liabilities	264,767	173,690	91,077	52%
Total working capital	$ 1,204,146	$ 1,252,493	$ (48,347)	(4)%

* NM: not meaningful

For the years ended December 31, 2019 and December 31, 2018, our principal source of liquidity was derived from proceeds from sales of our products and debt and equity financings. Our principal uses of cash are research and development expenses, selling, general and administrative expenses, investments, capital expenditures, business development transactions and other working capital requirements.

Our future expenditures and capital requirements may be substantial and will depend on many factors, including but not limited to the following:

- our ability to continue to generate revenues from sales of EXONDYS 51, VYONDYS 53, and potential future products;
- the timing and costs associated with our continuing global expansion;
- the timing and costs of building out our manufacturing capabilities;
- the timing of advanced payments related to our future inventory commitments and manufacturing obligations;
- the timing and costs associated with our clinical trials and pre-clinical trials;
- the attainment of milestones and our obligations to make milestone payments to Myonexus' selling shareholders, StrideBio, BioMarin, Lysogene, Lacerta, Nationwide, UWA and other institutions;
- repayment of outstanding debt; and
- the costs of filing, prosecuting, defending and enforcing patent claims and our other intellectual property rights.

Our cash requirements are expected to continue to increase as we advance our research, development and commercialization programs and we expect to seek additional financings primarily from, but not limited to, the sale and issuance of equity and debt securities, or the licensing or sale of our technologies or additional government contracts. We cannot provide assurances that financing will be available when and as needed or that, if available, the financings will be on favorable or acceptable terms. If we are unable to obtain additional financing when and if we require, this would have a material adverse effect on our business and results of operations. To the extent we issue additional equity securities, our existing stockholders could experience substantial dilution.

Cash Flows

The following table summarizes our cash flow activity for each of the periods indicated:

	For the Year Ended December 31,		Change	Change
	2019	2018		
	(in thousands)		$	%
Cash provided by (used in)				
Operating activities	$ (456,463)	$ (388,660)	$ (67,803)	17%
Investing activities	286,725	(370,488)	657,213	(177)%
Financing activities	642,554	530,150	112,404	21%
Increase (decrease) in cash and cash equivalents	$ 472,816	$ (228,998)	$ 701,814	(306)%

Operating Activities.

Cash used in operating activities increased by $67.8 million for 2019 compared with 2018, primarily due to the following:

- $179.9 million increase in net loss excluding acquired in-process research and development expense primarily driven by increases in research and development expense and selling, general and administrative expense partially offset by an increase in net product revenues for EXONDYS 51 and VYONDYS 53.

The increases were partially offset by:

- $41.7 million increase in non-cash adjustments; and
- $41.0 million increase in use of operating assets and liabilities.

Investing Activities.

Cash provided by investing activities was $286.7 million for 2019. Cash used in investing activities for 2018 was $370.5 million. The favorable change was primarily due to the following:

- $849.8 million increase in proceeds from the maturity or sale of available-for-sale securities; and,
- $1.5 million decrease in purchase of property and equipment.

The increases were partially offset by:

- $172.6 million increase as a result of the acquisition of Myonexus; and
- $22.0 million increase in the purchase of available-for-sale securities.

Financing Activities.

Cash provided by financing activities increased by $112.4 million for 2019 compared with 2018, primarily driven by the following:

- $9.8 million increase in proceeds from debt financings; and
- $269.4 million decrease in repayment of outstanding debts and debt extinguishment costs.

The increases were partially offset by:

- $148.1 million decrease in proceeds from sales of common stock;
- $13.6 million decrease in proceeds from the exercise of options and our employee stock purchase program; and
- $4.3 million increase in taxes paid related to net share settlement of equity awards.

Off-Balance Sheet Arrangements

During the periods presented, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or for another contractually narrow or limited purpose.

Contractual Payment Obligations

In our continuing operations, we have entered into long-term contractual arrangements from time to time for our facilities, the provision of goods and services, and issuance of debt securities, among others. The following table presents contractual obligations arising from these arrangements as of December 31, 2019:

	Payment Due by Period				
	Total	Less Than 1 Year	1 - 3 Years	3 - 5 Years	More than 5 Years
	(in thousands)				
Convertible debt (1)	$ 611,681	$ 8,550	$ 17,100	$ 586,031	$ —
Term loan (1)	336,299	22,313	43,090	270,896	—
Lease obligations	68,044	11,718	23,971	22,701	9,654
Manufacturing obligations (2)	893,036	378,744	248,314	116,628	149,350
Total contractual obligations	$ 1,909,060	$ 421,325	$ 332,475	$ 996,256	$ 159,004

(1) Interest is included.

(2) Purchase obligations include agreements to purchase goods or services that are enforceable and legally binding or subject to cancellation fees and that specify all significant terms. Purchase obligations relate primarily to our commercialization of EXONDYS 51 and VYONDYS 53, and clinical programs for DMD and gene therapy programs.

Milestone Obligations

For products and product candidates that are currently in various research and development stages, we may be obligated to make up to $3.0 billion of future development, regulatory, up-front royalty and sales milestone payments associated with our collaboration and license agreements. Payments under these agreements generally become due and payable upon achievement of certain development, regulatory or sales milestones. Because the achievement of these milestones is not probable and payment is not required as of December 31, 2019, such contingencies have not been recorded in our consolidated financial statements. Amounts related to contingent milestone payments are not yet considered contractual obligations as they are contingent on the successful achievement of certain development, regulatory approval and sales milestones.

Other Funding Commitments

We have several on-going clinical trials in various stages. Our most significant clinical trial expenditures are to contract research organizations (“CROs”). The CRO contracts are generally cancellable at our option. As of December 31, 2019, we had approximately $91.4 million in cancellable future commitments based on existing CRO contracts.

Recent Accounting Pronouncements

Please read *Note 2, Summary of Significant Accounting Policies and Recent Accounting Pronouncements* to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Our current investment policy is to maintain a diversified investment portfolio consisting of money market investments, commercial paper, government and government agency bonds and high-grade corporate bonds with maturities of 36 months or less. Our cash is deposited in and invested through highly rated financial institutions in North America. As of December 31, 2019, we had $1,134.4 million of cash, cash equivalents and investments, comprised of $835.1 million of cash and cash equivalents, $289.7 million short-term investments and $9.6 million of restricted cash and investments. The Company only holds debt securities classified as available-for-sale. The fair value of cash equivalents and short-term investments is subject to change as a result of potential changes in market interest rates. The potential change in fair value for interest rate sensitive instruments has been assessed on a hypothetical 10 basis point adverse movement across all maturities. For both of the years ended December 31, 2019 and 2018, we estimate that such hypothetical adverse 10 basis point movement would result in a hypothetical loss in fair value of approximately $0.1 million, to our interest rate sensitive instruments.

Item 8. Financial Statements and Supplementary Data.

The information required by this Item 8 begins on page F-1 in Item 15 of Part IV of this Annual Report on Form 10-K and is incorporated into this item by reference.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Disclosure Controls and Procedures

We carried out an evaluation as of the end of the period covered by this Annual Report on Form 10-K, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of our disclosure controls and procedures pursuant to paragraph (b) of Rule 13a-15 and 15d-15 under the Exchange Act. Based on that review, the principal executive officer and principal financial officer have concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act (1) is recorded, processed, summarized, and reported within the time periods specified in the SEC rules and forms, and (2) is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

We do not expect that our disclosure controls and procedures will prevent all errors and all fraud. A control procedure, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control procedure are met. Because of the inherent limitations in all control procedures, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our Company have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. We considered these limitations during the development of our disclosure controls and procedures, and will continually reevaluate them to ensure they provide reasonable assurance that such controls and procedures are effective.

Internal Control over Financial Reporting

Management's Annual Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting for our Company, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act.

Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2019. In making this assessment, management used the criteria set forth by the *Committee of Sponsoring Organizations of the Treadway Commission* ("COSO") in its 2013 Internal Control Integrated Framework.

Based on this assessment, management has concluded that, as of December 31, 2019, our internal control over financial reporting was effective based on those criteria.

The effectiveness of our internal control over financial reporting as of December 31, 2019, has been audited by KPMG LLP, an independent registered public accounting firm, as stated in their report which appears in this Annual Report on Form 10-K.

Changes in Internal Control over Financial Reporting

There have not been material changes in our internal control over financial reporting as defined in Rules 13a–15(f) and 15d–15(f) under the Exchange Act for the quarter ended December 31, 2019 that our certifying officers concluded materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information regarding our directors and executive officers required by this item will be included in either an amendment to this Annual Report on Form 10-K or in our definitive proxy statement for our 2020 annual meeting of stockholders to be filed with the Commission not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K and is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this item will be included in either an amendment to this Annual Report on Form 10-K or in our definitive proxy statement for our 2020 annual meeting of stockholders to be filed with the Commission not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item will be included in either an amendment to this Annual Report on Form 10-K or in our definitive proxy statement for our 2020 annual meeting of stockholders to be filed with the Commission not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item will be included in either an amendment to this Annual Report on Form 10-K or in our definitive proxy statement for our 2020 annual meeting of stockholders to be filed with the Commission not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this item will be included in either an amendment to this Annual Report on Form 10-K or in our definitive proxy statement for our 2020 annual meeting of stockholders to be filed with the Commission not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as part of this Annual Report on Form 10-K:

(1) Financial Statements

The following consolidated financial statements of the Company and the Report of KPMG LLP, Independent Registered Public Accounting Firm, are included in Part IV of this Annual Report on Form 10-K on the pages indicated:

(2) Financial Statement Schedules

All schedules are omitted because they are not applicable or the required information is shown in the consolidated financial statements or the notes thereto.

(3) Exhibits

The exhibits required by Item 601 of Regulation S-K are listed in paragraph (b) below.

(b) Exhibits.

The following exhibits are filed herewith or are incorporated by reference to exhibits filed with the SEC:

Exhibit Number	Description	Incorporated by Reference to Filings Indicated				Provided Herewith
		Form	File No.	Exhibit	Filing Date	
2.1	Agreement and Plan of Merger dated June 6, 2013 between Sarepta Therapeutics, Inc., a Delaware corporation, and Sarepta Therapeutics, Inc., an Oregon corporation.	8-K12B	001-14895	2.1	6/6/13	
2.2*	Warrant to Purchase Common Stock of Myonexus Therapeutics, Inc., issued by Myonexus Therapeutics, Inc. to Sarepta Therapeutics, Inc., dated as of May 3, 2018.	10-Q	001-14895	2.1	8/8/18	
3.1	Amended and Restated Certificate of Incorporation.	8-K12B	001-14895	3.1	6/6/13	
3.2	Amendment to the Amended and Restated Certificate of Incorporation.	8-K	001-14895	3.1	6/30/15	
3.3	Amended and Restated Bylaws.	8-K	001-14895	3.1	9/25/14	
3.4	Amendment No. 1 to the Amended and Restated Bylaws.	8-K	001-14895	3.1	1/13/20	
4.1	Form of Specimen Certificate for Common Stock.	10-Q	001-14895	4.1	8/8/13	
4.2	Indenture, dated as of November 14, 2017, by and between Sarepta Therapeutics, Inc. and U. S. Bank National Association (including the form of the 1.50% Convertible Senior Note due 2024).	8-K	001-14895	4.1	11/14/17	
4.3	Form of Note (included in Exhibit 4.2)	8-K	001-14895	4.1	11/14/17	
4.4	Description of Registered Securities					X
10.1†	AVI BioPharma, Inc. 2002 Equity Incentive Plan.	Schedule 14A	001-14895	Appendix A	4/11/02	

Exhibit Number	Description	Incorporated by Reference to Filings Indicated				Provided Herewith
		Form	File No.	Exhibit	Filing Date	
10.2†	Sarepta Therapeutics, Inc. Amended and Restated 2011 Equity Incentive Plan.	8-K	001-14895	10.1	7/1/16	
10.3†	Form of Stock Option Award Agreement under the Amended and Restated 2011 Equity Incentive Plan.	10-K	001-14895	10.13	2/28/17	
10.4†	Form of Restricted Stock Agreement under the Amended and Restated 2011 Equity Incentive Plan.	10-K	001-14895	10.14	2/28/17	
10.5†	Form of Restricted Stock Unit Award Agreement under 2011 Equity Incentive Plan.	10-K	001-14895	10.17	2/28/17	
10.6†	Form of Stock Appreciate Right Award Agreement under the 2011 Equity Incentive Plan.	10-K	001-14895	10.18	2/28/17	
10.7†	Sarepta Therapeutics, Inc. Amended and Restated 2013 Employee Stock Purchase Plan.	8-K	001-14895	10.2	7/1/16	
10.8†	Offer Letter dated October 23, 2013 by and between Sarepta Therapeutics, Inc. and Sandesh Mahatme.	10-K	001-14895	10.24	3/3/14	
10.9†	Offer Letter dated October 23, 2012 by and between Sarepta Therapeutics, Inc. and David Tyronne Howton.	10-K	001-14895	10.25	3/3/14	
10.10†	Sarepta Therapeutics, Inc. 2014 Employment Commencement Incentive Plan, as amended.	S-8	001-14895	4.4	2/25/16	
10.11	Form of Stock Option Award Agreement under 2014 Employment Commencement Incentive Plan	10-K	001-14895	10.28	3/3/14	
10.12*	Amended and Restated Exclusive License Agreement by and among The University of Western Australia, Sarepta Therapeutics, Inc., and Sarepta International CV dated April 10, 2013.	10-Q	001-14895	10.1	5/9/13	
10.13*	First Amendment to License Agreement by and among The University of Western Australia, Sarepta Therapeutics, Inc., and Sarepta International CV dated June 19, 2016.	10-Q	001-14895	10.1	8/9/16	
10.14	Lease Agreement dated June 25, 2013 by and between Sarepta Therapeutics, Inc. and ARE-MA Region No. 38, LLC.	8-K	001-14895	10.1	7/1/13	
10.15†	Amendment No. 1 to the Sarepta Therapeutics, Inc. Amended and Restated 2011 Equity Incentive Plan	8-K	001-14895	10.1	6/30/15	
10.16	Asset Purchase Agreement dated February 20, 2017 by and between Sarepta Therapeutics Inc. and Gilead Sciences, Inc.	10-Q	001-14895	10.1	5/4/17	
10.17†	Offer Letter dated December 3, 2012 by and between Sarepta Therapeutics, Inc. and Alexander “Bo” Cumbo	10-Q	001-14895	10.3	5/4/17	
10.18†	Form of Severance Letter Agreement entered between Sarepta Therapeutics, Inc. and each of Sandesh Mahatme, Alexander “Bo” Cumbo, David Tyronne Howton, Jr. and Shamim Ruff	10-K	001-14895	10.58	3/1/18	
10.19†	Employment Agreement, dated as of June 26, 2017, between Sarepta Therapeutics, Inc. and Douglas S. Ingram	8-K	001-14895	10.1	6/28/17	
10.20†	Change in Control and Severance Agreement by and between Douglas S. Ingram and Sarepta Therapeutics, Inc., effective June 26, 2017	8-K	001-14895	10.2	6/28/17	

Exhibit Number	Description	Incorporated by Reference to Filings Indicated				Provided Herewith
		Form	File No.	Exhibit	Filing Date	
10.21†	Amendment No. 1 to the Sarepta Therapeutics, Inc. 2014 Employment Commencement Incentive Plan	8-K	001-14895	10.3	6/28/17	
10.22†	Restricted Stock Agreement under the 2014 Employment Commencement Incentive Plan	8-K	001-14895	10.4	6/28/17	
10.23†	Performance Stock Option Award Agreement under the 2014 Employment Commencement Incentive Plan	8-K	001-14895	10.5	6/28/17	
10.24*	Settlement Agreement between Sarepta Therapeutics, Inc., Sarepta International C.V. and The University of Western Australia on the one hand, and BioMarin Leiden Holding BV, BioMarin Nederlands BV and BioMarin Technologies BV on the other hand dated July 17, 2017	10-Q	001-14895	10.7	8/3/17	
10.25*	License Agreement between Sarepta Therapeutics, Inc. and Sarepta International C.V. on the one hand and BioMarin Leiden Holding BV, BioMarin Nederlands BV and BioMarin Technologies BV on the other hand dated July 17, 2017	10-Q	001-14895	10.8	8/3/17	
10.26	Letter Agreement by and between Sarepta Therapeutics, Inc. and Catherine Stehman-Breen dated September 26, 2017	10-Q	001-14895	10.4	11/1/17	
10.27	Base Call Option Transaction Confirmation, dated as of November 8, 2017, between Sarepta Therapeutics, Inc. and JPMorgan Chase Bank, National Association, London Branch.	8-K	001-14895	10.1	11/14/17	
10.28	Base Call Option Transaction Confirmation, dated as of November 8, 2017, between Sarepta Therapeutics, Inc. and Goldman Sachs & Co. LLC.	8-K	001-14895	10.2	11/14/17	
10.29	Additional Call Option Transaction Confirmation, dated as of November 9, 2017, between Sarepta Therapeutics, Inc. and JPMorgan Chase Bank, National Association, London Branch	8-K	001-14895	10.3	11/14/17	
10.30	Additional Call Option Transaction Confirmation, dated as of November 9, 2017, between Sarepta Therapeutics, Inc. and Goldman Sachs & Co. LLC	8-K	001-14895	10.4	11/14/17	
10.31†	General Release and Amendment to Separation Agreement between Sarepta Therapeutics, Inc. and Dr. Catherine Stehman-Breen dated April 12, 2018	10-Q	001-14895	10.1	5/3/18	
10.32	Seventh Amendment to a Lease Agreement between the Company and ARE-MA Region No. 38, LLC dated April 27, 2018	10-Q	001-14895	10.4	5/3/18	
10.33†	Sarepta Therapeutics, Inc. 2018 Equity Incentive Plan	10-Q	001-14895	10.1	8/8/18	
10.34†	Employment Agreement between Sarepta Therapeutics, Inc. and Gilmore O'Neill, M.D., effective as of June 7, 2018	10-Q	001-14895	10.2	8/8/18	
10.35†	Change in Control and Severance Agreement between Sarepta Therapeutics, Inc. and Gilmore O'Neill, M.D., effective as of June 7, 2018	10-Q	001-14895	10.3	8/8/18	
10.36†	Letter Agreement between Douglas S. Ingram and Sarepta Therapeutics, Inc. dated June 26, 2018	10-Q	001-14895	10.4	8/8/18	
10.37†	Form of Restricted Stock Unit Award Agreement under Sarepta Therapeutics, Inc. 2014 Employment Commencement Incentive Plan	10-Q	001-14895	10.5	8/8/18	

Exhibit Number	Description	Incorporated by Reference to Filings Indicated				Provided Herewith
		Form	File No.	Exhibit	Filing Date	
10.38†	Amendment No. 2 to the Sarepta Therapeutics, Inc. 2014 Employment Commencement Incentive Plan	10-Q	001-14895	10.6	8/8/18	
10.39†	Form of Stock Option Award Agreement under Sarepta Therapeutics, Inc. 2018 Equity Incentive Plan	10-Q	001-14895	10.1	10/31/18	
10.40†	Form of Restricted Stock Award Agreement under Sarepta Therapeutics, Inc. 2018 Equity Incentive Plan	10-Q	001-14895	10.2	10/31/18	
10.41†	Form of Restricted Stock Unit Award Agreement under Sarepta Therapeutics, Inc. 2018 Equity Incentive Plan	10-Q	001-14895	10.3	10/31/18	
10.42†	Form of Stock Appreciation Right Award Agreement under Sarepta Therapeutics, Inc. 2018 Equity Incentive Plan	10-Q	001-14895	10.4	10/31/18	
10.43†	Amendment to Restricted Stock Award Agreement between Douglas S. Ingram and Sarepta Therapeutics, Inc. dated December 17, 2018	10-K	001-14895	10.75	2/28/19	
10.44^	Amendment No. 1 to License Agreement between Sarepta Therapeutics, Inc. and ST International Holdings Two, Inc. on the one hand and BioMarin Leiden Holding BV, BioMarin Nederlands BV and BioMarin Technologies BV on the other hand	10-Q	001-14895	10.1	8/7/19	
10.45†	Sub-Plan for Japan under the Sarepta Therapeutics, Inc. 2018 Equity Incentive Plan	10-Q	001-14895	10.2	8/7/19	
10.46†	Sub-Plan for Japan under the Sarepta Therapeutics, Inc. 2014 Employment Commencement Incentive Plan	10-Q	001-14895	10.3	8/7/19	
10.47†	Amendment No. 1 to the Sarepta Therapeutics, Inc. Amended and Restated 2013 Employment Stock Purchase Plan (as Amended and Restated on June 27, 2016)	10-Q	001-14895	10.4	8/7/19	
10.48	Letter Agreement between Sarepta Therapeutics, Inc. and Myonexus Therapeutics, Inc. dated February 26, 2019	10-Q	001-14895	10.1	5/8/19	
10.49†	Form of Executive Vice President Severance Letter Agreement	10-Q	001-14895	10.2	5/8/19	
10.50†	Form of Executive Vice President Change in Control and Severance Agreement	10-Q	001-14895	10.3	5/8/19	
10.51^	License, Collaboration, and Option Agreement between Sarepta Therapeutics Three, LLC and F. Hoffman-La Roche Ltd dated December 21, 2019					X
10.52	Stock Purchase Agreement between Sarepta Therapeutics, Inc. and Roche Finance Ltd dated December 21, 2019					X
10.53	Loan Agreement among Sarepta Therapeutics, Inc., BioPharma Credit PLC and BioPharma Credit Investments V (Master) LP dated December 13, 2019					X
10.54	Guaranty and Security Agreement between Sarepta Therapeutics, Inc. and BioPharma Credit PLC dated December 20, 2019					X
10.55†	Director Compensation Policy					X
10.56†	Offer Letter dated November 11, 2019 by and between Sarepta Therapeutics, Inc. and William F. Ciambrone					X

Exhibit Number	Description	Incorporated by Reference to Filings Indicated				Provided Herewith
		Form	File No.	Exhibit	Filing Date	
10.57†	Amendment to Offer Letter by and between Sarepta Therapeutics, Inc. and William F. Ciambrone					X
10.58†	Amendment No. 2 to the Sarepta Therapeutics, Inc. 2014 Employment Commencement Incentive Plan	8-K	001-14895	10.1	2/21/20	
21.1	Subsidiaries of the Registrant.					X
23.1	Consent of Independent Registered Public Accounting Firm.					X
24.1	Power of Attorney (contained on signature page).					X
31.1	Certification of the Company's President and Chief Executive Officer, Douglas S. Ingram, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of the Company's Executive Vice President, Chief Financial Officer and Chief Business Officer, Sandesh Mahatme, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1**	Certification of the Company's President and Chief Executive Officer, Douglas S. Ingram, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
32.2**	Certification of the Company's Executive Vice President, Chief Financial Officer and Chief Business Officer, Sandesh Mahatme, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
101	The following financial statements from the Annual Report on Form 10-K of Sarepta Therapeutics, Inc. for the year ended December 31, 2019, formatted in Inline XBRL: (i) Consolidated Balance Sheets; (ii) Consolidated Statements of Operations and Comprehensive Loss; (iii) Consolidated Statements of Stockholders' Equity; (iv) Consolidated Statements of Cash Flows; and (v) Notes to Consolidated Financial Statements, tagged as blocks of text and including detailed tags.					X
104	The Cover page from the Annual Report on Form 10-K of Sarepta Therapeutics, Inc for the year ended December 31, 2019, formatted in Inline XBRL.					X

† Indicates management contract or compensatory plan, contract or arrangement.

^ Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

* Confidential treatment has been granted for portions of this exhibit.

** Furnished herewith. This exhibit shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liability of that Section. Such exhibit shall not be deemed incorporated into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934.

Item 16. Form 10-K Summary.

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: February 26, 2020

SAREPTA THERAPEUTICS, INC.

By: /s/ Douglas S. Ingram
Douglas S. Ingram
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Douglas S. Ingram and Sandesh Mahatme, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file, any and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their and his or her substitute or substitutes, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated on February 26, 2020:

Signature	Title
/s/ Douglas S. Ingram Douglas S. Ingram	President, Chief Executive Officer and Director (Principal Executive Officer)
/s/ Sandesh Mahatme Sandesh Mahatme	Executive Vice President, Chief Financial Officer and Chief Business Officer (Principal Financial and Accounting Officer)
/s/ M. Kathleen Behrens M. Kathleen Behrens, Ph.D.	Chairwoman of the Board
/s/ Richard Barry Richard Barry	Director
/s/ Michael W. Bonney Michael W. Bonney	Director
/s/ Mary Ann Gray Mary Ann Gray, Ph.D.	Director
/s/ John C. Martin John C. Martin, Ph.D.	Director
/s/ Claude Nicaise, MD Claude Nicaise, MD	Director
/s/ Hans Wigzell Hans Wigzell, M.D., Ph.D.	Director

SAREPTA THERAPEUTICS, INC.
CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Sarepta Therapeutics, Inc.:

Opinions on the Consolidated Financial Statements and Internal Control Over Financial Reporting

We have audited the accompanying consolidated balance sheets of Sarepta Therapeutics, Inc. and subsidiaries (the Company) as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2019, and the related notes (collectively, the consolidated financial statements). We also have audited the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2019, in conformity with U.S. generally accepted accounting principles. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019 based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Change in Accounting Principle

As discussed in Note 2 to the consolidated financial statements, the Company has changed its method of accounting for leases as of January 1, 2019 due to the adoption of Accounting Standards Update (ASU) No. 2016-02, *Leases (Topic 842)*.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's consolidated financial statements and an opinion on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgment. The communication of a critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Evaluation of lower of cost or net realizable value of raw materials inventory

As described in Note 2 and Note 8 to the consolidated financial statements, approximately 48%, or $82.0 million, of the Company's total inventory balance is comprised of raw materials. The Company periodically analyzes its raw materials inventories, and writes down obsolete or otherwise unmarketable inventory to its estimated net realizable value.

We identified the evaluation of lower of cost or net realizable value of raw materials inventory as a critical audit matter. The estimate of expected future demand for raw materials inventory is difficult to assess and results in the application of greater auditor judgment. Specifically, challenging auditor judgment was required to assess the potential impact the Company's gene therapy technologies and competitor RNA-targeted therapeutic or gene therapy products could have on existing raw materials inventory.

The primary procedures we performed to address this critical audit matter included the following. We tested certain internal controls over the Company's inventory valuation process, including controls related to the estimate of expected future demand for raw materials. We compared the Company's prior period forecasted demand for raw materials to actual results to assess their ability to accurately estimate expected future demand. We evaluated clinical progress associated with the Company's gene therapy technologies by inspecting internal meeting minutes and interviewing research and development personnel of the Company and assessed the potential impact of those technologies on expected future demand for raw materials inventory. We also read publicly available information to identify information regarding other competitor entities with RNA-targeted therapeutic or gene therapy products that could impact the Company's estimates of expected future demand.

/s/ KPMG LLP

We have served as the Company's auditor since 2002.

Boston, Massachusetts
February 26, 2020

Sarepta Therapeutics, Inc.

Consolidated Balance Sheets

(in thousands, except share and per share amounts)

	As of December 31, 2019	As of December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 835,080	$ 370,829
Short-term investments	289,668	803,083
Accounts receivable	90,879	49,044
Inventory	171,379	125,445
Other current assets	81,907	77,782
Total current assets	1,468,913	1,426,183
Property and equipment, net	129,620	97,024
Intangible assets, net	12,497	11,574
Right of use assets, net	37,933	—
Other non-current assets	173,859	107,294
Total assets	$ 1,822,822	$ 1,642,075
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 68,094	$ 33,829
Accrued expenses	185,527	134,095
Other current liabilities	11,146	5,766
Total current liabilities	264,767	173,690
Long-term debt	681,900	420,554
Lease liabilities	47,720	—
Other non-current liabilities	10,248	15,555
Total liabilities	1,004,635	609,799
Commitments and contingencies (Note 21)		
Stockholders' equity:		
Preferred stock, $.0001 par value, 3,333,333 shares authorized; none issued and outstanding	—	—
Common stock, $.0001 par value, 99,000,000 shares authorized; 75,184,863 and 71,071,887 issued and outstanding at December 31, 2019 and 2018, respectively	8	7
Additional paid-in capital	3,112,130	2,611,294
Accumulated other comprehensive income (loss), net of tax	50	(99)
Accumulated deficit	(2,294,001)	(1,578,926)
Total stockholders' equity	818,187	1,032,276
Total liabilities and stockholders' equity	$ 1,822,822	$ 1,642,075

See accompanying notes to consolidated financial statements.

Sarepta Therapeutics, Inc.

Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except per share data)

	For the Year Ended December 31,		
	2019	2018	2017
Revenues:			
Product, net	$ 380,833	$ 301,034	$ 154,584
Total revenues	380,833	301,034	154,584
Cost and expenses:			
Cost of sales (excluding amortization of in-licensed rights)	56,586	34,193	7,353
Research and development	560,909	401,843	166,707
Selling, general and administrative	284,812	207,761	122,682
Acquired in-process research and development	173,240	—	—
Settlement and license charges	10,000	—	28,427
Amortization of in-licensed rights	849	865	1,053
Total cost and expenses	1,086,396	644,662	326,222
Operating loss	(705,563)	(343,628)	(171,638)
Other (loss) income:			
Other expense, net	(8,317)	(18,982)	(1,990)
Gain from sale of Priority Review Voucher	—	—	125,000
Total other (loss) income	(8,317)	(18,982)	123,010
Loss before income tax expense (benefit)	(713,880)	(362,610)	(48,628)
Income tax expense (benefit)	1,195	(692)	2,060
Net loss	(715,075)	(361,918)	(50,688)
Other comprehensive loss:			
Unrealized gains (losses) on investments	149	280	(259)
Total other comprehensive income (loss)	149	280	(259)
Comprehensive loss	$ (714,926)	$ (361,638)	$ (50,947)
Net loss per share — basic and diluted	$ (9.71)	$ (5.46)	$ (0.86)
Weighted average number of shares of common stock used in computing basic and diluted net loss per share	73,615	66,250	58,818

See accompanying notes to consolidated financial statements.

Sarepta Therapeutics, Inc.

Consolidated Statements of Stockholders' Equity

(in thousands)

	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive (Loss) Gain	Accumulated Deficit	Total Stockholders' Equity
BALANCE AT DECEMBER 31, 2016	**54,759**	**$ 5**	**$ 1,503,126**	**$ (120)**	**$ (1,166,320)**	**$ 336,691**
Exercise of options for common stock	793	—	13,799	—	—	13,799
Grant of restricted stock awards and vest of restricted stock units, net of cancellations	400	—	—	—	—	—
Shares withheld for taxes	(60)	—	(2,227)	—	—	(2,227)
Issuance of common stock for cash, net of offering costs	8,798	1	353,958	—	—	353,959
Issuance of common stock under employee stock purchase plan	102	—	1,425	—	—	1,425
Equity component of convertible notes	—	—	156,953	—	—	156,953
Purchase of capped call share options	—	—	(50,901)	—	—	(50,901)
Stock-based compensation	—	—	30,465	—	—	30,465
Unrealized loss from available-for-sale securities	—	—	—	(259)	—	(259)
Net loss	—	—	—	—	(50,688)	(50,688)
BALANCE AT DECEMBER 31, 2017	**64,792**	**6**	**2,006,598**	**(379)**	**(1,217,008)**	**789,217**
Exercise of options for common stock	2,119	—	47,916	—	—	47,916
Grant of restricted stock awards and vest of restricted stock units, net of cancellations	58	—	—	—	—	—
Shares withheld for taxes	(79)	—	(9,061)	—	—	(9,061)
Issuance of common stock for cash, net of offering costs	4,107	1	513,408	—	—	513,409
Issuance of common stock under employee stock purchase plan	75	—	2,306	—	—	2,306
Stock-based compensation	—	—	50,127	—	—	50,127
Unrealized gain from available-for-sale securities	—	—	—	280	—	280
Net loss	—	—	—	—	(361,918)	(361,918)
BALANCE AT DECEMBER 31, 2018	**71,072**	**7**	**2,611,294**	**(99)**	**(1,578,926)**	**1,032,276**
Exercise of options and stock appreciation rights for common stock	1,125	—	31,522	—	—	31,522
Grant of restricted stock awards and vest of restricted stock units, net of cancellations	68	—	—	—	—	—
Shares withheld for taxes	(78)	—	(9,135)	—	—	(9,135)
Issuance of common stock for cash, net of offering costs	2,604	1	365,353	—	—	365,354
Issuance of common stock for collaboration agreement	302	—	29,415	—	—	29,415
Issuance of common stock under employee stock purchase plan	92	—	5,079	—	—	5,079
Stock-based compensation	—	—	78,602	—	—	78,602
Unrealized gain from available-for-sale securities	—	—	—	149	—	149
Net loss	—	—	—	—	(715,075)	(715,075)
BALANCE AT DECEMBER 31, 2019	**75,185**	**$ 8**	**$ 3,112,130**	**$ 50**	**$ (2,294,001)**	**$ 818,187**

See accompanying notes to consolidated financial statements.

Sarepta Therapeutics, Inc.

Consolidated Statements of Cash Flows

(in thousands)

	For the Year Ended December 31,		
	2019	**2018**	**2017**
Cash flows from operating activities:			
Net loss	$ (715,075)	$ (361,918)	$ (50,688)
Adjustments to reconcile net loss to cash flows in operating activities:			
Acquired in-process research and development	173,240	—	—
Non-cash up-front payment to StrideBio	29,415	—	—
Gain from sale of Priority Review Voucher	—	—	(125,000)
Depreciation and amortization	30,547	12,245	8,092
Amortization of investment discount	(8,445)	(7,672)	(888)
Loss from debt extinguishment	—	2,322	—
Non-cash interest expense	21,444	20,190	2,679
Stock-based compensation	78,602	50,127	30,465
Other	690	3,938	805
Changes in operating assets and liabilities, net:			
Net increase in accounts receivable	(41,835)	(19,576)	(24,240)
Net increase in inventory	(45,934)	(41,840)	(70,792)
Net increase in other assets	(102,091)	(136,638)	(15,354)
Net increase in accounts payable, accrued expenses, lease liabilities and other liabilities	122,979	90,162	12,925
Net cash used in operations	(456,463)	(388,660)	(231,996)
Cash flows from investing activities:			
Purchase of property and equipment	(59,631)	(61,157)	(12,000)
Purchase of intangible assets	(3,082)	(3,188)	(9,215)
Purchase of available-for-sale securities	(1,193,632)	(1,171,603)	(589,520)
Maturity and sales of available-for-sale securities	1,715,626	865,813	296,225
Proceeds from sale of Priority Review Voucher	—	—	125,000
Purchase of restricted investment	—	(353)	—
Maturity of restricted investment	—	—	10,695
Acquisition of Myonexus Therapeutics, Inc., net of cash acquired	(172,556)	—	—
Net cash provided (used) in investing activities	286,725	(370,488)	(178,815)
Cash flows from financing activities:			
Proceeds from exercise of options and employee stock purchase program	36,601	50,222	15,224
Taxes paid related to net share settlement of equity awards	(4,337)	—	—
Proceeds from sales of common stock, net of offering costs	365,354	513,409	353,959
Proceeds from December 2019 Term Loan	245,625	—	—
Repayment of June 2015 and July 2017 Term Loan	—	(30,000)	(15,000)
Proceeds from July 2017 Term Loan	—	—	30,000
Proceeds from revolving line of credit	—	235,872	39,708
Repayment of revolving line of credit	—	(235,954)	(39,645)
Payment for debt extinguishment	—	(2,134)	—
Repayment of mortgage loans and notes payable	—	(1,265)	(109)
Purchase of capped call options	—	—	(50,901)
Proceeds from convertible debt offering	—	—	570,000
Debt issuance costs	(689)	—	(15,154)
Net cash provided by financing activities	642,554	530,150	888,082
Increase (decrease) in cash and cash equivalents	472,816	(228,998)	477,271
Cash, cash equivalents and restricted cash:			
Beginning of period	370,829	599,827	122,556
End of period	$ 843,645	$ 370,829	$ 599,827
Reconciliation of cash, cash equivalents and restricted cash:			
Cash and cash equivalents	$ 835,080	$ 370,829	$ 599,691
Restricted cash in other assets	8,565	—	136
Total cash, cash equivalents and restricted cash	$ 843,645	$ 370,829	$ 599,827
Supplemental disclosure of cash flow information:			
Cash paid during the period for interest	$ 8,550	$ 11,308	$ 1,912
Cash paid during the period for income taxes	$ 933	$ 1,548	$ 5,336
Supplemental schedule of non-cash investing activities and financing activities:			
Shares withheld for tax included in accrued expenses	$ 4,798	$ —	$ —
Accrued debt discount and issuance costs	$ 5,000	$ —	$ 625
Property and equipment included in accrued expenses	$ 1,181	$ 5,421	$ 2,525
Reclassification of long term investments to short term investments	$ —	$ 9,980	$ —

See accompanying notes to consolidated financial statements.

1. ORGANIZATION AND NATURE OF BUSINESS

Sarepta Therapeutics, Inc. (together with its wholly-owned subsidiaries, "Sarepta" or the "Company") is a commercial-stage biopharmaceutical company focused on helping patients through the discovery and development of unique RNA-targeted therapeutics, gene therapy and other genetic therapeutic modalities for the treatment of rare diseases. Applying its proprietary, highly-differentiated and innovative technologies, and through collaborations with its strategic partners, the Company is developing potential therapeutic candidates for a broad range of diseases and disorders, including Duchenne muscular dystrophy ("DMD"), Limb-girdle muscular dystrophies ("LGMDs"), Mucopolysaccharidosis type IIIA ("MPS IIIA") and other neuromuscular and central nervous system ("CNS") disorders.

Its first and second commercial products in the U.S., EXONDYS 51 (eteplirsen) Injection ("EXONDYS 51") and VYONDYS 53 (golodirsen) Injection ("VYONDYS 53"), respectively, were granted accelerated approval by the U.S. Food and Drug Administration ("FDA") on September 19, 2016 and December 12, 2019, respectively. EXONDYS 51 and VYONDYS 53 are indicated for the treatment of DMD in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 and exon 53 skipping, respectively. EXONDYS 51 and VYONDYS 53 use the Company's phosphorodiamidate morpholino oligomer ("PMO") chemistry and exon-skipping technology to skip exon 51 and exon 53, respectively, of the dystrophin gene. Exon skipping is intended to promote the production of an internally truncated but functional dystrophin protein.

As of December 31, 2019, the Company had approximately $1,134.4 million of cash, cash equivalents and investments, consisting of $835.1 million of cash and cash equivalents, $289.7 million of short-term investments, and $9.6 million of restricted cash and investments. The Company believes that its balance of cash, cash equivalents and investments as of December 31, 2019 is sufficient to fund its current operational plan for at least the next twelve months, though it may pursue additional cash resources through public or private debt and equity financings, seek additional government contracts and establish collaborations with or license its technology to other companies.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND RECENT ACCOUNTING PRONOUNCEMENTS

Basis of Presentation

The accompanying consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. ("U.S. GAAP"), reflect the accounts of Sarepta Therapeutics, Inc. and its wholly-owned subsidiaries. All intercompany transactions between and among its consolidated subsidiaries have been eliminated. Management has determined that the Company operates in one segment: helping patients through the discovery and development of unique RNA-targeted therapeutics, gene therapy and other genetic therapeutic modalities for the treatment of rare diseases. The Company's CEO, as the chief operating decision-maker, manages and allocates resources to the operations of the Company on a total company basis. The Company's research and development organization is responsible for the research and discovery of new product candidates and supports development and registration efforts for potential future products. The Company's supply chain organization manages the development of the manufacturing processes, clinical trial supply and commercial product supply. The Company's commercial organization is responsible for commercialization of EXONDYS 51 and VYONDYS 53 in the U.S. and internationally. The Company is supported by other back-office general and administration functions. Consistent with this decision-making process, the Company's CEO uses consolidated, single-segment financial information for purposes of evaluating performance, forecasting future period financial results, allocating resources and setting incentive targets.

Estimates and Uncertainties

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, equity, revenue, expenses and the disclosure of contingent assets and liabilities. Actual results could differ from those estimates.

Fair Value Measurements

The Company has certain financial assets that are recorded at fair value which have been classified as Level 1, 2 or 3 within the fair value hierarchy as described in the accounting standards for fair value measurements:

- Level 1—quoted prices for identical instruments in active markets;
- Level 2—quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, and model-derived valuations in which all significant inputs and significant value drivers are observable in active markets; and
- Level 3—valuations derived from valuation techniques in which one or more significant value drivers are unobservable.

The fair value of the majority of the Company's financial assets is categorized as Level 1 within the fair value hierarchy. These assets include money market funds, publicly traded debt, and equity securities. For additional information related to fair value measurements, please read *Note 5, Fair Value Measurements* to the consolidated financial statements.

Cash Equivalents

Only investments that are highly liquid and readily convertible to cash and have original maturities of three months or less are considered cash equivalents.

Investments

Available-For-Sale Debt Securities

Available-for-sale debt securities are recorded at fair value and unrealized gains and losses are included in accumulated other comprehensive income (loss) in stockholder's equity. Realized gains and losses are reported in other expense, net, on a specific identification basis.

Equity Investments

The Company's equity investments include its investments in a publicly traded biotechnology company and a privately held biotechnology company and are included in other non-current assets in the Company's consolidated balance sheets. The equity investment in the publicly traded biotechnology company has a readily determinable fair value and is carried at fair value with changes in value recorded as a gain or loss in the Company's consolidated statements of operations and comprehensive loss. The equity investment in the privately held biotechnology company does not have readily determinable fair value and is measured at cost less any impairment, plus or minus changes resulting from observable price changes for the identical or a similar investment of the same issuer, which is recorded as a gain or loss on the Company's consolidated statements of operations and comprehensive loss.

Accounts Receivable

The Company's accounts receivable primarily arise from product sales. They are generally stated at the invoiced amount and do not bear interest. Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established and which result from Medicaid rebates, governmental chargebacks including Public Health Services ("PHS") chargebacks, prompt pay discounts, co-pay assistance and distribution fees. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if no payments are required of the Company) for PHS chargebacks, prompt pay discounts and certain distribution fees, or a current liability (if a payment is required of us), for Medicaid rebates, co-pay assistance and certain distribution fees.

The accounts receivable from product sales represents receivables due from the Company's specialty distributor and specialty pharmacies in the U.S. as well as certain distributors in the EU, Brazil, Israel and the Middle East. The Company monitors the financial performance and creditworthiness of its customers so that it can properly assess and respond to changes in the customers' credit profiles. The Company provides reserves against trade receivables for estimated losses that may result from a customer's inability to pay. Amounts determined to be uncollectible are written-off against the established reserve. As of December 31, 2019, the credit profiles for the Company's customers are deemed to be in good standing and an allowance for doubtful accounts receivable is not considered necessary.

Concentration of Credit Risk

Financial instruments which potentially subject the Company to concentrations of credit risk consist of accounts receivable from customers and cash, cash equivalent and investments held at financial institutions.

For the year ended December 31, 2019, the majority of the Company's accounts receivable arose from product sales in the U.S. and all customers have standard payment terms which generally require payment within 60 to 91 days. Outside of the U.S., the payment terms range between 45 and 150 days. Three individual customers accounted for 43%, 41% and 13% of net product revenues for the year ended December 31, 2019, 42%, 38% and 18% for the year ended December 31, 2018, and 47%, 34% and 19% for the year ended December 31, 2017. Three individual customers accounted for 45%, 37% and 11% of accounts receivable from product sales for the year ended December 31, 2019 and 51%, 28% and 10% for the year ended December 31, 2018. As of December 31, 2019, the Company believes that such customers are of high credit quality.

As of December 31, 2019, the Company's cash equivalents and investments were concentrated at three financial institutions. The Company does not believe that there is significant risk of non-performance by the financial institutions.

Inventories

Inventories are stated at the lower of cost and net realizable value with cost determined on a first-in, first-out basis. The Company capitalizes inventory costs associated with products following regulatory approval when future commercialization is considered probable and the future economic benefit is expected to be realized. EXONDYS 51 and VYONDYS 53 inventory that may be used in clinical development programs is charged to research and development expense when the product enters the research and development process and no longer can be used for commercial purposes.

The Company periodically reviews its inventories for excess amounts or obsolescence and writes down obsolete or otherwise unmarketable inventory to its estimated net realizable value. Additionally, though the Company's product is subject to strict quality control and monitoring which it performs throughout the manufacturing processes, certain batches or units of product may not meet quality specifications resulting in a charge to cost of sales.

For products which are under development and have not yet been approved by regulatory authorities, purchased drug product is charged to research and development expense upon delivery. Delivery occurs when the inventory passes quality inspection and ownership transfers to the Company. Nonrefundable advance payments for research and development activities, including production of purchased drug product, are deferred and capitalized until the goods are delivered. If the Company does not expect the goods to be delivered or services to be rendered, the advanced payment capitalized will be charged to expense.

Property and Equipment

Property and equipment are initially recorded at cost, including the acquisition cost and all costs necessarily incurred to bring the asset to the location and working condition necessary for its intended use. The cost of normal, recurring or periodic repairs and maintenance activities related to property and equipment are expensed as incurred. The cost for planned major maintenance activities, including the related acquisition or construction of assets, is capitalized if the repair will result in future economic benefits. Interest costs incurred during the construction period of major capital projects are capitalized until the asset is ready for its intended use, at which point the interest costs are amortized as depreciation expense over the life of the underlying asset.

The Company generally depreciates the cost of its property and equipment using the straight-line method over the estimated useful lives of the respective assets, which are summarized as follows:

Asset Category	Useful lives
Lab equipment	5 years
Office equipment	5 years
Software and computer equipment	3 - 5 years
Furniture and fixtures	7 years
Leasehold improvements	Lesser of the useful life or the term of the respective lease
Land improvements	25 years
Land	Not depreciated
Building and improvements	30 years
Construction in Progress	Not depreciated until put into service

Intangible assets

The Company's intangible assets consist of in-licensed rights, patent costs, and software licenses, which are stated in the Company's consolidated balance sheets net of accumulated amortization and impairments, if applicable.

The in-licensed rights relate to agreements with BioMarin Pharmaceutical, Inc. ("BioMarin") and the University of Western Australia ("UWA"). The in-licensed rights are being amortized on a straight-line basis over the remaining life of the related patents because the life of the related patents reflects the expected time period that the Company will benefit from the in-licensed rights.

Patent costs consist primarily of external legal costs, filing fees incurred to file patent applications and renewal fees on proprietary technology developed or licensed by the Company. Patent costs associated with applying for a patent, being issued a patent and annual renewal fees are capitalized. Costs to defend a patent and costs to invalidate a competitor's patent or patent application are expensed as incurred. Patent costs are amortized on a straight-line basis over the shorter of the estimated economic lives or the initial term of the patents, which is generally 20 years.

Impairment of Long-Lived Assets

Long-lived assets held and used by the Company, intangible assets with definite lives and equity investments without a readily determinable fair value are reviewed for impairment whenever events or circumstances indicate that the carrying amount of assets may not be recoverable. The Company evaluates recoverability of assets to be held and used by comparing the carrying amount of an asset to future net undiscounted cash flows to be generated by the asset. If the asset is considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amount of the assets exceeds the fair value of the assets. Such reviews assess the fair value of the assets based upon estimates of future cash flows that the assets are expected to generate.

Convertible Debt

The Company separately accounts for the liability and equity components of convertible debt instruments that can be settled in cash by allocating the proceeds from issuance between the liability component and the embedded conversion option. The value of the equity component is calculated by first measuring the fair value of the liability component, using the interest rate of a similar liability that does not have a conversion feature, as of the issuance date. The difference between the proceeds from the convertible debt issuance and the amount measured as the liability component is recorded as the equity component with a corresponding discount recorded on the debt. The Company recognizes the amortization of the resulting discount as interest expense using the effective interest method. Simultaneously, the Company bought capped call options from certain counterparties to minimize the impact of potential dilution upon conversion. The premium for the capped call options was recorded as additional paid-in capital. For additional information related to the convertible debt transactions, please read *Note 13, Indebtedness* to the consolidated financial statements.

Revenue Recognition

The Company recognizes revenue when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for the goods or services provided. To determine revenue recognition for arrangements within the scope of ASC Topic 606, *"Revenue from Contracts with Customers"* ("ASC Topic 606"), the Company performs the following five steps: (1) identify the contract with the customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when or as the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers or provides to the customer. At contract inception, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when or as the performance obligation is satisfied. The only performance obligation in the Company's contracts with customers is to timely deliver drug products to the customer's designated location.

Product revenues

The Company distributes its products principally through its customers. The customers subsequently resell the product to patients and health care providers. The Company provides no right of return to the customers except in cases of shipping error or product defect. Product revenues are recognized when the customers take control of the product, which typically occurs upon delivery to the customers. For the years ended December 31, 2019, 2018 and 2017, the majority of the revenues recognized were generated by the specialty distributor and specialty pharmacies in the U.S.

Variable Consideration

Product revenues are recorded at the net sales price (transaction price) which includes estimated reserves for variable consideration, such as Medicaid rebates, governmental chargebacks, including Public Health Service ("PHS") chargebacks, prompt payment discounts, co-pay assistance and distribution fees. These reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the contracts. Additional details relating to variable consideration follows:

- Medicaid rebates relate to the Company's estimated obligations to states under established reimbursement arrangements. Medicaid rebate reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a liability which is included in accrued expenses.
- Governmental chargebacks, including PHS chargebacks, relate to the Company's estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices that the Company charges to wholesalers. The wholesaler charges the Company for the difference between what the wholesaler pays for the products and the ultimate selling price to the qualified healthcare providers. Chargeback reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable. Chargeback amounts are generally determined at the time of resale to the qualified healthcare provider from the wholesaler, and the Company generally issues credits for such amounts within a few weeks of receiving notification of resale from the wholesaler.
- Prompt payment discounts relate to the Company's estimated obligations for credits to be granted to specialty pharmacies for remitting payment on their purchases within established incentive periods. Reserves for prompt payment discounts are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable.
- Co-pay assistance relates to financial assistance provided to qualified patients, whereby the Company may assist them with prescription drug co-payments required by the patient's insurance provider. Reserves for co-pay assistance are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a liability which is included in accrued expenses.
- Distribution fees relate to fees paid to customers in the distribution channel that provide the Company with inventory management, data and distribution services and are generally accounted for as a reduction of revenue. To the extent that the services received are distinct from the Company's sale of products to the customers, these payments are accounted for as selling, general and administrative expenses. Reserves for distribution fees result in an increase in a liability if payments are required of the Company or a reduction of accounts receivable if no payments are required of the Company.

Research and Development

Research and development expenses consist of costs associated with research activities as well as those with the Company's product development efforts, conducting pre-clinical trials, clinical trials and manufacturing activities. Research and development expenses are expensed as incurred. Up-front fees and milestones paid to third parties in connection with technologies which have not reached technological feasibility and do not have an alternative future use are expensed when incurred.

Direct research and development expenses associated with the Company's programs include clinical trial site costs, clinical manufacturing costs, costs incurred for consultants and other external services, such as data management and statistical analysis support and materials and supplies used in support of clinical programs. Indirect costs of the Company's clinical programs include salaries, stock-based compensation and an allocation of its facility and technology costs.

When third-party service providers' billing terms do not coincide with the Company's period-end, the Company is required to make estimates of its obligations to those third parties, including clinical trial and pharmaceutical development costs, contractual services costs and costs for supply of its drug candidates, incurred in a given accounting period and record accruals at the end of the period. The Company bases its estimates on its knowledge of the research and development programs, services performed for the period, past history for related activities and the expected duration of the third-party service contract, where applicable.

Stock-Based Compensation

The Company's stock-based compensation programs include stock options, restricted stock awards ("RSAs"), restricted stock units ("RSUs"), stock appreciation rights ("SARs") and an employee stock purchase program ("ESPP"). The Company accounts for stock-based compensation using the fair value method.

The fair values of stock options and SARs are estimated on the date of grant using the Black-Scholes-Merton option-pricing model. The fair values of RSAs and RSUs are based on the fair market value of the Company's common stock on the date of the grant. The fair value of stock awards, with consideration given to estimated forfeitures, is recognized as stock-based compensation expense on a straight-line basis over the vesting period of the grants. For stock awards with performance-vesting conditions, the Company does not recognize compensation expense until it is probable that the performance-vesting condition will be achieved.

Under the Company's ESPP, participating employees purchase common stock through payroll deductions. The purchase price is equal to 85% of the lower of the closing price of the Company's common stock on the first business day and the last business day of the relevant purchase period. The fair value of stock purchase rights are estimated using the Black-Scholes-Merton option-pricing model. The fair value of the look-back provision with the 15% discount is recognized on a graded-vesting basis as stock-based compensation expense over the purchase period.

In addition to stock options with service and performance conditions, the Company also granted its CEO options with service and market conditions. A market condition relates to the achievement of a specified price of the Company's common stock, a specified amount of intrinsic value indexed to the Company's common stock or a specified price of the Company's common stock in terms of other similar equity shares. The grant date fair value for the options with service and market conditions is determined by a lattice model with Monte Carlo simulations and is recognized as stock-based compensation expense on a straight-line basis over the service period.

Income Taxes

The Company follows the asset and liability method of accounting for income taxes. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the consolidated financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. It is the intention of the Company to reinvest the earnings of its non-U.S. subsidiaries in those operations and not to repatriate the earnings to the U.S. Accordingly, the Company does not provide for deferred taxes on the excess of the financial reporting over the tax basis in its investments in foreign subsidiaries as they are considered permanent in duration.

Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered and settled. A valuation allowance is recorded to reduce the net deferred tax asset to zero when it is more likely than not that the net deferred tax asset will not be realized. The Company recognizes the effect of income tax positions only if those positions are more likely than not of being sustained upon an examination.

Leases

Effective January 1, 2019, the Company adopted ASC Topic 842, "*Leases*" ("ASC 842"), using the modified retrospective approach and utilizing the effective date as its date of initial application, for which prior periods are presented in accordance with the previous guidance in ASC Topic 840, "*Leases*" ("ASC 840").

As a result of adopting ASC 842, the Company recorded lease right-of-use ("ROU") assets of $42.5 million and lease liabilities of $60.1 million as of January 1, 2019, primarily related to real estate leases, based on the present value of future lease payments on the date of adoption. The difference between the ROU assets and lease liabilities was due to previously recorded net deferred rent liabilities that were reclassified into the ROU assets. There was no impact to retained earnings upon adoption of ASC 842. Amounts related to finance leases were immaterial as of adoption .

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present in the arrangement. Leases with a term greater than 12 months are recognized on the balance sheet as ROU assets and short-term and long-term lease liabilities, as applicable. The Company has elected not to recognize on the balance sheet leases with terms of 12 months or less. The Company typically only includes an initial lease term in its assessment of a lease arrangement. Options to renew a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew. The Company monitors its plans to renew its leases no less than on a quarterly basis. In addition, the Company's lease agreements generally do not contain any residual value guarantees or restrictive covenants.

Operating lease liabilities and their corresponding ROU assets are recorded based on the present value of future lease payments over the expected remaining lease term at lease commencement. Lease cost for operating leases is recognized on a straight-line basis over the lease term as an operating expense. Certain adjustments to the ROU asset may be required for items such as lease prepayments or incentives received. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. In transition to ASC 842, the Company utilized the remaining lease term of its leases in determining the appropriate incremental borrowing rate.

In accordance with ASC 842, components of a lease should be bifurcated between lease components and non-lease components. The fixed and in-substance fixed contract consideration identified must then be allocated based on the respective relative fair values to the lease components and non-lease components. However, ASC 842 provides a practical expedient that allows an accounting policy election to not separate lease and non-lease components by class of underlying asset. In using this expedient, the lease component and non-lease components are accounted for together as a single component. For real estate leases, the Company has elected to account for the lease and non-lease components together for existing classes of underlying assets and allocates the contract consideration to the lease component only. This practical expedient is not elected for manufacturing facilities and equipment embedded in product supply arrangements.

Embedded Derivatives

The Company evaluates certain of its financial and business development transactions to determine if embedded components of these contracts meet the definition of derivative under Topic ASC 815, "*Derivatives and Hedging*". In general, embedded derivatives are required to be bifurcated from the host instrument if (i) the embedded feature is not clearly and closely related to the host contract and (ii) the embedded feature, if considered a freestanding instrument, met the definition of a derivative. The embedded derivative is reported on the balance sheets at its fair value. Any change in fair value, as determined at each measurement period, is recorded as a component of the consolidated statements of operations and comprehensive loss.

Commitments and Contingencies

The Company records liabilities for legal and other contingencies when information available to the Company indicates that it is probable that a liability has been incurred and the amount of loss can be reasonably estimated. Legal costs in connection with legal and other contingencies are expensed as costs are incurred.

Recent Accounting Pronouncements

In December 2019, the Financial Accounting Standards Board ("FASB") issued ASU 2019-12, "*Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*", which is intended to simplify the accounting for income taxes. This ASU removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. The new standard will be effective beginning January 1, 2021. The Company is currently evaluating the potential impact this ASU may have on its financial position and results of operations upon adoption.

In November 2018, the FASB issued ASU 2018-18, "*Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*". The amendments in this update clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue when the collaborative arrangement participant is a customer in the context of a unit of account and precludes recognizing as revenue consideration received from a collaborative arrangement participant if the participant is not a customer. The new standard will be effective beginning January 1, 2020 and early adoption is permitted. As of December 31, 2019, the Company has elected to early adopt this ASU and the adoption did not have a material impact on its financial position and results of operations.

In August 2018, the FASB issued ASU No. 2018-13, "*Fair Value Measurement (Topic 820), Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*". This ASU removed the following disclosure requirements: (1) the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy; (2) the policy for timing of transfers between levels; and (3) the valuation processes for Level 3 fair value measurements. Additionally, this update added the following disclosure requirements: (1) the changes in unrealized gains and losses for the period included in other comprehensive income and loss for recurring Level 3 fair value measurements held at the end of the reporting period; (2) the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. For certain unobservable inputs, an entity may disclose other quantitative information (such as the median or arithmetic average) in lieu of the weighted average if the entity determines that other quantitative information would be a more reasonable and rational method to reflect the distribution of unobservable inputs used to develop Level 3 fair value measurements. ASU No. 2018-13 will be effective for fiscal years beginning after December 15, 2019 with early adoption permitted. As of December 31, 2019, the Company has not elected to early adopt this guidance but does not expect that the adoption of this guidance will have a material effect on its consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-15, "*Intangibles – Goodwill and Other – Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That is a Service Contract*". This ASU requires a customer in a cloud computing arrangement (i.e., hosting arrangement) that is a service contract to follow the internal-use software guidance contained in ASC Subtopic 350-40 to determine which implementation costs to capitalize as assets or expense as incurred. Capitalized implementation costs related to a hosting arrangement that is a service contract will be amortized over the term of the hosting arrangement, beginning when the module or component of the hosting arrangement is ready for its intended use. ASU No. 2018-15 will be effective for fiscal years beginning after December 15, 2019, with early adoption permitted. As of December 31, 2019, the Company has not elected to early adopt this guidance but believes that the adoption of this guidance will not have a material effect on its consolidated financial statements.

In June 2016, the FASB issued ASU No. 2016-13, "*Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*". This ASU requires that credit losses be reported using an expected losses model rather than the incurred losses model that is currently used, and establishes additional disclosures related to credit risks. For available-for-sale debt securities with unrealized losses, this standard now requires allowances to be recorded instead of reducing the amortized cost of the investment. ASU 2016-13 limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and requires the reversal of previously recognized credit losses if fair value increases. ASU 2016-13 will be effective for fiscal years beginning after December 15, 2019 with early adoption permitted, and requires adoption using a modified retrospective approach, with certain exceptions. As of December 31, 2019, the Company has not elected to early adopt this guidance. Based on the composition of the Company's investment portfolio as of December 31, 2019, current market conditions and historical credit loss activity, the adoption of this standard is not expected to have a material impact on the Company's consolidated financial statements. Additionally, for trade receivables, due to their short duration and the credit profile of the Company's customers, the effect of transitioning from the incurred losses model to the expected losses model is not expected to be material.

3. LICENSE AND COLLABORATION AGREEMENTS

Roche Holding A.G.

On December 21, 2019, the Company entered into a license, collaboration and option agreement and a stock purchase agreement (collectively, the "Roche Agreements") with F. Hoffman-La Roche Ltd ("Roche"), providing Roche with exclusive commercial rights to SRP-9001 (AAVrh74.MHCK7.micro-dystrophin) (the "Lead Product"), the Company's investigational gene therapy for DMD, outside the U.S. The Company retains all rights to SRP-9001 in the U.S. and will perform all development activities directed to obtaining and maintaining regulatory approvals for SRP-9001 in the U.S. and the EU. Further, global development expenses for SRP-9001 will be equally shared between the two parties.

The closing of the transaction was subject to the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 and other customary conditions. The agreement became effective as of February 4, 2020, and closed on February 14, 2020.

When the Roche Agreements became effective, the Company received payments totaling approximately $1.2 billion, consisting of $750.0 million in an up-front payment and $400.0 million in an equity investment. Additionally, the Company may receive up to approximately $1.7 billion in regulatory and sales milestones related to the Lead Product. Upon commercialization, the Company is also eligible to receive tiered royalty payments based on net sales.

In addition, Roche has options to in-license (1) certain exon-skipping products that target the dystrophin gene to induce exon skipping, including eteplirsen, golodirsen, casimersen and SRP-5051, (2) certain gene therapy products other than SRP-9001 that encode and directly express dystrophin or a derivative thereof and (3) certain gene-editing products that modify, repair, or activate an endogenous dysfunctional dystrophin gene (collectively, the "Option Products"). If and when Roche decides to exercise the options, it will be required to make an option exercise payment, on a per Option Product basis, in an amount ranging between $20.0 million and $125.0 million.

As of December 31, 2019, there was no accounting impact as a result of the execution of the Roche Agreements because the closing of the transaction did not occur until subsequent to year-end.

Genethon

In May 2017, the Company entered into a sponsored research agreement (the "Research Agreement") with Genethon for its micro-dystrophin gene therapy program for the treatment of DMD. The Research Agreement provided the Company with an option to in-license the corresponding technology. On November 22, 2019, the Company exercised the option and entered into a license and collaboration with Genethon (the "Genethon Collaboration Agreement"). The Genethon Collaboration Agreement grants the Company with exclusive rights in the majority of the world (primarily excluding the EU) to Genethon's micro-dystrophin gene therapy products ("Genethon Products") and other micro-dystrophin gene therapy products ("Other Licensed Products").

Under the Genethon Collaboration Agreement, a joint steering committee will be established to plan, monitor and coordinate development activities for Genethon Products and Other Licensed Products. The Company and Genethon will be responsible for 75% and 25%, respectively, of development costs related to both the Genethon Products and the Other Licensed Products. For the year ended December 31, 2019, the Company recorded $9.0 million of research and development expense related to reimbursable development costs incurred for Genethon Products to date.

Upon exercise of the option, the Company made an up-front payment of $28.0 million and may be liable for up to $157.5 million and $78.8 million in development, regulatory and sales milestones for the Genethon Products and Other Licensed Products, respectively. Furthermore, upon commercialization, the Company will be required to make tiered royalty payments based on net sales of the Genethon Products and the Other Licensed Products.

The up-front payment represents rights to potential future benefits associated with ongoing research and development activities that have no alternative future use. Accordingly, this amount has been recorded as research and development expense in the accompanying consolidated statements of operations and comprehensive loss for the year ended December 31, 2019. As of December 31, 2019, no development or regulatory milestones were deemed probable of being achieved and, accordingly, no additional expense has been recognized.

StrideBio, Inc.

On November 14, 2019 (the "StrideBio Effective Date"), the Company entered into a collaboration and license agreement (the "StrideBio Collaboration Agreement") and a stock purchase agreement (collectively, the "StrideBio Agreements") with StrideBio, Inc. ("StrideBio"). Under the terms of the StrideBio Collaboration Agreement, StrideBio granted the Company exclusive worldwide licenses to develop, collaborate and commercialize StrideBio's adeno-associated viral capsids for gene therapy with respect to multiple initial development targets ("Initial Targets"), and, at the option of the Company, additional development targets ("Additional Targets"). The Company also may be required to participate in StrideBio's next preferred equity round of financing, subject to certain conditions.

Both the Initial Targets and the Additional Targets are comprised of targets to which the Company will have the exclusive right to perform development activities ("Sarepta Development Targets") and targets that the two parties will jointly develop through completion of Phase 1/2 clinical trials ("Joint Development Targets"). The Company also has the right to select additional Sarepta Development Targets and Joint Development Targets. For each Sarepta Development Target, StrideBio is responsible for initial research activities and each party bears its own costs while the Company is responsible for all costs following transfer of responsibilities to the Company for additional development. For each Joint Development Target, the parties will be responsible to develop a joint development plan for which the parties will share equally all costs through Phase 1/2 of clinical trials after which the Company will be solely responsible for the continued development, regulatory approval and commercialization of the target, including all related costs. The Company and StrideBio will also form a joint steering committee to oversee the collaboration activities.

As a result of execution of the StrideBio Agreements, the Company recognized an up-front expense of $46.9 million, consisting of a cash payment of $17.5 million and 301,980 shares of the Company's common stock delivered to StrideBio equal to $29.4 million. For Sarepta Development Targets and Joint Development Targets, respectively, the Company may be liable for up to $450.0 million and $835.0 million in development, regulatory and sales milestone payments per target. Furthermore, the Company may be obligated to pay StrideBio up to $42.5 million in additional fees when and if Additional Targets are selected. Additionally, upon commercialization, the Company may be required to make tiered royalty payments based on net sales of each target.

The total up-front payment of $46.9 million, representing the fair value of the common shares delivered and cash, represents rights to potential future benefits associated with ongoing research and development activities that have no alternative future use. Accordingly, this amount has been recorded as research and development expense in the accompanying consolidated statements of operations and comprehensive loss for the year ended December 31, 2019. As of December 31, 2019, no development or regulatory milestones were deemed probable of being achieved and, accordingly, no additional expense has been recognized.

Myonexus Therapeutics

In May 2018, the Company entered into a Warrant to Purchase Common Stock Agreement ("Warrant Agreement") with Myonexus Therapeutics, Inc. ("Myonexus"), a clinical-stage gene therapy biotechnology company that was developing gene therapies for Limb-Girdle muscular dystrophies ("LGMD"). Pursuant to the terms of the Warrant Agreement, the Company made an up-front payment of $60.0 million to purchase an exclusive option to acquire Myonexus for $200.0 million plus sales-related and regulatory-related contingent payments. During the year ended December 31, 2018, the Company recorded $85.0 million to research and development expense in connection with the Warrant Agreement comprised of the $60.0 million up-front payment, two development milestone payments totaling $20.0 million, and a third development milestone for $5.0 million was deemed probable of being achieved as of December 31, 2018.

On February 27, 2019, the Company announced that it exercised the exclusive option to acquire Myonexus. The final exercise price as negotiated between the Company and Myonexus was $165.0 million. In addition, the Company incurred transaction fees and other fees associated with the exercise of approximately $8.8 million. The Company may also be required to make up to $200.0 million in additional payments to selling shareholders of Myonexus based on the achievement of certain sales- and regulatory-related milestones. The acquisition closed on April 4, 2019.

As a result of the acquisition, the Company added five LGMD gene therapy programs, including MYO-101, MYO-102 and MYO-201 that are currently in Phase 1/2 clinical trials, to its research and development portfolio. The acquisition of Myonexus has been accounted for as an asset acquisition as substantially all of the fair value of the gross assets acquired is concentrated in a group of similar identifiable assets (the five LGMD gene therapy programs).

Additionally, the Company assessed whether any of the contingent payments met the definition of a derivative under ASC 815 and, therefore, should be accounted for as contingent consideration. The Company identified that one regulatory-related milestone (not solely based on drug approval by the FDA) met the definition of a derivative. As a result, the Company recorded a contingent consideration liability of $4.5 million at the acquisition date. Any changes in the fair value of the contingent consideration liability after the acquisition date is included in the Company's statement of operations. This amount was estimated through a probability-weighted expected return method that incorporated industry-based probability adjusted assumptions relating to the achievement of the milestone and thus the likelihood of making the payments. This fair value measurement was based upon significant inputs not observable in the market and therefore represented a Level 3 fair value measurement. The Company did not assume any other liabilities as a result of the acquisition.

The following table summarizes the total consideration for the asset acquisition and the value of assets acquired and liability assumed:

Consideration (in thousands)		
Purchase price	$	165,000
Transactions costs and other fees		8,753
Contingent consideration		4,500
Total consideration	$	178,253

Assets Acquired (in thousands)		
Cash and cash equivalents	$	1,197
Prepaids		3,816
In-process research and development		173,240
Total assets acquired	$	178,253

Liability Assumed (in thousands)		
Contingent consideration		4,500
Total liability assumed	$	4,500

The acquired in-process research and development asset relates to the LGMD asset group. Due to the stage of development of this asset group, significant risk remains, and it is not yet probable that there is future economic benefit from this asset. Absent successful clinical results and regulatory approval, there is no alternative future use associated with the LGMD asset group. Accordingly, the value of this asset of $173.2 million was immediately expensed to research and development expense during the three months ended June 30, 2019.

The portion of the $200.0 million in contingent payments related to the sales milestone will be accrued when and if the sales milestone becomes probable of being achieved, and the related payment will be capitalized and amortized over the life of the patent. As of December 31, 2019, the sales milestone was not probable of being achieved.

Lysogene S.A.

In October 2018, the Company entered into a license and collaboration agreement to develop and commercialize LYS-SAF302, a gene therapy to treat MPS IIIA as well as an equity investment agreement with Lysogene S.A. ("Lysogene"). Under the license and collaboration agreement, in addition to the payment of up-front fees, the Company may be liable for a total of $102.8 million in development, regulatory and sales milestones. Furthermore, the Company may be required to make tiered royalty payments based on net sales of the LYS-SAF302 product subsequent to its commercialization. Under the equity investment agreement, the Company purchased 950,606 shares of common stock issued by Lysogene, representing 8% of the outstanding equity of Lysogene at the time of the transaction.

As a result of execution of the agreements, for the year ended December 31, 2018, the Company recorded research and development expense of $44.8 million, consisting of $26.1 million related to the payment of up-front fees and $18.7 million related to the achievement of a development milestone. In addition, $1.9 million of the total up-front fees paid was allocated to the equity investment in Lysogene and recorded as an other non-current asset. Changes in the fair value of this equity investment are recorded to other (loss) income in the Company's consolidated statements of operations and other comprehensive loss.

As of December 31, 2019, no additional development or regulatory milestones were deemed probable of being achieved and, accordingly, no additional expense has been recognized. Further, the changes in the fair value of the equity investment for the years ended December 31, 2019 and 2018 were not material.

Lacerta Therapeutics

In August 2018, the Company entered into a license, development and option agreement (the "Lacerta License Agreement") and a Series A Preferred Stock Purchase Agreement (the "Stock Purchase Agreement") with Lacerta Therapeutics, Inc. ("Lacerta"). Pursuant to the Lacerta License Agreement, the Company licensed exclusive worldwide rights to develop, manufacture and commercialize a pre-clinical Pompe product candidate (the "Pompe License"). Lacerta also granted the Company exclusive options to enter into exclusive license agreements to develop, manufacture and commercialize other gene therapy product candidates for Sanfilipo syndrome and L-Amino Acid Decarboxylase Deficiency for additional consideration of $42.0 million (collectively, the "Options") when (and if) the Options are exercised. Additionally, the Company may be liable for up to approximately $44.0 million in development, regulatory and sales milestones associated with the Pompe License and may be required to make tiered royalty payments based on net sales of the Pompe product subsequent to its commercialization. Under the Stock Purchase Agreement, the Company purchased approximately 4.5 million shares of Series A preferred stock issued by Lacerta.

Under the agreements, the Company made an up-front payment of $38.0 million to Lacerta, $30.0 million and $8.0 million of which were allocated to the Series A preferred stock investment and the Pompe License, respectively. The amount allocated to the Pompe License represents rights to potential future benefits associated with ongoing research and development activities that have no alternative future use. Accordingly, this amount was recorded as research and development expense in the accompanying consolidated statements of operations and comprehensive loss for the year ended December 31, 2018. As of December 31, 2019, no development or regulatory milestones were deemed probable of being achieved and, accordingly, no additional expense has been recognized.

The $30.0 million allocated to the Series A preferred stock investment was initially measured at cost and is classified as an other non-current asset in the accompanying consolidated balance sheets. Changes in the carrying value of the investment are reported as a component of earnings whenever there are observable price changes in orderly transactions for identical or similar investments of Lacerta in the future. For the years ended December 31, 2019 and 2018, the Company did not record any changes in carrying value of the investment as Lacerta did not issue identical or similar shares during the corresponding periods.

Nationwide Children's Hospital

In December 2016, the Company entered into an exclusive option agreement with Nationwide Children's Hospital ("Nationwide") from which the Company obtained an exclusive right to acquire a worldwide license of the micro-dystrophin gene therapy technology for DMD and Becker muscular dystrophy. In October 2018, the Company exercised the option and entered into a license agreement with Nationwide ("Nationwide License Agreement"). Pursuant to the Nationwide License Agreement, the Company licensed exclusive worldwide rights to develop, manufacture and commercialize micro-dystrophin gene therapy product candidates. Under the agreement, the Company made an up-front payment of $1.0 million to Nationwide, which was recorded as research and development expense in the accompanying consolidated statements of operations and comprehensive loss for the year ended December 31, 2018. Additionally, the Company may be required to make up to $29.0 million in development, regulatory and sales milestone payments per micro-dystrophin product and low-single-digit royalty payments based on net sales of the micro-dystrophin products upon commercialization. As of December 31, 2019, no development or regulatory milestones were deemed probable of being achieved and, accordingly, no additional expense has been recognized.

BioMarin Pharmaceutical, Inc.

In July 2017, the Company and the University of Western Australia ("UWA") entered into a settlement agreement with BioMarin Pharmaceutical, Inc. ("BioMarin"). On the same day, the Company entered into a license agreement, which was subsequently amended in April 2019, with BioMarin and Academisch Ziekenhuis Leiden ("AZL") (collectively with the Company, UWA and BioMarin, the "Settlement Parties"). Under these agreements and amendment, BioMarin agreed to provide the Company with an exclusive license to certain intellectual property with an option to convert the exclusive license into a co-exclusive license and the Settlement Parties agreed to stop most existing efforts to continue with ongoing litigation and opposition and other administrative proceedings concerning BioMarin's intellectual property. As a result of execution of the agreements, the Company made total up-front payments of $35.0 million. Additionally, the Company may be liable for up to approximately $65.0 million in regulatory and sales milestones for eteplirsen as well as casimersen and golodirsen. BioMarin is also eligible to receive tiered royalty payments, ranging from 4% to 8%, based on the net sales for the two products and product candidate. The royalty terms under the license agreement will expire in March 2024 in the U.S., December 2024 in the EU and no later than December 2024 in other countries.

Of the $35.0 million paid to BioMarin, $28.4 million was expensed as incurred and $6.6 million was recorded as an intangible asset, representing the fair value of the U.S. license to BioMarin's intellectual property. The intangible asset is being amortized on a straight-line basis over the remaining life of the patent and has a carrying value of $4.2 million as of December 31, 2019.

The FDA approval of VYONDYS 53 in December 2019 resulted in a settlement charge to BioMarin of $10.0 million and has been expensed as incurred. No regulatory or sales milestones were achieved for the years ended December 31, 2018 or 2017. For the years ended December 31, 2019, 2018 and 2017, the Company recognized royalty expense of $19.4 million, $15.1 million and $4.7 million, respectively. As of December 31, 2019, no other regulatory or sales milestones were deemed probable of being achieved and, accordingly, no additional in-licensed rights or expenses have been recognized.

University of Western Australia

In April 2013, the Company and UWA entered into an amendment to an existing exclusive license agreement relating to the treatment of DMD by inducing the skipping of certain exons. The agreement was further amended in June 2016. Under the amended agreement, the Company may be obligated to make payments to UWA totaling up to $26.0 million upon the achievement of certain development, regulatory and sales milestones. Additionally, the Company is required to pay a low-single-digit percentage royalty on net sales of products covered by issued patents licensed under the agreements with UWA. Corresponding with the FDA approval of EXONDYS 51 in 2016, the Company recorded a $1.0 million milestone payment as an in-licensed right intangible asset in its consolidated balance sheet. Similarly, corresponding to the milestone payments associated with the FDA approval of VYONDYS 53 in December 2019, the Company recorded a $0.5 million milestone payment as an in-licensed right intangible asset in its consolidated balance sheet. Both intangible assets are being amortized on a straight-line basis over the remaining life of the relevant patents and have a combined carrying value of $1.1 million as of December 31, 2019. For the year ended December 31, 2019, the Company recorded $3.5 million in royalty expense, which is included in cost of sales, related to agreements with UWA with no such an expense incurred in 2018 or 2017. As of December 31, 2019, no other development, regulatory or sales milestones were deemed probable of being achieved and, accordingly, no additional in-licensed rights or expenses have been recognized.

Milestone Obligations

As of December 31, 2019, the Company may be obligated to make up to $3.0 billion of future development, regulatory, commercial, and up-front royalty payments associated with its collaboration and license agreements. For the years ended December 31, 2019, 2018 and 2017, the Company recognized approximately $113.2 million, $142.4 million and $22.0 million relating to certain up-front, milestone and settlement payments as research and development expense, respectively, under these agreements. The Company is also obligated to pay royalties on net sales of certain of its products related to these collaboration and license agreements. The royalty rates range from the low-single-digit to high teens percentages for both inside and outside the U.S.

4. GAIN FROM SALE OF PRIORITY REVIEW VOUCHER

In March 2017, the Company completed a sale of its Rare Pediatric Disease Priority Review Voucher ("PRV") to Gilead Sciences, Inc. for $125.0 million, which was recorded as a gain from sale of the PRV as it did not have a carrying value at the time of the sale.

5. FAIR VALUE MEASUREMENTS

The tables below present information about the Company's financial assets that are measured and carried at fair value and indicate the level within the fair value hierarchy of the valuation techniques it utilizes to determine such fair value:

	Fair Value Measurement as of December 31, 2019			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Assets				
Money market funds	$ 203,410	$ 203,410	$ —	$ —
Government and government agency bonds	809,159	809,159	—	—
Strategic equity investments	31,937	1,937	—	30,000
Certificates of deposit	1,001	1,001	—	—
Total assets	$ 1,045,507	$ 1,015,507	$ —	$ 30,000
Liabilities				
Contingent consideration	5,200	—	—	5,200
Total liabilities	$ 5,200	$ —	$ —	$ 5,200

	Fair Value Measurement as of December 31, 2018			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Assets				
Money market funds	$ 42,920	$ 42,920	$ —	$ —
Commercial paper	125,907	—	125,907	—
Government and government agency bonds	760,235	760,235	—	—
Corporate bonds	43,468	43,468	—	—
Strategic equity investments	31,739	1,739	—	30,000
Certificates of deposit	1,001	1,001	—	—
Total	$ 1,005,270	$ 849,363	$ 125,907	$ 30,000

The Company's assets with fair value categorized as Level 1 within the fair value hierarchy include money market funds, government and government agency bonds, corporate bonds, certificates of deposit, and the Company's strategic investment in Lysogene, a publicly traded company in France, as more fully described in *Note 3, License and Collaboration Agreements*. Certain of the government and government agency bonds and corporate bonds are publicly traded fixed income securities and are presented as cash equivalents on the consolidated balance sheets.

The Company's assets with fair value categorized as Level 2 within the fair value hierarchy consist of commercial paper and government and government agency bonds. These assets have been initially valued at the transaction price and subsequently valued, at the end of each reporting period, through income-based approaches utilizing market observable data.

The Company's assets with fair value categorized as Level 3 within the fair value hierarchy consists of a strategic investment in Series A preferred stock of Lacerta as more fully described in *Note 3, License and Collaboration Agreements*. The fair value of the asset was initially based on a cost approach corroborated by the Black-Scholes option pricing model. The most significant assumptions in the option pricing model include historical volatility of similar public companies, estimated term through Lacerta's potential exit and a risk-free rate based on certain U.S. Treasury rates. At the end of each reporting period, the fair value will be adjusted if Lacerta issues similar or identical equity securities or when there is a triggering event for impairment. There were no changes in the fair value of the Lacerta strategic investment during the year ended December 31, 2019.

The Company's contingent consideration liability with fair value categorized as Level 3 within the fair value hierarchy relate to the regulatory-related contingent payments to Myonexus selling shareholders as well as to an academic institution under a separate license agreement that meet the definition on a derivative. For more information related to Myonexus, please read *Note 3, License and Collaboration Agreements*. This amount was estimated through an income approach based on the probability-weighted expected cash flows that incorporated industry-based probability adjusted assumptions relating to the achievement of the milestone and thus the likelihood of making the payments. This fair value measurement was based upon significant inputs not observable in the market and therefore represented a Level 3 measurement. At the end of each reporting period, the fair value is adjusted to reflect the most current assumptions through earnings. There were no changes in the fair value of the contingent consideration during the year ended December 31, 2019. As of December 31, 2019, the contingent consideration was recorded as a non-current liability on the Company's consolidated balance sheets.

The carrying amounts reported in the consolidated balance sheets for cash and cash equivalents, accounts receivable and accounts payable approximate fair value because of the immediate or short-term maturity of these financial instruments. For fair value information related to the Company's debt facilities, please read *Note 13, Indebtedness*.

6. CASH, CASH EQUIVALENTS AND MARKETABLE SECURITIES

The following table summarizes the Company's financial assets with maturities of equal to or less than three months from the date of purchase included in cash equivalents in the consolidated balance sheets for each of the periods indicated:

	As of December 31,	
	2019	2018
	(in thousands)	
Money market funds	$ 203,410	$ 42,920
Government and government agency bonds	519,491	111,587
Commercial paper	—	14,940
Total	$ 722,901	$ 169,447

It is the Company's policy to mitigate credit risk in its financial assets by maintaining a well-diversified portfolio that limits the amount of exposure as to maturity and investment type. The weighted average maturity of the Company's available-for-sale securities as of December 31, 2019 and 2018 was approximately two months. The following tables summarize the Company's cash, cash equivalents and investments for each of the periods indicated:

	As of December 31, 2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
	(in thousands)			
Cash and money market funds	$ 315,589	$ —	$ —	$ 315,589
Government and government agency bonds	809,090	71	(2)	809,159
Total cash, cash equivalents and investments	$ 1,124,679	$ 71	$ (2)	$ 1,124,748
As reported:				
Cash and cash equivalents	$ 835,044	$ 36	$ —	$ 835,080
Short-term investments	289,635	35	(2)	289,668
Total cash, cash equivalents and investments	$ 1,124,679	$ 71	$ (2)	$ 1,124,748

	As of December 31, 2018			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
	(in thousands)			
Cash and money market funds	$ 244,302	$ —	$ —	$ 244,302
Commercial paper	125,907	—	—	125,907
Government and government agency bonds	760,258	12	(35)	760,235
Corporate bonds	43,544	—	(76)	43,468
Total cash, cash equivalents and investments	$ 1,174,011	$ 12	$ (111)	$ 1,173,912
As reported:				
Cash and cash equivalents	$ 370,827	$ 3	$ (1)	$ 370,829
Short-term investments	803,184	9	(110)	803,083
Total cash, cash equivalents and investments	$ 1,174,011	$ 12	$ (111)	$ 1,173,912

7. ACCOUNTS RECEIVABLE AND RESERVES FOR PRODUCT SALES

The following table summarizes the components of the Company's accounts receivable for the periods indicated:

	As of December 31,	
	2019	2018
	(in thousands)	
Product sales, net of discounts and allowances	$ 90,409	$ 48,252
Government contract receivables	470	792
Total accounts receivable, net	$ 90,879	$ 49,044

The balance for government contract receivables for both periods presented is subject to government audit and will not be collected until the completion of the audit.

The following table summarizes an analysis of the change in reserves for discounts and allowances for the periods indicated:

	Chargebacks	Rebates	Prompt Pay	Other Accruals	Total
			(in thousands)		
Balance, as of December 31, 2017	$ 995	$ 6,959	$ 169	$ 464	$ 8,587
Provision	12,284	28,420	2,624	5,286	48,614
Payments/credits	(11,901)	(11,103)	(2,255)	(3,432)	(28,691)
Balance, as of December 31, 2018	$ 1,378	$ 24,276	$ 538	$ 2,318	$ 28,510
Provision	9,698	44,749	4,897	9,643	68,987
Payments/credits	(10,488)	(24,287)	(3,929)	(7,290)	(45,994)
Balance, as of December 31, 2019	$ 588	$ 44,738	$ 1,506	$ 4,671	$ 51,503

The following table summarizes the total reserves above included in the Company's consolidated balance sheets for the periods indicated:

	As of December 31,	
	2019	2018
	(in thousands)	
Reduction to accounts receivable	$ 6,254	$ 2,364
Component of accrued expenses	45,249	26,146
Total reserves	$ 51,503	$ 28,510

8. INVENTORY

The following table summarizes the components of the Company's inventory for each of the periods indicated:

	As of December 31,	
	2019	2018
	(in thousands)	
Raw materials	$ 82,030	$ 71,313
Work in progress	88,031	47,279
Finished goods	1,318	6,853
Total inventory	$ 171,379	$ 125,445

9. OTHER ASSETS

The following table summarizes the Company's other current assets for each of the periods indicated:

	As of December 31,	
	2019	2018
	(in thousands)	
Manufacturing-related deposits and prepaids	$ 54,276	$ 39,036
Prepaid clinical and pre-clinical expenses	8,263	9,706
Prepaid maintenance services	4,366	2,994
Leasehold improvement receivable	3,059	13,474
Prepaid insurance	2,573	1,006
Prepaid income tax	2,114	2,130
Prepaid research expenses	2,007	1,932
Other	5,249	7,504
Total other current assets	$ 81,907	$ 77,782

The following table summarizes the Company's other non-current assets for each of the periods indicated:

	As of December 31,	
	2019	2018
	(in thousands)	
Manufacturing-related deposits and prepaids	$ 122,091	$ 62,821
Strategic investments	31,937	31,739
Restricted cash and investments	9,566	1,001
Prepaid clinical expenses	4,665	7,541
Alternative minimum tax credit	3,367	3,367
Other	2,233	825
Total other non-current assets	$ 173,859	$ 107,294

10. PROPERTY AND EQUIPMENT, NET

Property and equipment are recorded at historical cost, net of accumulated depreciation. The following table summarizes components of property and equipment, net for each of the periods indicated:

	As of December 31,	
	2019	2018
	(in thousands)	
Leasehold improvements	$ 53,950	$ 20,937
Software and computer equipment	30,683	15,774
Lab equipment	30,053	17,659
Building and improvements	23,108	22,972
Furniture and fixtures	7,090	3,227
Land	5,183	4,158
Land improvements	3,403	—
Office equipment	1,157	436
Construction in progress	25,988	40,010
Property and equipment, gross	180,615	125,173
Less: accumulated depreciation	(50,995)	(28,149)
Property and equipment, net	$ 129,620	$ 97,024

For the years ended December 31, 2019, 2018 and 2017, depreciation expense totaled $22.8 million, $10.2 million and $6.4 million, respectively.

11. INTANGIBLE ASSETS

The following table summarizes the components of the Company's intangible assets for each of the periods indicated:

	As of December 31,	
	2019	2018
	(in thousands)	
Patents	$ 8,902	$ 7,227
In-licensed rights	8,073	7,573
Software licenses	1,029	626
Intangible assets, gross	18,004	15,426
Less: accumulated amortization	(5,507)	(3,852)
Intangible assets, net	$ 12,497	$ 11,574

The in-licensed rights relate to agreements with BioMarin and UWA. As a result of the FDA approval of EXONDYS 51 and VYONDYS 53, the Company recorded in-licensed rights of $1.0 million and $0.5 million, respectively. Following the execution of the settlement and license agreements with BioMarin in July 2017, the Company recorded a $6.6 million intangible asset related to EXONDYS 51 in the U.S. The in-licensed rights are being amortized on a straight-line basis over the remaining life of the related patent because the life of the related patent reflects the expected time period that the Company will benefit from the in-licensed right. For more information about the in-licensed rights, please read *Note 3, License and Collaboration Agreements*. For the years ended December 31, 2019, 2018 and 2017, the Company recorded $0.8 million, $0.9 million and $1.1 million, respectively, of amortization related to the in-license rights.

Patent amortization expense was $0.4 million, $0.7 million and $0.6 million for the years ended December 31, 2019, 2018 and 2017, respectively. Total amortization expense was $1.7 million, $2.1 million and $1.7 million for the years ended December 31, 2019, 2018 and 2017, respectively. The Company also expensed the remaining net book value of previously capitalized patents that were later abandoned of $0.2 million, $0.1 million and $0.6 million for the years ended December 31, 2019, 2018 and 2017, respectively, which were included in research and development expenses on the consolidated statements of operations and comprehensive loss.

Additionally, in 2018, the Company reviewed its patent portfolio and identified technology that the Company will no longer pursue. As a result, the Company impaired these patent assets and recorded $3.8 million in impairment loss for the year ended December 31, 2018, which was included in research and development expense on the consolidated statement of operations and comprehensive loss. There was no such loss recorded in the years ended December 31, 2019 and 2017.

The following table summarizes the estimated future amortization for intangible assets:

	As of December 31, 2019 (in thousands)
2020	$ 1,358
2021	1,168
2022	1,156
2023	1,156
2024	1,149
Thereafter	6,510
Total	$ 12,497

12. ACCRUED EXPENSES

The following table summarizes the Company's accrued expenses for each of the periods indicated:

	As of December 31,	
	2019	2018
	(in thousands)	
Product revenue related reserves	$ 45,249	$ 26,146
Accrued employee compensation costs	43,240	24,692
Accrued contract manufacturing costs	27,622	15,794
Accrued milestone expense	18,390	24,020
Accrued clinical and pre-clinical costs	18,010	11,396
Accrued professional fees	10,707	11,319
Accrued collaboration cost-sharing	9,000	2,167
Accrued royalties	6,301	8,254
Other	7,008	10,307
Total accrued expenses	$ 185,527	$ 134,095

13. INDEBTEDNESS

2024 Convertible Notes

On November 14, 2017, the Company issued $570.0 million senior notes due on November 15, 2024 (the "2024 Notes"). The 2024 Notes were issued at face value and bear interest at the rate of 1.50% per annum, payable semi-annually in cash on each May 15 and November 15, commencing on May 15, 2018. The 2024 Notes contain customary covenants and events of default, occurrence of which will permits the certain holders to accelerate all outstanding obligations, including principal and interest.

Upon conversion, the Company may pay cash, shares of its common stock or a combination of cash and stock, as determined by the Company in its discretion. The 2024 Notes may be convertible into 7,763,552 shares of the Company's common stock under certain circumstances prior to maturity at a conversion rate of 13.621 shares per $1,000 principal amount of the 2024 Notes, which represents a conversion price of $73.42 per share, subject to adjustment under certain conditions.

The Company allocated the proceeds received from issuance of the 2024 Notes between the liability component and the embedded conversion option, or equity component. The liability component was determined by measuring the fair value of similar notes that do not include the embedded conversion option. The Company allocated $161.1 million to the equity component, which was determined by deducting the fair value of the liability component from the par value of the 2024 Notes. The equity component, net of allocated offering costs of $4.2 million, was recorded as an increase additional paid-in capital. The equity component, plus $10.6 million of offering costs allocated to the liability component, represent the total debt discount on the 2024 Notes at issuance. The debt discount is amortized under the effective interest method and recorded as additional interest expense over the life of the 2024 Notes. The effective interest rate on the liability component of the 2024 Notes for the year ended December 31, 2019, 2018 and 2017 was 6.9%.

Upon the occurrence of a "fundamental change", which includes (1) change in beneficial ownership of the Company where any person/group possesses more than 50% of the voting power of the Company, (2) consolidation or merger of the Company, (3) shareholder approval of a liquidation plan or (4) the Company is delisted from NYSE or NASDAQ, the holders may require the Company to repurchase all or a portion of the 2024 Notes for cash at 100% of the principal amount of the 2024 Notes being purchased, plus any accrued and unpaid interest. Additionally, upon the occurrence of a "make-whole fundamental change" prior to the maturity date, the Company shall adjust the conversion rate on a sliding scale basis detailed in the agreement

To minimize the impact of potential dilution upon conversion of the 2024 Notes, the Company separately entered into capped call transactions with certain counterparties. The capped calls have a strike price of $73.42 and a cap price of $104.88 and are exercisable when and if the 2024 Notes are converted. If, upon conversion of the 2024 Notes, the price of the Company's common stock is between the strike price and the cap price of the capped calls, the counterparties will deliver shares of the Company's common stock and/or cash with an aggregate value equal to the difference between the price of the Company's common stock at the conversion date and the strike price, multiplied by the number of shares of the Company's common stock related to the capped calls being exercised. The Company paid $50.9 million for these capped calls transactions, which was recorded as additional paid-in capital.

Term Loans and Revolving Line of Credit

December 2019 Term Loan

On December 13, 2019, the Company entered into a loan agreement (the "Loan Agreement") which provides a term loan ("December 2019 Term Loan") of $500.0 million with Biopharma Credit PLC and Biopharma Credit Investments V (Master) LP (collectively, the "Lenders"). The 2019 Term Loan has two tranches: A and B, each of which has a loan amount of $250.0 million. On December 20, 2019, Sarepta drew down tranche A of the 2019 Term Loan and has the option of draw down tranche B of the loan no later than December 31, 2020, subject to certain conditions. The December 2019 Term Loan matures on December 20, 2023, when the principal amount of the loan will become due.

Borrowings under the Loan Agreement bore interest at a rate per annum equal to 8.5%, which shall be payable quarterly in arrears. The Company is also required to pay the Lenders (1) a fee of 1.75% of the amounts drawn under both tranche A and tranche B due on closing (if and when drawn down), (2) a fee of 2.0% of principal amount on the December 2019 Term Loan maturity date or prepayment amount on each prepayment date and (3) certain out-of-pocket expenses incurred by the Lenders.

The Company may voluntarily prepay, in whole or in part, the outstanding balance under the December 2019 Term Loan at any time after the tranche A closing date. Upon occurrence of a change in control, the Company is required to repay any amounts outstanding under the December 2019 Term Loan. In the event of a permitted prepayment, the Company would be obligated to make the following premium payments: (1) an amount equal to the sum of all interest that would have been accrued and payable from the prepayment date through December 20, 2021 ("Makewhole Amount"), and (2) an amount equal to 1.0% to 2.0% of the prepayment amount depending on the date of the prepayment ("Prepayment Premium").

The Loan Agreement contains customary affirmative and negative covenants as well as events of default, the occurrence of which would permit the Lenders to accelerate the payment of all outstanding obligations, including the payment of the Makewhole Amount and Prepayment Premium.

As of December 31, 2019, the Company recorded a debt discount of $9.4 million and debt issuance costs of $0.7 million, both of which are being treated as deduction to the carrying value of the December 2019 Term Loan and amortized as interest expense over the term of the loan based on an effective interest method. The debt discount of $9.4 million is inclusive of (1) the initial fee of 1.75% payable to the Lenders and (2) the 2.0% fee payable to the Lenders at maturity or prepayment of the December 2019 Term Loan. This amount is recorded within other long-term liabilities in the Company's consolidated balance sheets. After certain debt discounts and debt issuance costs, the Company received net proceeds of $244.9 million.

July 2017 Term Loan and Revolving Line of Credit

In July 2017, the Company entered into an amended and restated credit agreement (the "Amended and Restated Credit and Security Agreement") with MidCap Financial Trust ("MidCap") which provided a term loan of $60.0 million, bearing interest at a rate of 6.25%, plus the one-month London Interbank Offered Rate ("LIBOR"). In addition, in July 2017, the Company entered into a revolving credit and security agreement (the "Revolving Credit Agreement") with MidCap which provided an aggregate revolving loan commitment of $40.0 million, bearing interest at a rate of 3.95%, plus the one-month LIBOR. In September 2018, the Company terminated both the Amended and Restated Credit and Security Agreement and the Revolving Credit Agreement with MidCap and paid off all amounts due thereunder, including any accrued and unpaid interest. As a result, the Company recorded a debt extinguishment loss of $2.3 million primarily related to the write-off of unamortized debt issuance costs and prepayment fees.

As of December 31, 2019, the Company recorded approximately $681.9 million as long-term debt on the consolidated balance sheets. For the years ended December 31, 2019, 2018 and 2017, the Company recorded $30.7 million, $33.7 million and $5.8 million of interest expense, respectively.

The following table summarizes the Company's debt facilities for the periods indicated:

	As of December 31,	
	2019	2018
	(in thousands)	
Principal amount of the 2024 Notes	$ 570,000	$ 570,000
Unamortized discount - equity component	(120,182)	(140,206)
Unamortized discount - debt issuance costs	(7,922)	(9,240)
Net carrying value of 2024 Notes	441,896	420,554
Principal amount of the 2019 Term Loan	250,000	—
Unamortized discounts	(9,996)	—
Net carrying value of 2019 Term Loan	240,004	—
Total carrying value of debt facilities	681,900	420,554
Fair value of 2024 Notes	1,141,288	952,681
Fair value of 2019 Term Loan	250,000	—
Total fair value of debt facilities	$ 1,391,288	$ 952,681

The fair value of the 2024 Notes is based on open market trades and is classified as level 1 in the fair value hierarchy. The fair value of the December 2019 Term Loan, approximating its principal amount due to the close proximity of the reporting date and the tranche A close date, is classified as level 2 in the fair value hierarchy as it is based on market observable inputs.

The following table summarizes the total gross payments due under the Company's debt arrangements:

	As of December 31, 2019 (in thousands)
2020	$ —
2021	—
2022	—
2023	250,000
2024	570,000
Thereafter	—
Total payments	$ 820,000

14. EQUITY

In March 2019, the Company sold approximately 2.6 million shares of common stock through an underwritten public offering. The offering price was $140.41 per share. The Company received net proceeds of approximately $365.4 million from the offering, net of commission and offering expenses of approximately $0.3 million.

In November 2019, the Company issued approximated 0.3 million shares of common stock with a fair value of $29.4 million as part of the up-front consideration to StrideBio (see *Note 3, License and Collaboration Agreements*).

In November 2018, the Company sold approximately 4.1 million shares of common stock through an underwritten public offering, including 0.3 million shares sold to the underwriters. The offering price was $131.00 per share. The Company received net proceeds of approximately $513.4 million from the offering, net of commission and offering expenses of approximately $24.6 million.

In July 2017, the Company sold approximately 8.8 million shares of common stock through an underwritten public offering, including 1.2 million shares sold to the underwriters. The offering price was $42.50 per share. The Company received net proceeds of approximately $354.0 million from the offering, net of commission and offering expenses of approximately $20.0 million.

15. STOCK-BASED COMPENSATION

In June 2011, the Company's stockholders approved the 2011 Equity Incentive Plan ("2011 Plan"). The 2011 Plan, which as amended authorized 16.0 million shares of common stock to be issued, allowed for the grant of stock options, stock appreciation rights ("SARs"), restricted stock awards ("RSAs"), restricted stock units ("RSUs"), performance shares and performance units. During 2018, the 2011 Plan was merged into the 2018 Plan (defined below). As a result, there were no shares of common stock remaining available for future grant under the 2011 Plan.

In June 2013, the Company's stockholders approved the 2013 Employee Stock Purchase Plan ("ESPP") with approximately 0.3 million shares of common stock available to be issued. In June 2016 and 2019, the Company's stockholders approved additional approximately 0.3 million and 0.5 million shares, respectively, of common stock available to be issued to be added to the 2013 ESPP. As of December 31, 2019, 0.6 million shares of common stock remain available for future grant under the 2013 ESPP.

In September 2014, the Company initiated the 2014 Employment Commencement Incentive Plan ("2014 Plan") with approximately 0.6 million shares of common stock available to be issued. In October 2015, June 2017 and July 2018, the 2014 Plan was increased by 1.0 million, 3.8 million and 1.2 million shares of common stock available to be issued, respectively. As of December 31, 2019, 0.6 million shares of common stock remain available for future grant under the 2014 Plan.

In June 2018, the Company's stockholders approved the 2018 Equity Incentive Plan ("2018 Plan"). The 2018 Plan, which authorized 2.9 million shares of common stock to be issued, allows for the grant of stock options, SARs, RSAs, RSUs, performance shares and performance units. The 2011 Plan was merged into the 2018 Plan and, as a result, all remaining shares in the 2011 Plan were transferred into the 2018 Plan. As of December 31, 2019, 3.4 million shares of common stock remain available for future grant under the 2018 Plan.

Stock Options

In general, stock options have a ten-year term and vest over a four-year period, with one-fourth of the underlying shares vesting on the first anniversary of the grant and 1/48th of the underlying shares vesting monthly thereafter, such that the underlying shares will be fully vested on the fourth anniversary of the grant, subject to the terms of the applicable plan under which they were granted.

The fair values of stock options granted during the periods presented are measured on the date of grant using the Black-Scholes-Merton option-pricing model, with the following assumptions:

	For the Year Ended December 31,		
	2019	2018	2017
Risk-free interest rate (1)	1.4 - 2.5%	2.5 - 3.0%	1.6 - 2.1%
Expected dividend yield (2)	—	—	—
Expected term (3)	5.04 years	5.06 years	4.2 - 4.8 years
Expected volatility (4)	52.5 - 68.9%	52.4 - 60.8%	54.0 - 63.0%

(1) The risk-free interest rate is estimated using an average of Treasury bill interest rates over a historical period commensurate with the expected term of the option that correlates to the prevailing interest rates at the time of grant.
(2) The expected dividend yield is zero as the Company has not paid any dividends to date and does not expect to pay dividends in the future.
(3) The expected term is estimated using historical exercise behavior.
(4) The expected volatility is the implied volatility in exchange-traded options of the Company's common stock.

The amounts estimated according to the Black-Scholes-Merton option-pricing model may not be indicative of the actual values realized upon the exercise of these options by the holders.

The following tables summarize the Company's stock option activity for each of the periods indicated:

	For the Year Ended December 31,					
	2019		2018		2017	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Grants outstanding at beginning of the period	8,391,171	$ 46.09	8,806,204	$ 29.74	5,436,951	$ 22.70
Granted	1,429,652	132.97	2,152,439	90.15	4,805,722 (1)	35.09
Exercised	(1,055,715)	30.73	(2,119,306)	22.89	(792,845)	17.40
Expired and forfeited	(418,760)	84.15	(448,166)	46.11	(643,624)	25.44
Grants outstanding at end of the period	8,346,348	$ 61.01	8,391,171	$ 46.09	8,806,204	$ 29.74
Grants exercisable at end of the period	2,368,621	$ 45.33	2,304,791	$ 27.69	3,288,712	$ 24.76
Grants vested and expected to vest at end of the period	7,987,427	$ 58.65	6,643,835	$ 45.43	6,910,022	$ 28.49

(1) Includes 3,300,000 options with service and market conditions granted to the Company's CEO. These options have a five-year cliff vesting schedule. The fair value of $13.48 for these options was determined by a lattice model with Monte Carlo simulations.

The weighted-average grant date fair value per share of stock options granted during the years ended December 31, 2019, 2018 and 2017 was $70.93, $44.66 and $14.78, respectively.

	Aggregate Intrinsic Value (in thousands)	Weighted Average Remaining Contractual Life (Years)
Options outstanding at December 31, 2019	$ 587,191	7.5
Options exercisable at December 31, 2019	$ 199,438	6.0
Options vested and expected to vest at December 31, 2019	$ 578,938	7.4

The following table summarizes the Company's stock options vested and exercised for each of the periods indicated:

	For the Year Ended December 31,		
	2019	2018	2017
	(in thousands)		
Aggregate grant date fair value of stock options vested	$ 50,878	$ 16,316	$ 18,225
Aggregate intrinsic value of stock options exercised	$ 109,707	$ 158,936	$ 20,922

For the years ended December 31, 2019, 2018 and 2017, the Company has recognized approximately $0.1 million, $0.2 million and $0.9 million in stock-based compensation expense related to the options with performance-based criteria, respectively.

Restricted Stock Awards

The Company grants RSAs to members of its board of directors and certain employees. The following table summarizes the Company's RSA activity for each of the periods indicated:

	For the Year Ended December 31,					
	2019		2018		2017	
	Shares	Weighted Average Grant Date Fair Value	Shares	Weighted Average Grant Date Fair Value	Shares	Weighted Average Grant Date Fair Value
Grants outstanding at beginning of the period	252,321	$ 42.37	411,781	$ 37.23	153,170	$ 34.53
Granted	—	—	27,590	98.57	341,500	34.58
Vested	(100,840)	40.54	(187,050)	39.34	(63,264)	14.60
Cancelled	(15,356)	48.94	—	—	(19,625)	43.02
Grants outstanding at end of the period	136,125	$ 42.98	252,321	$ 42.37	411,781	$ 37.23

In September 2016, the Company granted certain executives RSAs with a performance conditions relating to certain sales targets. If the sales targets are achieved within the required time frame, the number of RSAs may be increased from 71,925 to 89,906 shares. In December 2017, the Company modified the expiration date of these RSAs from June 30, 2018 to January 1, 2019. As a result of this modification, the fair value per RSA was changed from $48.94 to $54.29. Through December 31, 2017, the Company had not recorded any stock-based compensation expense associated with these awards as the achievement of the performance conditions was not deemed probable. As of December 31, 2018, the first sales target related to these RSAs was achieved and, accordingly, the Company recognized approximately $3.3 million of stock-based compensation expense during the year ended December 31, 2018. The second target was not achieved and the shares related to this target were subsequently cancelled and no expense was recognized.

Restricted Stock Units

The Company also grants RSUs to members of its board of directors and employees. The following table summarizes the Company's RSU activity for the periods indicated:

	For the Year Ended December 31,					
	2019		2018		2017	
	Shares	Weighted Average Grant Date Fair Value	Shares	Weighted Average Grant Date Fair Value	Shares	Weighted Average Grant Date Fair Value
Grants outstanding at beginning of the period	251,298	$ 81.21	66,552	$ 33.72	—	$ —
Granted	511,283	131.18	230,736	87.95	181,029	33.03
Vested	(84,068)	75.12	(30,276)	33.23	(78,017)	32.63
Cancelled	(72,639)	103.03	(15,714)	71.45	(36,460)	32.63
Grants outstanding at end of the period	605,874	$ 121.61	251,298	$ 81.21	66,552	$ 33.72

In March 2017, the Company granted certain executives 156,029 RSUs with performance conditions relating to certain sales target and regulatory milestones, which were achieved between June 2017 and March 2019. As of December 31, 2019, there were no RSUs with performance conditions remaining to be vested. For the years ended December 31, 2019, 2018 and 2017, the Company recognized approximately $0.5 million, $0.2 million and $2.9 million of stock-based compensation expense, respectively.

Stock Appreciation Rights

The Company issues SARs on the same terms as options granted to employees. The grant date fair value of the SARs is determined using the same valuation assumptions as for stock options described above. Stock-based compensation expense is recognized on a straight-line basis over the vesting period of the SARs.

The following table summarizes the Company's SAR activity for each of the periods indicated:

	For the Year Ended December 31,					
	2019		2018		2017	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Grants outstanding at beginning of the period	100,000	$ 23.85	100,000	$ 23.85	100,000	$ 23.85
Exercised	(100,000)	$ (23.85)	—	$ —	—	$ —
Grants outstanding at end of the period	—	$ —	100,000	$ 23.85	100,000	$ 23.85
Grants exercisable at end of the period	—	$ —	100,000	$ 23.85	100,000	$ 23.85
Grants vested and expected to vest at end of the period	—	$ —	100,000	$ 23.85	100,000	$ 23.85

2013 Employee Stock Purchase Plan

Under the Company's 2013 ESPP, participating employees purchase common stock through payroll deductions. The purchase price is equal to 85% of the lower of the closing price of the Company's common stock on the first business day and the last business day of the relevant purchase period. The 24-month offering period will end between February 29, 2020 and August 31, 2021. The following table summarizes the Company's ESPP activity for each of the periods indicated:

	For the Year Ended December 31,		
	2019	2018	2017
Number of shares purchased	92,086	75,094	102,698
Proceeds received (in millions)	$ 5.1	$ 2.3	$ 1.4

Stock-based Compensation Expense

For the years ended December 31, 2019, 2018 and 2017, total stock-based compensation expense was $78.6 million, $50.1 million and $30.5 million, respectively. Included in the amounts for the year ended December 31, 2017 is $2.1 million of stock-based compensation expense incurred in connection with the resignation of the Company's former CEO.

The following table summarizes stock-based compensation expense by function included within the consolidated statements of operations and comprehensive loss:

	For the Year Ended December 31,		
	2019	2018	2017
	(in thousands)		
Research and development	$ 27,681	$ 14,214	$ 8,542
Selling, general and administrative	50,921	35,913	21,923
Total stock-based compensation	$ 78,602	$ 50,127	$ 30,465

The following table summarizes stock-based compensation expense by grant type included within the consolidated statements of operations and comprehensive loss:

	For the Year Ended December 31,		
	2019	2018	2017
	(in thousands)		
Stock options	$ 53,427	$ 37,671	$ 23,416
Restricted stock awards/units	20,103	10,632	5,295
Employee stock purchase plan	5,072	1,824	1,754
Total stock-based compensation	$ 78,602	$ 50,127	$ 30,465

As of December 31, 2019, there was $181.1 million of total unrecognized stock-based compensation expense related to the Company's stock-based compensation plans. The expense is expected to be recognized over a weighted-average period of approximately 3 years. Of this amount, $109.5 million relates to options with service conditions only, $22.1 million relates to awards with service and market conditions, less than $0.1 million relates to awards with performance conditions, and the remaining $49.5 million related to restricted stock awards or restricted stock units with service conditions only.

16. 401 (K) PLAN

The Company sponsors a 401(k) Plan ("the Plan") in the U.S. and other retirement plans in the rest of the world, all of which are defined contribution plans. The Plan is available to all employees who are age 21 or older. Participants may make voluntary contributions and the Company makes matching contributions according to the Plan's matching formula. Matching contributions fully vest after one year of service for all employees. The expense related to the Plan primarily consists of the Company's matching contributions.

Expense related to the Plan totaled $3.4 million, $2.1 million and $1.4 million for the years ended December 31, 2019, 2018 and 2017, respectively.

17. OTHER (LOSS) INCOME

The following table summarizes other income and loss for the periods indicated:

	For the Year Ended December 31,		
	2019	2018	2017
	(in thousands)		
Interest expense	$ (30,669)	$ (33,709)	$ (5,801)
Interest income	7,238	6,810	1,809
Amortization of investment discount	15,350	8,573	1,401
Other expense	(236)	(656)	601
Gain from sale of Priority Review Voucher	—	—	125,000
Total other (loss) income	$ (8,317)	$ (18,982)	$ 123,010

18. INCOME TAXES

The following table summarizes the loss before the provision for income taxes by jurisdiction for the periods indicated:

	For the Year Ended December 31,		
	2019	2018	2017
	(in thousands)		
Domestic	$ (489,747)	$ (309,294)	$ (45,686)
Foreign	(224,133)	(53,316)	(2,942)
Total	$ (713,880)	$ (362,610)	$ (48,628)

The following table summarizes provision for income taxes in the accompanying consolidated financial statements for the periods indicated:

	For the Year Ended December 31,		
	2019	2018	2017
	(in thousands)		
Current provision:			
Federal	$ —	$ (110)	$ 204
State	521	(653)	1,856
Foreign	1,050	311	—
Total current provision	1,571	(452)	2,060
Deferred benefit:			
Federal	(15)	—	—
State	(5)	—	—
Foreign	(356)	(240)	—
Total deferred benefit	(376)	(240)	—
Total current provision	$ 1,195	$ (692)	$ 2,060

The following table summarizes the reconciliation between the Company's effective tax rate and the income tax rate for each of the periods indicated:

	For the Year Ended December 31,		
	2019	2018	2017
Federal income tax rate	21.0 %	21.0 %	34.0 %
State taxes	6.3	12.3	(27.7)
Research and development and other tax credits	3.3	3.1	8.5
Valuation allowance	(16.8)	(45.5)	(93.2)
Permanent differences	1.8	6.9	6.4
Sarepta International C.V. return to provision	—	(0.1)	62.1
Impact of tax reform, net of valuation allowance	—	—	5.9
Basis difference in subsidiary	(8.4)	—	—
Foreign rate differential	(7.4)	(0.9)	(0.6)
Other	—	3.4	0.4
Effective tax rate	(0.2)%	0.2 %	(4.2)%

Permanent differences affecting the Company's effective tax rate primarily include excess stock-based compensation tax deductions, net of non-deductible stock-based compensation and limitation on officer compensation deduction.

In February 2019, the Company exercised its option to acquire Myonexus. Accumulated costs of $253.7 million, associated with the Myonexus acquisition, were expensed for U.S. GAAP purposes. Of the $253.7 million in accumulated costs, $85.0 million relates to up-front and milestone payments as a result of the execution of the Warrant Agreement in May 2018 as well as certain development milestones being achieved or becoming probable of being achieved and $168.7 million relates to the exercise of the exclusive option to acquire Myonexus in February 2019. For U.S. income tax purposes, these costs are considered to be an outside investment in the subsidiary and are not currently deductible for tax purposes. The permanent difference related to this acquisition is separately stated in the rate reconciliation above.

In December 2012, the Company licensed certain intellectual property of Sarepta Therapeutics, Inc. to its wholly owned Netherlands subsidiary, Sarepta International C.V. The parties also entered into a contract research agreement under which Sarepta Therapeutics, Inc. performs research services for Sarepta International C.V. In January 2016, Sarepta Therapeutics, Inc. entered into a manufacturing and distribution agreement as well as service agreement with Sarepta International C.V. In conjunction with its recent filings, it was determined that beginning in 2016, Sarepta International C.V. is effectively connected with the conduct of a trade or business by the entity in the U.S. and, accordingly, the 2016, 2017 and 2018 losses are subject to U.S. income taxes. In May 2018, Sarepta International C.V. merged into another wholly owned U.S. subsidiary of Sarepta Therapeutics, Inc.

The following table summarizes the analysis of the deferred tax assets and liabilities for each of the periods indicated:

	As of December 31,	
	2019	2018
	(in thousands)	
Deferred tax assets:		
Net operating loss carryforwards	$ 304,033	$ 212,342
Difference in depreciation and amortization	40,095	55,162
Research and development tax credits	103,806	67,309
Stock-based compensation	24,114	15,538
Lease liabilities	15,796	4,831
Deferred revenue	939	888
Capitalized inventory	18,255	22,943
Other	16,270	15,727
Total deferred tax assets	523,308	394,740
Deferred tax liabilities:		
Right of use asset	(10,782)	—
Debt discount	(23,099)	(25,162)
Total deferred tax liabilities	(33,881)	(25,162)
Valuation allowance	(488,829)	(369,345)
Net deferred tax assets	$ 598	$ 233

The Company has evaluated the positive and negative evidence bearing upon the realizability of its U.S. net deferred tax assets, which are comprised principally of federal and state net operating loss carryforwards, research and development tax credit carryforwards, stock-based compensation expense, capitalized inventory, and intangibles. Under the applicable accounting standards, management has considered the Company's history of losses and concluded that it is more likely than not that the Company will not recognize the benefits of net federal and state deferred tax assets. Accordingly, a full valuation allowance of the U.S. net deferred tax asset had been established at December 31, 2019 and 2018. The net change in the valuation allowance for deferred tax assets was an increase of $119.5 million and $164.8 million for the years ended December 31, 2019 and 2018, respectively. This increase for the year ended December 31, 2019 was primarily due to the generation of federal and state net operating losses and income tax credits.

The Company generated foreign deferred tax assets mainly consisting of net operating loss carryforwards, stock-based compensation and unrealized gain/losses. Based upon the income projections in the majority of the foreign jurisdictions, the Company believes it will realize the benefit of its future deductible differences in these jurisdictions. As such, the Company has not recorded a valuation allowance against these foreign jurisdictions. Brazil, the Netherlands, Czech Republic, and Spain have generated deferred tax assets, which consist of net operating loss carryforwards and stock-based compensation expense. The Company has concluded that it is more likely than not that we will not recognize the future benefits of the deferred tax assets, and accordingly, a full valuation allowance has been recorded against these foreign deferred tax assets. In 2019, the Company undertook an internal restructuring involving its subsidiary in Switzerland. The restructuring resulted in the utilization of all of its net operating loss carryforwards and the release of its previously established valuation allowance of $7.9 million.

As of December 31, 2019, the Company had federal and state net operating loss carryforwards of $1,166.2 million and $859.0 million, respectively, available to reduce future taxable income. The federal and state net operating loss carry forwards of $579.9 million and $807.7 million will expire at various dates between 2020 and 2039. The federal and state net operating loss carry forwards of $586.3 million and $51.3 million, respectively, can be carried forward indefinitely. Utilization of these net operating losses could be limited under Section 382 of the Internal Revenue Code and similar state laws based on ownership changes and the value of the Company's stock. Additionally, the Company has $74.7 million and $34.1 million of federal and state research and development credits, respectively, available to offset future taxable income. These federal and state research and development credits begin to expire between 2020 and 2039 and between 2020 and 2034, respectively. The Company also has foreign net operating loss carryforwards of $8.0 million, mainly derived from the net operating loss generated by its subsidiary in Brazil, which may be carried forward indefinitely.

The Company or one of its subsidiaries files income tax returns in the U.S., and various state and foreign jurisdictions. The federal, state and foreign income tax returns are generally subject to tax examinations for the tax years ended December 31, 2016 through December 31, 2018. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service, state or foreign tax authorities to the extent utilized in a future period.

The follow table summarizes the reconciliation of the beginning and ending amount of total unrecognized tax benefits for each of the periods indicated:

	For the Year Ended December 31,		
	2019	2018	2017
	(in thousands)		
Balance at beginning of the period	$ 37,544	$ 5,134	$ 4,644
Increase related to current year tax positions	4,275	2,164	735
Increase related to prior year tax positions	109	30,246	—
Decrease related to prior year tax positions	(175)	—	(245)
Balance at end of the period	$ 41,753	$ 37,544	$ 5,134

The balance of total unrecognized tax benefits at December 31, 2019, if recognized, would not affect the effective tax rate on income from continuing operations, due to a full valuation allowance against the Company's U.S. deferred tax assets. The Company does not expect that the amount of unrecognized tax benefits to change significantly in the next twelve months. The Company's policy is to recognize interest and/or penalties related to income tax matters in income tax expense. It had no accrual for interest or penalties on its balance sheet at December 31, 2019 or 2018. No interest and/or penalties were recognized in 2018 or 2017.

19. LEASES

The adoption of ASC 842 resulted in the recognition of operating lease liabilities and ROU assets of $60.1 million and $42.5 million, respectively, on the Company's balance sheet relating to its leases for its corporate headquarters and its office and lab space on the January 1, 2019 transition date. Further, the Company reclassified upon adoption $18.0 million of deferred rent which reduced the ROU assets recognized on the balance sheet, in accordance with the transition guidance.

As of December 31, 2019, operating lease assets were $37.9 million and operating lease liabilities were $55.6 million. Amounts related to financing leases were immaterial. The following table contains a summary of the lease costs recognized under ASC 842 and other information pertaining to the Company's operating leases for the year ended December 31, 2019:

	For the Year Ended December 31, 2019
	(in thousands)
Lease cost	
Operating lease cost	$ 10,335
Variable lease cost	3,967
Total lease cost	$ 14,302
Other information	
Operating lease payments	10,416
Operating lease liabilities arising from obtaining ROU assets	—
Weighted average remaining lease term	5.5
Weighted average discount rate	7.50%

The following table summarizes maturities of lease liabilities and the reconciliation of lease liabilities as of December 31, 2019:

	As of December 31, 2019 (in thousands)
2020	$ 11,718
2021	12,891
2022	11,080
2023	11,230
2024	11,471
Thereafter	9,654
Total minimum lease payments	68,044
Less: imputed interest	(12,478)
Total operating lease liabilities	$ 55,566
Included in the condensed consolidated balance sheet:	
Current portion of lease liabilities within other current liabilities	$ 7,846
Lease liabilities	47,720
Total operating lease liabilities	$ 55,566

For comparable purposes, aggregate future minimum non-cancellable commitments under leases as of December 31, 2018, are as follows:

	As of December 31, 2018 (in thousands)
2020	$ 11,395
2021	12,558
2022	10,757
2023	10,898
2024	11,128
Thereafter	9,396
Total minimum lease payments	$ 66,132

Excluded from the table above are obligations under manufacturing agreements with Brammer Bio MA, LLC (“Brammer”) and Paragon Bioservices, Inc. (“Paragon”). The Company has determined that both agreements contain an embedded lease. However, both leases have not yet commenced as of December 31, 2019, and as such, right of use assets and lease liabilities have not yet been recognized on the Company’s consolidated balance sheets. Refer to *Note 21, Commitments and Contingencies* for additional details relating to these two agreements.

20. NET LOSS PER SHARE

Basic net loss per share is computed by dividing net loss by the weighted-average number of shares of common stock outstanding. Diluted net loss per share is computed by dividing net loss by the weighted-average number of shares of common stock and dilutive common stock equivalents outstanding. Given that the Company recorded a net loss for each of the periods presented, there is no difference between basic and diluted net loss per share since the effect of common stock equivalents would be anti-dilutive and are, therefore, excluded from the diluted net loss per share calculation.

	For the Year Ended December 31,		
	2019	2018	2017
	(in thousands, except per share amounts)		
Net loss	$ (715,075)	$ (361,918)	$ (50,688)
Weighted-average common shares outstanding - basic	73,615	66,250	58,818
Effect of dilutive securities*	—	—	—
Weighted-average common shares outstanding - diluted	73,615	66,250	58,818
Net loss per share — basic and diluted	$ (9.71)	$ (5.46)	$ (0.86)

* For the years ended December 31, 2019, 2018 and 2017, stock options, RSAs, RSUs, SARs and ESPP to purchase approximately 9.1 million, 9.1 million and 9.4 million shares of common stock, respectively, were excluded from the net loss per share calculation as their effect would have been anti-dilutive. The Company accounts for the effect of the 2024 Notes on diluted net earnings per share using the if-converted method as they may be settled in cash or shares at the Company's option. While the closing price on December 31, 2019 exceeded the conversion price of $73.42, the potential shares issuable under the 2024 Notes were excluded from the calculation of diluted loss per share as they were anti-dilutive using the if-converted method. In the period of conversion, the 2024 Notes will have no impact on diluted net loss if they are settled in cash and will have an impact on diluted earnings per share if the 2024 Notes are settled in shares upon conversion and when the Company is in an income position.

21. COMMITMENTS AND CONTINGENCIES

Manufacturing Obligations

The Company has entered into long-term contractual arrangements from time to time for the provision of goods and services.

Brammer Bio MA, LLC

The Company entered into a Development, Commercial Manufacturing and Supply Agreement (the "Brammer Manufacturing Agreement") and, subsequently, entered into the first amendment (the "Amendment") to the Brammer Manufacturing Agreement with Brammer in June 2018 and May 2019, respectively (collectively, "Brammer Supply Agreements"). Pursuant to the terms of the Brammer Supply Agreements, Brammer agreed to provide the Company with access to clinical and commercial manufacturing capacity for its gene therapy programs.

Under the Brammer Manufacturing Agreement, the Company will purchase product in batches from Brammer, subject to minimum and maximum annual purchase requirements. Further, the Company: (i) was required to make a $20.0 million advance payment to Brammer upon execution of the agreement in June 2018, (ii) was required to make two non-refundable payments of $5.0 million each to Brammer in the third and fourth quarter of 2018 to be used in the specification, selection, and procurement of the related process equipment to be utilized under the agreement, and (iii) was required to make a $10.0 million quarterly capacity access fee payment to Brammer throughout the term of the agreement.

As a result of the Amendment: (i) the Company now has access to substantially all of the related facility's capacity, subject to certain minimum and maximum volume limitations, (ii) the Company was required to make a $6.0 million advance payment to Brammer upon execution of the Amendment, and (iii) the quarterly capacity access fee payments due to Brammer throughout the term of the agreement increased from $10.0 million to $13.3 million, starting January 1, 2020. However, through December 31, 2019, a reduced quarterly capacity access fee was in effect as Brammer worked towards achieving full capacity at its facility. In addition, the application of the advance payments will reduce the quarterly capacity access fees paid through 2021.

The term of the Brammer Supply Agreements will continue for a period of six years following the first regulatory approval of a product manufactured under the agreements. The term will automatically renew for successive two years unless the Company notifies Brammer of its intention not to renew (no less than twenty-four months prior to the expiration of the term). The Company also has the ability to terminate the agreement prior to expiration but would be required to continue remitting capacity access fees to Brammer for up to eight additional quarters.

Upon execution of the Amendment, the Company determined that the Brammer Supply Agreements contain an embedded lease because the Company now has the right to direct the use of the facility and related equipment therein. Further, the Company determined that it did not control the facility or related equipment during construction and, thus, the lease did not fall in the scope of "build-to-suit" accounting. The lease has not commenced as of December 31, 2019 because of the clean room suites at the Brammer facility are not yet available for use by the Company. Accordingly, total cumulative payments made to Brammer of $75.5 million have been recorded as an other non-current asset in the accompanying consolidated balance sheets and will be considered in the initial measurement of the cost of the right-of-use asset at the lease commencement date. This amount, along with any additional quarterly access fees payable prior to the lease commencement date, will be amortized on a straight-line basis as rent expense over the term of the embedded lease, beginning on the lease commencement date, currently anticipated to occur during the first half of 2020. Rent expense recognized prior to regulatory approval of the related product will be classified to research and development expense. Upon regulatory approval, rent expense will be classified to cost of inventory with the recognition in cost of sales as the sales of product occur.

Paragon Bioservices, Inc.

The Company entered into a manufacturing collaboration agreement (the "Paragon Collaboration Agreement") and, subsequently, entered into a manufacturing and supply agreement (the "Paragon Supply Agreement") with Paragon in October 2018 and February 2019, respectively (collectively, the "Paragon Agreements"). Pursuant to the terms of the Paragon Agreements, Paragon agreed to provide the Company with two dedicated clean room suites and an option to reserve two additional clean room suites for its gene therapy programs. In September 2019, the Company exercised the option to gain access to the additional clean room suites. The Paragon Agreements will expire on December 31, 2024. The Company has the ability to terminate the Paragon Agreements prior to expiration, subject to potential additional financial consideration.

Under the Paragon Agreements, the Company will purchase product in batches from Paragon subject to minimum annual purchase requirements during two periods: the pre-launch period and the post-launch period. During the pre-launch period, the Company is obligated to purchase a minimum amount of $4.0 million of services per quarter per clean room. During the post-launch period, on an annual basis, the Company is obligated to purchase a minimum number of batches per clean room. Further, the Company is required to pay Paragon: (i) use fees of $1.0 million per year per clean room suite after the clean rooms are fully qualified and validated to manufacture the Company's materials, and (ii) clean room reservation fees totaling $48.0 million. Additional use fees and reservation fees are required if the Company has equipment needs beyond the basic equipment package included in the initial clean room suites. In addition, Paragon will provide the Company with a credit of up to 100% of the clean room use fee if certain clean room capacity utilization thresholds are met.

The Company has concluded that the Paragon Agreements contain an embedded lease as the Company has the right to direct the use of the facility and related equipment therein. The Company also determined that it did not control the facility or related equipment during construction and, thus, the lease did not fall in the scope of "build-to-suit" accounting. The lease has not commenced as of December 31, 2019 because the clean room suites at the Paragon facility are not yet available for use by the Company. Accordingly, cumulative payments totaling $40.1 million made to Paragon have been recorded as an other non-current asset in the accompanying consolidated balance sheets and will be considered in the initial measurement of the cost of the right-of-use asset at the lease commencement date. This amount, along with any additional payments made prior to the lease commencement date, will be amortized on a straight-line basis as rent expense over the term of the embedded lease, beginning on the lease commencement date, currently anticipated to occur in the first quarter of 2020. Use fees associated with the clean room suites are considered contingent rental payments and will be charged to rent expense when (and if) incurred. Rent expense recognized prior to regulatory approval of the related product will be classified to research and development expense. Upon regulatory approval, rent expense will be classified to cost of inventory with the recognition in cost of sales as the sales of product occur.

Aldevron, LLC

In December 2018, the Company entered into a Clinical and Commercial Supply Agreement (the "CCSA") with Aldevron LLC ("Aldevron") for the supply of plasmid DNA to fulfill its needs for gene therapy clinical trials and commercial supply. Pursuant to the terms of the CCSA, Aldevron agreed to reserve a certain number of manufacturing slots ("Reserved Slots") on a quarterly basis. The initial term of the CCSA expired on December 31, 2019. The Company exercised the option to extend the CCSA to December 31, 2020 (the "2020 Option") and has another option to extend the term of the CCSA for an additional year to December 31, 2021 (the "2021 Renewal Right").

The Company may be required to make an additional $20.0 million in prepayments associated with the CCSA should the Company exercise the 2021 Renewal Right. The prepayments will be credited back to Sarepta, until exhausted, for each batch of product delivered by Aldevron, in an amount equal to 50% of the batch invoice amount. The Company has determined that the CCSA does not contain an embedded lease because it does not convey the right to control the use of Aldevron's facility or related equipment therein. As of December 31, 2019, the Company recorded $22.8 million in other current assets in the accompanying balance sheets related to the prepayments made to Aldevron under the CCSA. The gross cost of batches purchased from Aldevron since inception of the agreement have been classified as research and development expense. In the event the Company does not expect services under the CCSA to be rendered to fully exhaust any prepayments made to Aldevron, the applicable balance will be charged to expense at the time this determination is made.

The following table presents non-cancelable contractual obligations arising from long-term contractual arrangements:

	As of December 31, 2019 (in thousands)
2020	$ 378,744
2021	183,661
2022	64,653
2023	58,319
2024	58,309
Thereafter	149,350
Total manufacturing commitments	$ 893,036

Additionally, should the Company obtain regulatory approval for any drug product candidate produced as a part of the Company's manufacturing obligations above, additional minimum batch requirements with the respective manufacturing parties would be required.

Other Funding Commitments

The Company has several on-going clinical trials in various clinical trial stages. Its most significant clinical trial expenditures are to contract research organizations ("CROs"). The CRO contracts are generally cancellable at the Company's option. As of December 31, 2019, the Company has approximately $91.4 million in cancellable future commitments based on existing CRO contracts. For the years ended December 31, 2019, 2018 and 2017, the Company recognized approximately $31.6 million, $19.6 million and $13.9 million, respectively, for expenditures incurred by CROs.

Litigation

In the normal course of business, the Company may from time to time be named as a party to various legal claims, actions and complaints, including matters involving securities, employment, intellectual property, effects from the use of therapeutics utilizing its technology, or others. For example, on August 30, 2019, Plaintiff Andrew Salinger filed a putative class action complaint against the Company and two of its current officers, Douglas S. Ingram and Sandesh Mahatme (collectively, the "Defendants"), in the United States District Court for the Southern District of New York. The complaint alleges that the Defendants violated Section 10(b) of the Securities Exchange Act of 1934, as amended ("Exchange Act"), and Rule 10b-5 promulgated thereunder, as well as Section 20(a) of the Exchange Act, in connection with the Company's disclosures related to golodirsen. The proposed class consists of all persons or entities who acquired Company securities between September 6, 2017 and August 19, 2019. On December 17, 2019, the district court appointed Bernard Portnoy as lead plaintiff, and set a briefing schedule requiring the amended complaint to be filed on February 18, 2020 and requiring Defendants to answer or otherwise respond to the amended complaint on April 17, 2020. Defendants' motion to transfer the case to the United States District Court for the District of Massachusetts is pending. On February 14, 2020, the lead plaintiff filed a Notice of Voluntary Dismissal of his claims against all Defendants and the clerk referred the Notice to the court for review and approval. The court has taken no further action. The Company is unable to provide an estimate of possible loss or range of possible loss.

On January 7, 2020, Plaintiff Al Lutzker filed a stockholder derivative complaint, purportedly on behalf of the Company, against two of the Company's current officers, Douglas S. Ingram and Sandesh Mahatme, and six current members of Company's Board of Directors, M. Kathleen Behrens, Richard J. Barry, Michael W. Bonney, Mary Ann Gray, Claude Nicaise, and Hans Wigzell (collectively, the "Defendants"), in the United States District Court for the District of Delaware. The complaint asserts claims for breach of fiduciary duty, insider selling, unjust enrichment, waste of corporate assets, and violations of Section 14(a) of the Securities Exchange Act of 1934, and Rule 14a-9 promulgated thereunder, in connection with the Company's disclosures related to golodirsen. The Company is unable to provide an estimate of possible loss or range of possible loss.

22. SUBSEQUENT EVENT

On February 14, 2020, the Company entered into an agreement to sell the rare pediatric disease PRV it received from the FDA in connection with the approval of VYONDYS 53 for consideration of $111.0 million. The closing of the transaction is subject to the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 and other customary conditions. When the transaction closes, the net proceeds will be recorded as a gain from sale of the PRV as it does not have a carrying value at the time of the sale.

The Company has evaluated subsequent events from the date of the consolidated balance sheet through the date the consolidated financial statements were issued.

23. FINANCIAL INFORMATION BY QUARTER (UNAUDITED)

	2019 for Quarter Ended			
	December 31	September 30	June 30	March 31
	(in thousands)			
Revenues:				
Product, net	$ 100,113	$ 99,041	$ 94,668	$ 87,011
Total revenues	100,113	99,041	94,668	87,011
Cost and expenses:				
Cost of sales (excluding amortization of in-licensed rights)	15,567	13,037	15,919	12,063
Research and development	223,141	133,949	113,266	90,553
Selling, general and administrative	81,424	75,429	67,393	60,566
Acquired in-process research and development	—	—	173,240	—
Settlement and license charges	10,000	—	—	—
Amortization of in-licensed rights	200	216	217	216
Total cost and operating expenses	330,332	222,631	370,035	163,398
Operating loss	(230,219)	(123,590)	(275,367)	(76,387)
Other loss:				
Other expense, net	(4,773)	(2,510)	(862)	(172)
Other loss	(4,773)	(2,510)	(862)	(172)
Loss before income tax expense	(234,992)	(126,100)	(276,229)	(76,559)
Income tax expense	711	226	174	84
Net loss	$ (235,703)	$ (126,326)	$ (276,403)	$ (76,643)
Net loss per share - basic and diluted	$ (3.16)	$ (1.70)	$ (3.74)	$ (1.07)
Weighted average number of shares of common stock used in computing basic and diluted net loss per share	74,557	74,177	73,958	71,731

	2018 for Quarter Ended			
	December 31	September 30	June 30	March 31
	(in thousands)			
Revenues:				
Product, net	$ 84,415	$ 78,486	$ 73,529	$ 64,604
Total revenues	84,415	78,486	73,529	64,604
Cost and expenses:				
Cost of sales (excluding amortization of in-licensed rights)	13,135	8,741	6,735	5,582
Research and development	146,207	86,584	122,848	46,204
Selling, general and administrative	64,220	53,044	47,156	43,341
Amortization of in-licensed rights	216	216	217	216
Total cost and operating expenses	223,778	148,585	176,956	95,343
Operating loss	(139,363)	(70,099)	(103,427)	(30,739)
Other loss:				
Interest expense and other, net	(2,311)	(6,968)	(5,218)	(4,485)
Total other loss	(2,311)	(6,968)	(5,218)	(4,485)
Loss before income (benefit) tax expense	(141,674)	(77,067)	(108,645)	(35,224)
Income tax (benefit) expense	(779)	(674)	622	139
Net loss	$ (140,895)	$ (76,393)	$ (109,267)	$ (35,363)
Net loss per share - basic and diluted	$ (2.05)	$ (1.15)	$ (1.67)	$ (0.55)
Weighted average number of shares of common stock used in computing basic and diluted net loss per share	68,653	66,209	65,484	64,631

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following description sets forth certain material terms and provisions of the common stock, par value $0.0001 per share, of Sarepta Therapeutics, Inc. (the "Company", "us", "we", or "our").

For the complete terms of our common stock, please refer to our articles of incorporation and bylaws as amended and restated, each of which is an exhibit to the Annual Report on Form 10-K to which this description is an exhibit and to the applicable provisions of the Delaware General Corporation Law.

COMMON STOCK

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. An election of directors by our stockholders shall be determined by a majority of the votes cast by the stockholders entitled to vote on the election. Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of any series of preferred stock that is outstanding at the time of the dividend. In the event of our liquidation or dissolution, the holders of common stock are entitled to receive proportionately our net assets available for distribution to stockholders after payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock. All shares of common stock will, when issued, be duly authorized, fully paid and nonassessable. The rights, preferences and privileges of holders of common stock are subject to the rights of the holders of shares of any series of preferred stock that the Company may designate and issue in the future.

Anti-Takeover Effects of our Certificate of Incorporation and Bylaws and Delaware Law

Certain provisions of Delaware law, our certificate of incorporation and our bylaws could have the effect of delaying, deferring or discouraging another party from acquiring control of us. These provisions, which are summarized below, encourage persons seeking to acquire control of us to first negotiate with our board of directors and the holders of our capital stock.

Delaware Law

We are subject to Section 203 of the Delaware General Corporation Law. This statute regulating corporate takeovers prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for three years following the date that the stockholder became an interested stockholder, unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction that resulted in the interested stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (a) shares owned by persons who are directors and also officers, and (b) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to the date of the transaction, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Generally, a business combination includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. An interested stockholder is any person who, together with such person's affiliates and associates (i) owns 15% or more of a corporation's voting securities or (ii) is an affiliate or associate of a corporation and was the owner of 15% or more of the corporation's voting securities at any time within the three year period immediately preceding a business combination of the corporation governed by Section 203. We expect the existence of this provision to have an anti-takeover effect with respect to transactions our board of directors does not approve in advance. We also anticipate that Section 203 may discourage takeover attempts that might result in a premium over the market price for the shares of common stock held by our stockholders.

Staggered board of directors

Our certificate of incorporation and our bylaws divide our board of directors into two classes with staggered two-year terms, when the board is comprised of more than six members. Eight individuals currently serve on our board of directors, which is divided into two classes. At each annual meeting of stockholders, a class of directors is to be elected for a two-year term to succeed the directors of the same class whose terms are then expiring. As a result, a portion of our board of directors will be elected each year. Our bylaws authorize our board of directors to fix the number of directors from time to time by a resolution of the majority of our board of directors, provided the board shall consist of a minimum of one and a maximum of eight members. The division of our board of directors into two classes with staggered two-year terms may delay or prevent a change of our management or a change in control. Between stockholder meetings, directors may be removed by a vote of a majority of the voting power of all outstanding shares of voting stock only for cause. Under our certificate of incorporation and bylaws, any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office unless our board of directors determines by resolution that any such vacancies or newly created directorships shall be filled by the stockholders. These provisions may prevent a stockholder from removing incumbent directors and simultaneously gaining control of the board of directors by filling the resulting vacancies with its own nominees. The classification of our board of directors and the limitations on the ability of our stockholders to remove directors, change the authorized number of directors and fill vacancies could make it more difficult for a third party to acquire, or discourage a third party from seeking to acquire, control of our company.

Stockholder action; special meeting of stockholders; advance notice requirements for stockholder proposals and director nominations

Our certificate of incorporation and our bylaws provide that any action required or permitted to be taken by our stockholders at an annual meeting or special meeting of stockholders may only be taken if it is properly brought before such meeting and may not be taken by written action in lieu of a meeting. Our certificate of incorporation and our bylaws also provide that, except as otherwise required by law, special meetings of the stockholders can only be called by our president or our board of directors, or by our president at the request of holders of not less than one-tenth of all outstanding shares of capital stock. In addition, our bylaws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of stockholders, including proposed nominations of candidates for election to our board of directors. Stockholders at an annual meeting may only consider proposals or nominations specified in the notice of the meeting or brought before the meeting by or at the direction of our board of directors, or by a stockholder of record on the record date for the meeting who is entitled to vote at the meeting and who has delivered timely written notice in proper form to our secretary of the stockholder's intention to bring such business before the meeting. These provisions could have the effect of delaying until the next stockholder meeting stockholder actions that are favored by the holders of a majority of our outstanding voting securities. These provisions also could discourage a third party from making a tender offer for our common stock, because even if it acquired a majority of our outstanding voting stock, it would be able to take action as a stockholder, such as electing new directors or approving a merger, only at a duly called stockholders meeting and not by written consent.

Super-majority voting

The Delaware General Corporation Law provides generally that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or bylaws, unless a corporation's certificate of incorporation or bylaws, as the case may be, requires a greater percentage. Our bylaws may be amended or repealed by a majority vote of our board of directors or the affirmative vote of the holders of at least 66 2/3% of the voting power of all of the then-outstanding shares of our capital stock entitled to vote at an election of directors. In addition, the affirmative vote of the holders of at least 66 2/3% of the voting power of all of the then-outstanding shares of voting stock, voting together as a single class, is required to alter, amend or repeal certain provisions of our certificate of incorporation.

EXHIBIT 10.51

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [**], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO SAREPTA THERAPEUTICS, INC. IF PUBLICLY DISCLOSED.

LICENSE, COLLABORATION, AND OPTION AGREEMENT

BY AND BETWEEN

SAREPTA THERAPEUTICS THREE, LLC

AND

F. HOFFMANN-LA ROCHE LTD

DATED DECEMBER 21, 2019

TABLE OF CONTENTS

TABLE OF CONTENTS (CONTINUED)

TABLE OF CONTENTS (CONTINUED)

Schedules

License, Collaboration, And Option Agreement

This **License, Collaboration, and Option Agreement** (this "**Agreement**") is made and entered into as of December 21, 2019 (the "**Execution Date**") between Sarepta Therapeutics Three LLC, a limited liability company organized and existing under the laws of the State of Delaware, United States of America, with its principal offices at 215 First Street, Cambridge, MA, 02142 ("**Sarepta**") and F. Hoffmann-La Roche Ltd, a company organized and existing under the laws of Switzerland, with its principal office at Grenzacherstrasse 124, 4070 Basel, Switzerland ("**Roche**").

Sarepta and Roche may be referred to herein individually as a "**Party**" and collectively as the "**Parties.**"

RECITALS

WHEREAS, Sarepta is the owner of, or otherwise Controls, the Sarepta Technology, the Option Product Know-How, the Option Product Patent Rights, the Sarepta Products, and the Sarepta Diagnostic Products;

WHEREAS, Roche (itself and through its Affiliates) has expertise in the development of biopharmaceutical products and has regulatory, development, and commercial capabilities in the Roche Territory; and

WHEREAS, the Parties desire to collaborate to Develop, perform Medical Affairs for, and Commercialize the Licensed Products, and Sarepta wishes to grant Roche and Roche wishes to receive an exclusive license to Develop, perform Medical Affairs for, and Commercialize the Licensed Products in the Roche Territory and Sarepta wishes to grant Roche and Roche wishes to receive an exclusive option to acquire an exclusive license to Develop, perform Medical Affairs for, and Commercialize the Option Products in the Roche Territory, in each case, as set forth in, and subject to the terms of, this Agreement.

NOW THEREFORE, the Parties agree as follows:

ARTICLE 1
DEFINITIONS

1.1 "**Abbreviated Application**" means (a) any application submitted to the FDA under (i) subsection (k) of Section 351 of the PHSA (42 U.S.C. 262(k)) or (ii) Section 505(j) of the FD&C Act (21 U.S.C. 355(j)), or (iii) Section 505(b)(2) of the FD&C Act (21 U.S.C. 355), (b) any application submitted to the EMA under a provision of Articles 10, 10a, or 10b of Parliament and Council Directive 2001/83/EC as amended (including any application under Article 6.1 of Parliament and Council Regulation (EC) No 726/2004 that relies for its content on any such provision), or (c) any analogous application to those applications set forth in clauses (a) or (b) submitted to any Regulatory Authority in the US, European Union, or in another country or jurisdiction in the world.

1.2 "**Absent Countries**" has the meaning set forth in Section 2.5.5(b)(A) (Absent Countries).

1.3 "**Accounting Standard**" means, with respect to a Party or any of its Affiliates or Sublicenses, either IFRS or GAAP, as used at the applicable time by such Party or such Affiliate or Sublicensee.

1.4 "**Acquisition**" has the meaning set forth in Section 2.6.2 (Acquisitions of Third Parties).

1.5 "**Affiliate**" means, with respect to a Person, any other Person, directly or indirectly through one or more intermediaries, controlled by, controlling, or under common control with such Person, whether now or in the future, with "control" meaning (a) direct or indirect beneficial ownership of more than 50% of the voting stock or other ownership interest of, or more than 50% interest in the income of, the applicable Person, or (b) the possession, directly or indirectly, of the power to direct the management or policies of the applicable Person, whether through the ownership of voting securities or other equity rights, by contract relating to voting rights or corporate governance, or otherwise. Notwithstanding the foregoing, Chugai will not be deemed an Affiliate of Roche for any purpose under this Agreement unless and until Roche provides Sarepta with written notice of its desire to include Chugai as an Affiliate (it being understood that if Roche provides Sarepta with such notice, Chugai will be deemed an Affiliate of Roche for all purposes under this Agreement as of and after the date of such notice).

1.6 "**Alliance Manager**" has the meaning set forth in Section 3.9 (Alliance Managers).

1.7 "**Allowable Overruns**" means any and all Development Costs or Medical Affairs Costs, as applicable, incurred by or on behalf of Sarepta or its Affiliates with respect to any Licensed Product in any Calendar Quarter that are (a) above the then-current Joint Global Development Budget or Joint Global Medical Affairs Budget, as applicable, approved by the JSC by [**] or less or (b) otherwise attributable to Roche's action or inaction that constitutes a breach of this Agreement.

1.8 "**Antitrust Clearance Date**" means the earliest date on which all applicable waiting periods and approvals required under Antitrust Laws in the U.S. with respect to the transactions contemplated under this Agreement and the Stock Purchase Agreement have expired or have been terminated (in the case of waiting periods) or been received (in the case of approvals), in each case, without the imposition of any conditions.

1.9 "**Antitrust Filing**" means filings by Sarepta and Roche with the United States Federal Trade Commission and the United States Department of Justice and any applicable Governmental Authority in the Territory, as required under any Antitrust Laws with respect to the transactions contemplated under this Agreement, together with all required documentary attachments thereto.

1.10 "**Antitrust Laws**" means any and all Applicable Laws designed to prohibit, restrict, or regulate actions for the purpose or effect of monopolization or restraint of trade.

1.11 "**Applicable Law**" means any applicable law (including common law), statute, rule, regulation, order, judgment, decree, directive, injunction, or ordinance of any Governmental Authority (including any Regulatory Authority), including those concerning environmental, health, regulatory, privacy, and safety matters.

1.12 "**Approved Labeling**" means, with respect to any Licensed Product and any jurisdiction: (a) the applicable Regulatory Authority-approved full prescribing information for such Licensed Product in such jurisdiction; and (b) the applicable Regulatory Authority-approved labels and other written, printed, or graphic materials on any container, wrapper, or any package insert that is used with or for such Licensed Product in such jurisdiction.

1.13 "**Asian Region**" means all countries and territories of Asia other than (a) the Russian Federation, (b) the Middle Eastern Countries, and (c) Japan.

1.14 "**Average Supply Price**" has the meaning set forth in Section 8.7 (Supply Price).

1.15 "**Biosimilar Competition**" means, on a Licensed Product-by-Licensed Product and country-by-country basis, that, in a given Calendar Quarter, one or more Third Parties are Commercializing a Biosimilar Product with respect to such Licensed Product in such country.

1.16 "**Biosimilar Product**" means, with respect to any Licensed Product, a biologic product that is "biosimilar" (as such term is defined in 42 U.S.C. § 262(i)(2)), "similar biological medicinal product" (as such term is defined in EU CHMP/437/04 Rev 1), or its foreign equivalents, as applicable, to such Licensed Product.

1.17 "**Breaching Party**" has the meaning set forth in Section 14.2.1 (Notice and Cure).

1.18 "**Business Day**" means any day (other than a Saturday or Sunday) on which the banks in New York, New York and Basel, Switzerland are both open for business.

1.19 "**Calendar Quarter**" means each successive period of three calendar months ending on (and including) each of March 31, June 30, September 30, and December 31; except that (a) the first Calendar Quarter during the Term will begin on the Effective Date and end on the last day of the Calendar Quarter within which the Effective Date falls, and (b) the last Calendar Quarter during the Term will end upon the expiration of the Term.

1.20 "**Calendar Year**" means the period of 12 consecutive calendar months beginning on January 1 and ending on December 31; except that (a) the first Calendar Year during the Term will begin on the Effective Date and end on December 31 of the Calendar Year within which the Effective Date falls, and (b) the last Calendar Year during the Term will end upon expiration of the Term.

1.21 "**Capacity Plan**" has the meaning set forth in Section 8.2 (Capacity Plan).

1.22 "**Change of Control**" means, with respect to a Party, that: (a) any Third Party acquires directly or indirectly the beneficial ownership of any voting security of such Party, or if the percentage ownership of such Third Party in the voting securities of such Party is increased through stock redemption, cancellation, or other recapitalization, and immediately after such acquisition or increase such Third Party is, directly or indirectly, the beneficial owner of voting securities representing more than 50% of the total voting power of all of the then outstanding voting securities of such Party; (b) any merger, consolidation, recapitalization, or reorganization of such Party is consummated that would result in shareholders or equity holders of such Party immediately prior to such transaction owning 50% or less of the outstanding voting securities of the surviving entity (or its parent entity) immediately following such transaction; (c) the shareholders or equity holders of such Party approve any plan of complete liquidation of such Party, or an agreement for the sale or disposition by such Party of all or substantially all of such Party's assets, in each case, through one or more related transactions, other than to an Affiliate or pursuant to one or more related transactions that would result in shareholders or equity holders of such Party immediately prior to such transaction owning more than 50% of the outstanding voting securities of the surviving entity (or its parent entity) immediately following such transaction; or (d) the sale or transfer to any Third Party, in one or more related transactions, of all or substantially all of such Party's consolidated assets taken as a whole.

1.23 "**Chugai**" means Chugai Pharmaceutical Co., Ltd.

1.24 "**Clinical Trial**" means any clinical trial in humans.

1.25 "**CMO**" means a contract manufacturing organization.

1.26 "**Collaboration In-License**" means any Potential In-License [**].

1.27 "**Collaboration Know-How**" means any and all Know-How developed or invented by or on behalf of a Party's or any of its Affiliates' employees, agents, or independent contractors, or any other Persons contractually required to assign or license such Know-How to such Party or any Affiliate of such Party, either alone or jointly with the other Party's or any of its Affiliates' employees, agents, or independent contractors, or any other Persons contractually required to assign or license such Know-How to such other Party or any Affiliate of such other Party, in each case, in the performance of any activities related to the Exploitation of Licensed Products or Sarepta Diagnostic Products under this Agreement during the Term.

1.28 "**Collaboration Patent Rights**" means any and all Patent Rights that Cover any Collaboration Know-How.

1.29 "**Commercial Supply Agreement**" has the meaning set forth in Section 8.6.2 (Commercial Supply Agreement) and the corresponding quality agreements fulfilling the requirements set forth in **Schedule 1.263**.

1.30 "**Commercialization**" means with respect to any product, any and all activities directed to the marketing, promotion, distribution, pricing, reimbursement, import, export, offering for sale, and sale of such product and interacting with Regulatory Authorities following receipt of Regulatory Approval in the applicable country or region for such product regarding the foregoing, including seeking and maintaining any required Reimbursement Approval, but excluding any activities directed to Manufacturing, Development, or Medical Affairs. "**Commercialize,**" "**Commercializing,**" and "**Commercialized**" will be construed accordingly.

1.31 "**Commercially Reasonable Efforts**" means, with respect to the Exploitation of any Sarepta Product by a Party, those efforts and resources, including allocation of reasonably necessary personnel, equivalent to the efforts and resources that a biopharmaceutical company or a pharmaceutical company, in each case, that is of comparable size and resources to such Party would typically devote as part of an active and continuing program of Development, Manufacturing, and Commercialization of any pharmaceutical or biologic product of similar market potential, at a similar stage of its product life, taking into account the competitiveness of the marketplace and the proprietary position (including with respect to Patent Rights), product profile, market exclusivity, regulatory status and regulatory environment, cost of goods, price and reimbursement status, approved labeling, payors' policies and regulations, and relative safety and efficacy of such product.

1.32 "**Competing Acquisition Program**" has the meaning set forth in Section 2.6.2 (Acquisitions of Third Parties).

1.33 "**Competitive Infringement**" means any infringement, unauthorized use, misappropriation or other violation or threatened infringement, unauthorized use, misappropriation, or other violation by any Third Party with respect to any Sarepta Patent Right, Sarepta Know-How, Roche Collaboration Patent Right, Roche Collaboration Know-How, Joint Collaboration Patent Right, or Joint Collaboration Know-How by reason of the making, using, offering to sell, selling or importing of any compound, product, method, or process that would be competitive with any Licensed Product in the Field.

1.34 "**Competitive Product**" has the meaning set forth in Section 2.6.1 (Exclusivity Obligation).

1.35 "**Compulsory Sublicense**" means a license or sublicense granted to any Third Party (a "**Compulsory Sublicensee**") through the order, decree, or grant of a Governmental Authority having competent jurisdiction, authorizing such Third Party to Manufacture and Commercialize any Licensed Product in any country in the Roche Territory.

1.36 "**Compulsory Sublicensee**" has the meaning set forth in Section 1.35 (Compulsory Sublicensee).

1.37 "**Confidential Disclosure Agreement**" has the meaning set forth in Section 17.2 (Entire Agreement; Amendment).

1.38 "**Confidential Information**" means, subject to Section 12.3 (Exemptions), any and all (a) Know-How and any technical, scientific, pre-clinical, clinical, regulatory, trade, research, manufacturing, business, financial, marketing, product, supplier, intellectual property, and other non-public or proprietary data or information (including unpublished patent applications) that may be disclosed (whether in writing, orally, or by any other method) by one Party or any of its Affiliates or Sublicensees to the other Party or any of its Affiliates or Sublicensees pursuant to this Agreement (including information disclosed prior to the Effective Date pursuant to the Confidential Disclosure Agreement), regardless of whether such information is specifically marked or designated as confidential or proprietary and regardless of whether such information is in written, oral, electronic, or other form, and (b) the terms of this Agreement.

1.39 "**Continuation Election Notice**" has the meaning set forth in Section 14.8.3 (Sarepta Designees).

1.40 "**Continued Countries List**" has the meaning set forth in Section 14.8.3 (Sarepta Designees).

1.41 "**Controlled**" means the possession by a Party (whether by ownership, license, or otherwise other than pursuant to this Agreement) of, (a) with respect to any materials or other tangible Know-How, the legal authority or right to physical possession of such materials or tangible Know-How, with the right to provide such materials or tangible Know-How to the other Party on the terms set forth herein, (b) with respect to Patent Rights, Regulatory Approvals, Regulatory Submissions, intangible Know-How, or other intellectual property, the legal authority or right to grant a license, sublicense, access, or right to use (as applicable) to the other Party under such Patent Rights, Regulatory Approvals, Regulatory Submissions, intangible Know-How, or other intellectual property on the terms set forth herein, in each case ((a) and (b)), without breaching or otherwise violating the terms of any arrangement or agreement with a Third Party in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such access, right to use, license, or sublicense or incurring any additional payment obligations to a Third Party as a result of such access, right to use, license, or sublicense, other than payment obligations incurred under an Existing In-License or Collaboration In-License, and (c) with respect to any product, the legal authority or right to grant an exclusive license or sublicense under Patent Rights that Cover such product or Know-How that relates to such product. Notwithstanding the foregoing, a Party and its Affiliates will not be deemed to "**Control**" any of the foregoing (a) – (c) that, prior to the consummation of a Change of Control of such Party, is owned or in-licensed by a Third Party that becomes an Affiliate of such acquired Party (or that merges or consolidates with such Party) after the Effective Date as a result of such Change of Control.

1.42 "**Country Designees List**" has the meaning set forth in Section 14.8.3 (Sarepta Designees).

1.43 "**Cover**" means, with respect to any particular subject matter at issue and any relevant Patent Right or individual claim in such Patent Right, as applicable, that the Manufacture, use, sale, offer for sale, importation, or other Exploitation of such subject matter would fall within the scope of one or more claims in such Patent Right.

1.44 "**CREATE Act**" has the meaning set forth in Section 10.3 (Disclosure; Inventorship).

1.45 "**Debarred/Excluded**" has the meaning set forth in Section 11.1.11 (Mutual Representations and Warranties).

1.46 "**Demand Forecast Plans**" has the meaning set forth in Section 8.3.2 (Development Demand Forecast Plan).

1.47 "**Development**" means, with respect to any product, any and all internal and external research, development and regulatory activities regarding such product, including (a) research, process development, non-clinical testing, toxicology, non-clinical activities, IND-Enabling Studies, and Clinical Trials, and (b) preparation, submission, review, and development of data or information for the purpose of submission to a Regulatory Authority to obtain authorization to conduct Clinical Trials and to obtain, support, or maintain Regulatory Approval of such product, but excluding any activities directed to Manufacturing, Medical Affairs, or Commercialization. Development will include research, development, and regulatory activities for additional presentations or indications for a product after receipt of Regulatory Approval of such product, including Clinical Trials initiated following receipt of Regulatory Approval or any Clinical Trial to be conducted after receipt of Regulatory Approval that was mandated by the applicable Regulatory Authority as a condition of such Regulatory Approval with respect to an approved indication (such as post-marketing approval studies and observational studies, if required by any Regulatory Authority in any country in the Territory to support or maintain Regulatory Approval for a product in such country). "**Develop,**" "**Developing,**" and "**Developed**" will be construed accordingly.

1.48 "**Development Costs**" means any and all costs and expenses actually incurred in connection with the performance of any Development activities for any Licensed Product, including [**]. In addition, Development Costs will include [**]. Development Costs will be recognized only in accordance with the applicable Accounting Standard.

1.49 "**Development Supply Agreement**" has the meaning set forth in Section 8.6.1 (Development Supply Agreement) and the corresponding quality agreements fulfilling the requirements set forth in **Schedule 1.263**.

1.50 "**Disclosing Party**" has the meaning set forth in Section 12.1.1 (Duty of Confidence).

1.51 "**DMD**" means Duchenne muscular dystrophy.

1.52 "**DMD ROFN Exercise Notice**" has the meaning set forth in Section 2.8.1 (DMD ROFN).

1.53 "**DMD ROFN Negotiation Period**" has the meaning set forth in Section 2.8.1 (DMD ROFN).

1.54 "**DMD ROFN Notice**" has the meaning set forth in Section 2.8.1 (DMD ROFN).

1.55 "**DMD ROFN Rights**" has the meaning set forth in Section 2.8.1 (DMD ROFN).

1.56 "**Effective Date**" has the meaning set forth in Section 15.1 (Effective Date).

1.57 "**Eligible Global Development Costs**" means the Development Costs, [**], actually incurred by or on behalf of Sarepta or its Affiliates with respect to any Licensed Product commencing as of the Execution Date and continuing thereafter during the Term to the extent in compliance with both the Joint Global Development Plan and the amount budgeted therefor in the Joint Global Development Budget, *plus* applicable Allowable Overruns or other amounts approved by the JSC. In addition, Eligible Global Development Costs will include [**]. Eligible Global Development Costs will be recognized only in accordance with Sarepta's then-applicable Accounting Standard. For clarity, the Eligible Global Development Costs shall exclude all Internal Costs and External Costs, in each case, incurred by Sarepta prior to the Effective Date or to be incurred thereafter, in each case, in connection with any Clinical Trials included in the Joint Global Development Plan that are Initiated on or prior to the Execution Date.

1.58 "**Eligible Medical Affairs Costs**" means the Medical Affairs Costs actually incurred by or on behalf of a Party or its Affiliates with respect to any Licensed Product to the extent in compliance with both the Joint Global Medical Affairs Plan and the amount budgeted therefor in the Joint Global Medical Affairs Budget, *plus* applicable Allowable Overruns or other amounts approved by the JSC.

1.59 "**EMA**" means the European Medicines Agency or any successor agency thereto.

1.60 "**European Region**" means (a) all members of the European Union or the European Economic Area (EEA) as of the Effective Date, and (b) the following countries: Switzerland, Andorra, San Marino, Monaco, and Vatican City.

1.61 "**European Union**" or "**E.U.**" means the economic, scientific, and political organization of member states of the European Union as it may be constituted from time to time; provided that, for the purposes of this Agreement, the term "European Union" will be deemed to include the United Kingdom regardless of whether it is a member of the European Union at the applicable time.

1.62 "**[**] Development Costs**" means the Development Costs incurred by or on behalf of Sarepta in the course of [**].

1.63 "**[**]**" has the meaning set forth in [**].

1.64 "**Exclusivity Period**" has the meaning set forth in Section 2.6.1 (Exclusivity Obligation).

1.65 "**Execution Date**" has the meaning set forth in the Preamble.

1.66 "**Executive Officer**" means with regard to Sarepta, the chief executive officer, or his or her designee, and with regard to Roche, the head of Pharma Partnering, or his or her designee.

1.67 "**Existing In-Licenses**" means any and all agreements entered into by either Party or an Affiliate of such Party with a Third Party prior to the Execution Date, including any amendments or restatements thereto entered into during the Term, pursuant to which such Party or its Affiliate Controls any Sarepta Technology or Roche Technology (as applicable).

1.68 "**Exon-Skipping Product Clinical Milestone Event**" has the meaning set forth in Section 9.4.2 (Clinical and Regulatory Milestones for Exon-Skipping Products that are Licensed Products).

1.69 "**Exon-Skipping Product Clinical Milestone Payment**" has the meaning set forth in Section 9.4.2 (Clinical and Regulatory Milestones for Exon-Skipping Products that are Licensed Products).

1.70 "**Exon-Skipping Product Regulatory Milestone Event**" has the meaning set forth in Section 9.4.2 (Clinical and Regulatory Milestones for Exon-Skipping Products that are Licensed Products).

1.71 "**Exon-Skipping Product Regulatory Milestone Payment**" has the meaning set forth in Section 9.4.2 (Clinical and Regulatory Milestones for Exon-Skipping Products that are Licensed Products).

1.72 "**Exon-Skipping Products**" means [**].

1.73 "**Exploit**" means to make, have made, use, import, export, offer to sell, sell, Develop, Manufacture, perform Medical Affairs activities, Commercialize, or otherwise exploit. "**Exploitation**" will be construed accordingly.

1.74 "**External Costs**" means any and all expenses paid to Third Parties (or payable to Third Parties and accrued in accordance with the applicable Accounting Standard) by a Party (or any of its Affiliates) in consideration of the performance of activities under this Agreement, and excluding a Party's Internal Costs.

1.75 "**FD&C Act**" means the United States Federal Food, Drug and Cosmetic Act, as amended from time-to-time, together with any rules, regulations, and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

1.76 "**FDA**" means the U.S. Food and Drug Administration or any successor agency thereto.

1.77 "**Field**" means all prophylactic, therapeutic, and diagnostic uses in all indications.

1.78 "**Filing for Regulatory Approval**" means the filing or submission of (a) an MAA with the FDA as defined in the FD&C Act and applicable regulations, or (b) an equivalent MAA with the equivalent agency in any other country or group of countries, the official approval of which application is required before any lawful commercial sale or marketing of Licensed Products in the applicable country is permitted.

1.79 "**First Commercial Sale**" means, for each Licensed Product in a country, (a) with regards to the Milestone Payments due upon achievement of each of First Commercial Sale in Section 9.4.1 (Regulatory Milestones for Lead Product), Section 9.4.2 (Clinical and Regulatory Milestones for Exon-Skipping Products that are Licensed Products), Section 9.4.3 (Regulatory Milestones for Licensed Products other than Lead Product, a Gene-Editing Licensed Product, and Exon-Skipping Products), and Article 9.4.4 (Regulatory Milestones for Gene-Editing Licensed Products) the first sale of such Licensed Product in such country by a Party, or its Affiliates or Sublicensees after the receipt of Regulatory Approval and Reimbursement Approval in the Field for such Licensed Product from the relevant Regulatory Authority in such country, and (b) with regards to royalty payments due under Section 9.5 (Royalties) the sale in such country by a Party, or its Affiliates or Sublicensees in the Field for such Licensed Product in such country. First Commercial Sale excludes any sale or other distribution for use in a Clinical Trial or other Development activity or for compassionate use sold or distributed at or below the applicable Seller's costs.

1.80 "**Force Majeure**" means any of the following events: embargoes, war or acts of war (including terrorism, insurrections, riots, or civil unrest), epidemics, fire, floods, earthquakes, or other acts of nature.

1.81 "**FTE**" means the equivalent of the work of one duly qualified employee of a Party full time for one year (consisting of a total of [**] hours per year) carrying out Development or Medical Affairs activities under this Agreement. Overtime, and work on weekends, holidays and the like will not be counted with any multiplier (*e.g.*, time-and-a-half or double time) toward the number of hours that are used to calculate the FTE contribution, and no individual may be charged at greater than one FTE, regardless of that individual's hours worked during that year. The portion of an FTE billable by a Party for one employee during a given accounting period will be determined by dividing the number of hours worked directly by such employee on the work to be conducted under this Agreement during such accounting period by the number of FTE hours applicable for such accounting period based on [**] working hours per Calendar Year.

1.82 "**FTE Rate**" means the rate of $[**] per FTE per Calendar Year for FTEs performing Medical Affairs or Development activities, which rate will be prorated on a daily basis as necessary, and which rate is subject to annual adjustment in each Calendar Year during the Term by the percentage increase in the CPI as of December 31 of each Calendar Year, over the level of the CPI as of December 31 of the prior Calendar Year, with the first such increase to be effective on January 1, 2021. For the avoidance of doubt, such FTE Rate will be the fully-burdened rate and is intended to cover the cost of salaries, benefits, infrastructure costs, travel, general laboratory or office supplies, postage, insurance, training, and all other general expenses and overhead items. Notwithstanding the foregoing, for any Calendar Year during the Term that is less than a full year, the above referenced rate will be proportionately reduced to reflect such portion of such full Calendar Year.

1.83 "**GAAP**" means the generally accepted accounting principles in the United States.

1.84 "**Gene-Editing Licensed Product**" means a Licensed Product that is a Gene-Editing Product.

1.85 "**Gene-Editing Licensed Product Regulatory Milestone Events**" has the meaning set forth in Section 9.4.4 (Clinical and Regulatory Milestones for Gene-Editing Licensed Products).

1.86 "**Gene-Editing Licensed Product Regulatory Milestone Payments**" has the meaning set forth in Section 9.4.4 (Clinical and Regulatory Milestones for Gene-Editing Licensed Products).

1.87 "**Gene-Editing Option Product**" has the meaning as set forth in Section 1.178.

1.88 "**Gene-Editing Product**" means a product that, alone or in combination with one or more other agents, modifies, repairs, or activates an endogenous dysfunctional dystrophin gene.

1.89 "**Gene-Editing Sales Milestone Events**" has the meaning set forth in Section 9.4.6 (Sales Milestones for Gene-Editing Licensed Products).

1.90 "**Gene-Editing Sales Milestone Payments**" has the meaning set forth in Section 9.4.6 (Sales Milestones for Gene-Editing Licensed Products).

1.91 "**Gene Therapy Option Product**" has the meaning as set forth in Section 1.178.

1.92 "**Gene Therapy Product**" means any product that delivers to cells as a therapeutic agent a transgene that encodes and directly expresses dystrophin or a derivative thereof (such as micro-dystrophin or mini-dystrophin). The Lead Product is a Gene Therapy Product.

1.93 "**Gene Therapy Product Regulatory Milestone Event**" has the meaning set forth in Section 9.4.3 (Regulatory Milestones for Licensed Products other than Lead Product and Exon-Skipping Product).

1.94 "**Gene Therapy Product Regulatory Milestone Payment**" has the meaning set forth in Section 9.4.3 (Regulatory Milestones for Licensed Products other than Lead Product and Exon-Skipping Product).

1.95 "**[**]**" means [**].

1.96 "**[**] Agreement**" means that certain Clinical Research Collaboration and License Agreement, dated as of [**], by and between [**] and Sarepta Therapeutics [**].

1.97 "**[**] Countries**" means [**].

1.98 "**[**] Product**" has the meaning set forth in the [**] Agreement.

1.99 "**Global Development Program**" means the Joint Global Development Program and the Option Product Development Program.

1.100 "**Global Trade Control Laws**" means the U.S. Export Administration Regulations, the U.S. International Traffic in Arms Regulations, the economic sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Control, E.U. Council Regulations on export controls, including Nos. 428/2009, 267/2012, other E.U. Council sanctions regulations, as implemented in the E.U. member states, United Nations sanctions policies, and all relevant regulations made under any of the foregoing.

1.101 "**Good Clinical Practices**" or "**GCP**" means the then-current good clinical practice standards, practices, and procedures promulgated or endorsed by the applicable Regulatory Authority as set forth in the guidelines imposed by such Regulatory Authority, as may be updated from time-to-time.

1.102 "**Good Laboratory Practices**" or "**GLP**" means the then-current good laboratory practice standards, practices, and procedures promulgated or endorsed by the applicable Regulatory Authority as set forth in the guidelines imposed by such Regulatory Authority, as may be updated from time-to-time.

1.103 "**Good Manufacturing Practices**" or "**GMP**" means the then-current good manufacturing practice standards, practices, and procedures promulgated or endorsed by the applicable Regulatory Authority as set forth in the guidelines imposed by such Regulatory Authority, as may be updated from time-to-time.

1.104 "**Government Official**" means any official, officer, employee, or representative of: (a) any federal, state, provincial, administrative division, county, or municipal government or any department or agency thereof; (b) any public international organization or any department or agency thereof; or (c) any company or other entity owned or controlled by any government or Governmental Authority.

1.105 "**Governmental Authority**" means any court, agency, department, authority, tribunal, or other instrumentality of any supra-national, national, state, provincial, county, city, or other political subdivision. For clarity, Governmental Authorities include all Regulatory Authorities.

1.106 "**IFRS**" means the International Financial Reporting Standards, as consistently applied.

1.107 "**IND**" means an Investigational New Drug application required pursuant to 21 C.F.R. Part 312 or any comparable filings outside of the U.S. (such as an application for a Clinical Trial Authorization in the E.U.).

1.108 "**IND-Enabling Study**" means a toxicology study, in species that satisfies applicable regulatory requirements, using applicable GLP that meets the standard necessary for submission as part of an IND with the applicable Regulatory Authority.

1.109 "**Indemnified Party**" has the meaning set forth in Section 13.3 (Indemnification Procedure).

1.110 "**Indemnifying Party**" has the meaning set forth in Section 13.3 (Indemnification Procedure).

1.111 "**Initiation**" means with respect to any Clinical Trial, first dosing of the first human subject in such Clinical Trial.

1.112 "**Insufficient Supply Event**" has the meaning set forth in Section 8.10.3(b) (Insufficient Quantities; To Meet Demand Under the Capacity Plan).

1.113 "**Internal Costs**" means, for any period of time, (a) the product obtained by multiplying (i) the actual total FTEs (or portion thereof) devoted to the performance of activity under this Agreement during such period, by (ii) the applicable FTE Rate for such period, *plus* (b) a Party's reasonably allocated other internal costs with respect to such activity to the extent not included in the FTE Rate.

1.114 "**Invention**" means any process, method, composition of matter, article of manufacture, discovery, or finding that is conceived or reduced to practice (whether or not patentable).

1.115 "**IP Committee**" has the meaning set forth in Section 10.4 (IP Committee).

1.116 "**JCC**" has the meaning set forth in Section 3.4.1 (Formation and Purpose of the JCC).

1.117 "**JDC**" has the meaning set forth in Section 3.3.1 (Formation and Purpose of the JDC).

1.118 "**JMC**" has the meaning set forth in Section 3.5.1 (Formation and Purpose of the JMC).

1.119 "**Joint Collaboration Know-How**" means any and all Collaboration Know-How developed or invented jointly by a Party's or any of its Affiliates' employees, agents, or independent contractors, or any Persons contractually required to assign or license such Collaboration Know-How to such Party or any Affiliate of such Party, on the one hand, and the other Party's or any of its Affiliates' employees, agents, or independent contractors, or any Persons contractually required to assign or license such Collaboration Know-How to such other Party or any Affiliate of such Party, on the other hand.

1.120 "**Joint Collaboration Patent Rights**" means any and all Collaboration Patent Rights that Cover any Joint Collaboration Know-How.

1.121 "**Joint Collaboration Technology**" means the Joint Collaboration Know-How and the Joint Collaboration Patent Rights.

1.122 "**Joint Global Branding and Marketing Strategy**" has the meaning set forth in Section 6.4 (Branding and Marketing Plans).

1.123 "**Joint Global Development Budget**" means the budget of all Internal Costs and External Costs to be incurred from and after Execution Date in the performance of activities under the Joint Global Development Plan for any Licensed Product.

1.124 "**Joint Global Development Plan**" means the plan setting forth (a) all Clinical Trials for any Licensed Products and corresponding Sarepta Diagnostic Products, in each case, through the completion of Pivotal Clinical Trials and any other Development activities necessary to obtain and maintain Regulatory Approvals for such Licensed Products and corresponding Sarepta Diagnostic Products in the U.S. and the European Union, including process development activities and any post-Regulatory Approval studies, the data from which may be used in both the U.S. and the European Union to obtain or maintain Regulatory Approval, (b) the timelines for such activities, and (c) the Joint Global Development Budget, in each case ((a) through (c)), as the same may be amended from time-to-time in accordance with this Agreement. The initial Joint Global Development Plan is attached as **Schedule 4.3.1** of this Agreement.

1.125 "**Joint Global Development Program**" means the program of Development activities conducted under the Joint Global Development Plan.

1.126 "**Joint Global Medical Affairs Budget**" means the budget of External Costs to be incurred in the performance of activities under the Joint Medical Affairs Plan for any Licensed Product.

1.127 "**Joint Global Medical Affairs Plan**" has the meaning set forth in Section 7.1 (Medical Affairs Plan).

1.128 "**Joint Medical Affairs Team**" has the meaning set forth in Section 3.3.3(c).

1.129 "**Joint Publication Strategy**" has the meaning set forth in Section 12.6 (Publications).

1.130 "**JSC**" has the meaning set forth in Section 3.1.1 (Formation and Purpose of the JSC).

1.131 "**Know-How**" means proprietary Inventions, discoveries, trade secrets, materials, information, experience, data, formulas, procedures, technology, and results (whether or not patentable), including practices, knowledge, know-how, experience and test data (including physical, chemical, biological, toxicological, pharmacological, clinical and veterinary data), dosage regimens, assays, diagnostics, product specifications, manufacturing techniques and costs, analytical and quality control data and marketing, pricing and distribution costs, and sales practices, methods, data, and descriptions.

1.132 "**Knowledge**" means, with respect to a Party and any matter in question, the actual knowledge of such Party's senior management as of the Execution Date, without any inquiry or investigation as to such matter. For this purpose, "**senior management**" means any Person who is an "**officer**" of the applicable Party, as defined in Rule 16a-1(f) of the U.S. Securities Exchange Act of 1934 or the foreign equivalent thereof.

1.133 "**Latin American Region**" means all of the following countries and territories: countries and territories of South America (excluding French Guiana), Mexico, Belize, Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, Panama, Cuba, Dominican Republic, Haiti, Guadeloupe, and Martinique.

1.134 "**Lead Product**" means SRP-9001, in any dosage strength, concentration, or formulation Controlled by Sarepta or any of its Affiliates.

1.135 "**Lead Product Regulatory Milestone Event**" has the meaning set forth in Section 9.4.1 (Lead Product Regulatory Milestones).

1.136 "**Lead Product Regulatory Milestone Payment**" has the meaning set forth in Section 9.4.1 (Lead Product Regulatory Milestones).

1.137 "**Lead Product Royalties**" has the meaning set forth in Section 9.5.1 (Royalty Payments For Lead Product).

1.138 "**Lead Product Royalty Rates**" has the meaning set forth in Section 9.5.1 (Royalty Payments For Lead Product).

1.139 "**Lead Product Royalty Term**" has the meaning set forth in Section 9.5.1 (Royalty Payments For Lead Product).

1.140 "**Lead Product Sales Milestone Events**" has the meaning set forth in Section 9.4.5 (Sales Milestones).

1.141 "**Lead Product Sales Milestone Payments**" has the meaning set forth in Section 9.4.5 (Sales Milestones).

1.142 "**LGMD Diligence Package**" means, with respect to each LGMD Product, a package of documents or information to be provided or made available to Roche containing the following: (a) the information set forth on **Schedule 1.142**; (b) a reasonably detailed summary of all Development activities undertaken by or on behalf of Sarepta or any of its Affiliates with respect to such LGMD Product; (c) all Regulatory Submissions related to such LGMD Product, if any, and a summary of all substantive correspondence to or from any Regulatory Authority related to such LGMD Product, if any; (d) a list of any Patent Rights Covering such LGMD Product and a description of the material Sarepta Know-How related to such LGMD Product; and (e) copies of all material agreements between Sarepta and any Third Party pursuant to which Sarepta is granted rights with respect to an LGMD Product.

1.143 "**LGMD Evaluation Period**" has the meaning set forth in Section 2.8.3 (LGMD ROFN Evaluation Period).

1.144 "**LGMD Initial Response**" has the meaning set forth in Section 2.8.3 (LGMD ROFN Evaluation Period).

1.145 "**LGMD Products**" means any and all products Controlled by Sarepta or any of its Affiliates as of the Effective Date or at any time during the Term for the treatment, prevention, cure, amelioration, or therapy of Limb Girdle Muscular Dystrophy.

1.146 "**LGMD ROFN Exercise Notice**" has the meaning set forth in Section 2.8.4 (LGMD ROFN Exercise).

1.147 "**LGMD ROFN Negotiation Period**" has the meaning set forth in Section 2.8.4 (LGMD ROFN Exercise).

1.148 "**LGMD ROFN Notice**" has the meaning set forth in Section 2.8.2 (LGMD ROFN).

1.149 "**LGMD ROFN Rights**" has the meaning set forth in Section 2.8.2 (LGMD ROFN).

1.150 "**Licensed Products**" means (a) as of the Effective Date, the Lead Product, and (b) thereafter during the Term, any and all Option Products for which Roche exercises the applicable Option in accordance with Section 2.7 (Exercise of Option).

1.151 "**Losses**" has the meaning set forth in Section 13.1 (Indemnification by Sarepta).

1.152 "**MAA**" or "**Marketing Authorization Application**" means any (a) Biologics License Application submitted under Section 351(a) of the PHSA, (b) New Drug Application as defined in the FD&C Act, or (c) substantially similar application or submission to those set forth in clause (a) or clause (b) filed with a Regulatory Authority in a country or group of countries to obtain Regulatory Approval to Commercialize a biopharmaceutical or diagnostic product in that country or in that group of countries, including, with respect to the E.U., a Marketing Authorization Application filed with the EMA pursuant to the centralized approval procedure or with the applicable Regulatory Authority of a country in the EU with respect to the mutual recognition or any other national approval, in each case ((a) through (c)), including any amendments thereto, and supplemental applications, but excluding Reimbursement Approval applications.

1.153 "**Manufacture**" means with respect to any product, any and all activities directed to manufacturing, processing, packaging, labeling, filling, finishing, assembly, quality assurance, quality control, testing, and release, shipping, supply, or storage of such product (or any components or process steps involving such product or any companion diagnostic), placebo, or comparator agent, as the case may be, including qualification, validation, and scale-up, pre-clinical, clinical, and commercial manufacture and analytic development, product characterization, and stability testing, but excluding any activities directed to Development, Medical Affairs, or Commercialization. "**Manufacturing**" and "**Manufactured**" will be construed accordingly.

1.154 "**Manufacturing Costs**" means, with respect to a Licensed Product, the fully-burdened cost incurred by Sarepta or its Affiliates in Manufacturing such Licensed Product (including all activities related to CMC, formulation, quality control, packaging and labeling, scale-up, failed batches (as to the extent it can be reasonably expected on normal operating variations) and expired materials, and including all activities related to the supply of plasmids, raw materials, drug substance, and drug product) in accordance with this Agreement and consistent with the applicable Supply Agreement, including: (a) to the extent that such Licensed Product is Manufactured by one or more CMOs, (i) the actual External Costs paid by Sarepta or its Affiliates to such CMOs for the Manufacture thereof plus (ii) to the extent allocable to the Licensed Products, the actual Internal Costs incurred to engage with and oversee such Third Party; and (b) to the extent that such Licensed Product is Manufactured by Sarepta or its Affiliates: material costs, depreciation of capital expenditures, actual External Costs, and actual Internal Costs, in each case, directly attributable to the Manufacture of such Licensed Product, and in each case, to the extent such costs are fairly allocated to the Licensed Product. Notwithstanding the foregoing, Manufacturing Costs exclude all costs and expenses related to or occasioned by (A) any and all unused Manufacturing capacity of Sarepta or any of its Affiliates or CMOs, in each case, that is not reserved for any Licensed Product, (B) any and all unused Manufacturing capacity of Sarepta or any of its Affiliates that is reserved for any Licensed Product to the extent Sarepta or any of its Affiliates can, using reasonable efforts, allocate such capacity to any product that is not a Licensed Product or to any Third Party, (C) the Manufacture of any products other than the Licensed Products at the same facilities in which any Licensed Product is Manufactured, and (D) any overhead costs that are not reasonably allocated to Manufacturing the Licensed Products. Manufacturing Costs will be recognized only in accordance with the applicable Accounting Standard.

1.155 "**Manufacturing Plan**" has the meaning set forth in Section 8.8 (Manufacturing Plan).

1.156 "**Manufacturing Transition Notice**" has the meaning set forth in Section 8.11.1 (Request for Technology Transfer).

1.157 "**Manufacturing Transition Period**" has the meaning set forth in Section 8.11.2 (Manufacturing Transition Period).

1.158 "**Manufacturing Transition Plan**" has the meaning set forth in Section 8.11.2 (Manufacturing Transition Period).

1.159 "**Mark**" means any trademark, trade name, service mark, service name, product name, brand, domain name, trade dress, logo, slogan, or other indicia of origin or ownership, and any and all (a) registrations and applications for registrations, and, as applicable, other intellectual property rights associated with any of the foregoing, and (b) goodwill associated with each of the foregoing.

1.160 "**Material Communication**" means material written, telephonic, or in person communications from or with any Regulatory Authority concerning any of the following: key product quality attributes (*e.g.*, purity), safety findings affecting the platform (*e.g.*, serious adverse events, emerging safety signals), clinical or non clinical findings affecting patient safety, lack of efficacy, receipt or denial of Regulatory Approval, the design of Clinical Trials, or the need for additional non clinical studies or IND-Enabling Studies (*e.g.*, additional toxicology or carcinogenicity studies).

1.161 "**Medical Affairs**" means any and all activities conducted by or on behalf of a Party's or any of its Affiliates' medical affairs departments, including communications with key opinion leaders, medical education, symposia, advisory boards (to the extent related to medical affairs or clinical guidance), activities performed in connection with patient registries, and other medical programs and communications, including educational grants, research grants (including conducting investigator-initiated studies), and charitable donations to the extent related to medical affairs and not to activities that involve the promotion, marketing, sale, or other Commercialization of the Sarepta Products or any corresponding Sarepta Diagnostic Product and are not conducted by or on behalf of a Party's or any of its Affiliates' medical affairs departments. Medical Affairs excludes any activities directed to Manufacturing, Development, or Commercialization.

1.162 "**Medical Affairs Costs**" means any and all costs and expenses actually incurred in connection with the performance of any Medical Affairs activities for any Licensed Product, including External Costs actually incurred in connection with the performance of any Medical Affairs activities for any Licensed Product. Medical Affairs Costs will be recognized only in accordance with the applicable Accounting Standard.

1.163 "**Middle Eastern Countries**" means all of the following countries and territories: Bahrain, Egypt, Iran, Iraq, Israel, Jordan, Kuwait, Lebanon, Oman, the Palestinian territories, Qatar, Saudi Arabia, Syria, Turkey, United Arab Emirates, and Yemen.

1.164 "**Milestone Events**" has the meaning set forth in Section 9.4.7 (Notification of Milestone Events).

1.165 "**Milestone Payments**" has the meaning set forth in Section 9.4.7 (Notification of Milestone Events).

1.166 "**Net Sales**" means, with respect to a Licensed Product, for any period, the amounts stated in Roche's and its Affiliates' and Sublicensees' "Sales" lines of their respective externally published audited (in the case of Roche) financial statements with respect to such Licensed Product for such period, which amount reflects the gross invoice price of such Licensed Product sold or otherwise disposed of (other than for use as clinical supplies or free samples) by Roche and its Affiliates and Sublicensees (other than Third Party Distributors and Compulsory Sublicensees) during such period (such sales, "**Sales**" and such Persons, each, a "**Seller**") less the following gross-to-net deductions (to the extent applied consistently by the applicable Seller with respect to sales of their respective other products) not previously deducted from the amount invoiced:

1.166.1 [**];

1.166.2 [**];

1.166.3 [**]; and

1.166.4 [**].

Sales for such Licensed Product will be reflective of *bona fide*, arms length transactions, as determined in accordance with the then-currently used applicable Accounting Standards. As such, the following will not be considered a Sale or count toward Net Sales: [**]. Also by way of example, the gross-to-net deductions of Sales in accordance with Accounting Standards as of the Effective Date are the following:

(a) [**];

(b) [**];

(c) [**]; and

(d) [**].

To the extent that any Seller receives consideration other than or in addition to cash upon the Sale of a Licensed Product, or in consideration of the performance of any services (including preliminary treatments or follow-up treatments) related to such Licensed Product, Net Sales will include the fair market value of such additional consideration.

1.167 "**Non-Breaching Party**" has the meaning set forth in Section 14.2.1 (Notice and Cure).

1.168 "**OFAC**" means the Office of Foreign Assets Control of the United States Department of the Treasury or any successor agency thereto.

1.169 "**Option**" has the meaning set forth in Section 2.7.1 (Grant of Option).

1.170 "**Option Data Package**" means, with respect to each Option Product, a package of documents or information to be provided or made available to Roche containing the following: (a) the information set forth on **Schedule 1.170**; (b) a reasonably detailed summary of all Development activities undertaken by or on behalf of Sarepta or any of its Affiliates or Sublicensees with respect to such Option Product; (c) all Regulatory Submissions related to such Option Product, if any, and a summary of all substantive correspondence to or from any Regulatory Authority related to such Option Product, if any; (d) a list of any and all Patent Rights Covering such Option Product, and a description of the material Sarepta Know-How related to such Option Product; (e) an updated disclosure letter containing all applicable disclosures related to the representations and warranties set forth in Section 11.1 (Mutual Representations and Warranties) and Section 11.2 (Additional Sarepta Warranties) with respect to such Option Product; and (f) copies of all material agreements between Sarepta and any Third Party pursuant to which Sarepta is granted rights with respect to an Option Product or any agreement with any CMO related to the Manufacture of an Option Product.

1.171 "**Option Exercise Fee**" has the meaning set forth in Section 9.3 (Option Exercise Fee).

1.172 "**Option Exercise Notice**" has the meaning set forth in Section 2.7.3 (Exercise of Option).

1.173 "**Option Exercise Period**" means (a) for all the Exon-Skipping Products, the period commencing on [**] and ending [**] after Sarepta's delivery to Roche of the Option Data Package, and (b) for each other Option Product that is not an Exon-Skipping Product, on an Option Product-by-Option Product basis, the period commencing on the Effective Date and ending on the date that is [**] after Sarepta's delivery to Roche of an Option Data Package for such Option Product; *provided*, *however*, that Roche may terminate prior to its natural expiration any Option Exercise Period by delivering a notice to Sarepta indicating that it does not intend to exercise the Option for the Option Product to which such Option Exercise Period relates, as such period may be extended pursuant to Section 2.7.2(d) (Incomplete Option Data Package and Right to Ask Questions).

1.174 "**Option Product Development Plan**" means the plan setting forth (a) all Clinical Trials for all Option Products and any corresponding Sarepta Diagnostic Product through the completion of Pivotal Clinical Trials and any other Development activities necessary to obtain and maintain Regulatory Approvals for each Option Product and any corresponding Sarepta Diagnostic Product in the U.S. and the European Union, including process development activities, and (b) the timelines for such activities, in each case ((a) and (b)), as the same may be amended from time-to-time in accordance with this Agreement.

1.175 "**Option Product Development Program**" means the program of Development activities conducted under the Option Product Development Plan.

1.176 "**Option Product Know-How**" means, with respect to any Option Product, any and all Know-How that is (a) Controlled by Sarepta or any of its Affiliates as of the Effective Date or at any time during the Term and (b) necessary or useful to Exploit such Option Product or any corresponding Sarepta Diagnostic Products in the Field.

1.177 "**Option Product Patent Rights**" means, with respect to any Option Product, any and all Patent Rights that are (a) Controlled by Sarepta or any of its Affiliates as of the Effective Date or at any time during the Term and (b) necessary or useful to Exploit such Option Product or any corresponding Sarepta Diagnostic Products in the Field in the Roche Territory.

1.178 "**Option Products**" means (a) any Gene Therapy Product, other than the Lead Product, [**] ("**Gene Therapy Option Product**"), (b) all Gene-Editing Products [**] ("**Gene-Editing Option Products**") and (c) all Exon-Skipping Products.

1.179 "**Orphan Drug Designation**" means the granting of special status by a competent Regulatory Authority to a drug for treating a rare disease or condition that meets the applicable legal criteria such as those set forth in Regulation No 141/2000 of the European Parliament and of the Council as of December 16, 1999. Such a drug is protected by exclusive legal rights ("orphan drug exclusivity") only after it receives Regulatory Approval by the Regulatory Authority for use in treating said rare disease or condition.

1.180 "**Other Covered Party**" means any political party or party official, or any candidate for political office, in each case, in any jurisdiction.

1.181 "**Other Product Royalties**" has the meaning set forth in Section 9.5.2 (Royalty Payments for Licensed Products other than Lead Product).

1.182 "**Other Product Royalty Term**" has the meaning set forth in Section 9.5.2 (Royalty Payments for Licensed Products Other than the Lead Product).

1.183 "**Packaging and Labeling**" means any and all primary, secondary, or tertiary packaging and labeling of a Licensed Product (in its commercial packaging presentation) for sale or use in a country, including the Approved Labeling and insertion of materials such as patient inserts, patient medication guides, and professional inserts and any other written, printed, or graphic materials accompanying such Licensed Product and any brand security or anti-counterfeiting measures included in the packaging elements for such Licensed Product considered to be part of the finished packaged Licensed Product, and all testing and release thereof.

1.184 "**Party Vote**" has the meaning set forth in Section 3.7 (Decision-Making).

1.185 "**Patent Challenge**" means any action that contests anywhere in the world the scope, validity, or enforceability of a Patent Right in any court, arbitration proceeding, tribunal, or administrative agency, including the U.S. Patent and Trademark Office, European Patent Office, a national court in any country or jurisdiction and the Unified Patent Court (as applicable if and when in force). For clarity, a Patent Challenge shall not include arguments made by a Party that distinguishes the inventions claimed in Patent Rights owned or Controlled by such Party from those claimed in another Patent Right. As used in this definition the term "**contest**" includes (a) filing an action seeking a determination of invalidity or unenforceability of any such Patent Right; (b) filing, or joining in, a post-grant proceeding, including (i) a petition under 35 U.S.C. § 311 to institute inter partes review of any such Patent Right or (ii) a petition under 35 U.S.C. § 321 to institute post-grant review of any such Patent Right or any portion thereof; (c) filing, or joining in, any opposition, nullity, or similar proceedings challenging the validity of any such Patent Right in any country, (d) filing, or joining in, any derivation proceedings before an administrative agency, interferences, inventorship challenges or any other proceeding that challenges the inventorship or ownership of any such Patent Right, and (e) any foreign equivalent of clauses (a), (b), (c), or (d).

1.186 "**Patent Rights**" means any and all (a) patents, patent applications, and utility models in any country or jurisdiction, including provisional applications, priority applications, and international applications, (b) patent applications filed either from such patents or patent applications or from an application claiming priority from any of these, including divisionals, continuations, and continuations-in-part, (c) patents that have issued or in the future issue from the foregoing patent applications, (d) substitutions, renewals, registrations, confirmations, revalidations, reissues, and re-examinations of the foregoing patents or patent applications, and (e) extensions, restorations, supplemental protection certificates, and the like based on any of the foregoing patents or patent applications.

1.187 "**Person**" means any corporation, sole proprietorship, limited or general partnership, limited liability partnership, limited liability company, business trust, joint stock company, joint venture, trust, incorporated or unincorporated association, governmental or political body, subdivision, authority, bureau, or agency, or any other entity or body similar to any of the foregoing, or an individual.

1.188 "**Pharmacovigilance Agreement**" means an agreement regarding receipt, investigation, and reporting of product complaints, adverse events, product recalls, and any other information related to the safety of a Licensed Product in the Territory.

1.189 "**PHSA**" means the United States Public Health Service Act, as amended from time-to-time, together with any rules, regulations, and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

1.190 "**Pivotal Clinical Trial**" means any Clinical Trial of the active substance of a pharmaceutical or biologic product, the results of which, together with prior data and information concerning such product, are intended to be sufficient, without any additional Clinical Trial, to meet the evidentiary standard for demonstrating the safety, purity, and potency of such active substance of such product established by a Regulatory Authority in any particular jurisdiction and is intended to support the filing of a MAA by a Regulatory Authority in such jurisdiction.

1.191 "**Potential In-License**" has the meaning set forth in Section 2.5.2 (Potential In-Licenses).

1.192 "**Product Marks**" means any and all Marks (whether registered or unregistered), other than any Sarepta Housemark or Roche Housemark, for use on, with, or to refer to any Licensed Product or used with patient support or other information or services or Product Materials associated with any Licensed Product in the Territory during the Term, together with any and all (a) registrations, applications for registrations, and other intellectual property rights associated with any of the foregoing, and (b) goodwill associated with each of the foregoing.

1.193 "**Product Materials**" means any and all promotional materials, training materials, medical education materials, Packaging and Labeling, and all other literature or other information related to any Licensed Product.

1.194 "**Professional Requirements**" means (a) the codes and standards of the European Accreditation Council for Continuing Medical Education (EACCME) and the European Federation of Pharmaceutical Industries and Associations (EFPIA), (b) the codes of the Prescription Medicines Code of Practice Authority (PMCPA) and the Association of the British Pharmaceutical Industry (ABPI), (c) FDA's regulations, guidance, and enforcement letters concerning the advertising of prescription drug products, (d) the American Medical Association's Guidelines on Gifts to Physicians from Industry, (e) the Accreditation Council for Continuing Medical Education (ACCME) Standards for Commercial Support of Continuing Medical Education, (f) the Pharmaceutical Supply Chain Initiative (PSCI) and Pharmaceutical Industry Principles for Responsible Supply Chain Management, (g) the Code on Interactions with Healthcare Professionals promulgated by the Pharmaceutical Research and Manufacturers of America (PhRMA Code), (h) the Department of Health and Human Services Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers (OIG Compliance Guidance), and (i) all other accepted national and international pharmaceutical industry codes of practice in and for the relevant countries in the Territory, as any of the foregoing may be amended from time-to-time.

1.195 "**Proof of Concept Trial**" means a Clinical Trial (including any portion thereof) of an Option Product [**].

1.196 "**Proof of Concept Trial Success**" means, with respect to an Option Product, [**].

1.197 "**Prosecuting Party**" has the meaning set forth in Section 10.6.1 (Filing of Joint Collaboration Patent Rights).

1.198 "**Publication**" has the meaning set forth in Section 12.6 (Publications).

1.199 "**Publishing Notice**" has the meaning set forth in Section 12.6(b).

1.200 "**Publishing Party**" has the meaning set forth in Section 12.6(b).

1.201 "**[**]**" means [**].

1.202 "**Receiving Party**" has the meaning set forth in Section 12.1.1 (Duty of Confidence).

1.203 "**Region**" means any of the Asian Region, the European Region, the Latin American Region, Japan, or the ROW Region.

1.204 "**Regulatory Approval**" means, with respect to a particular country or other regulatory jurisdiction, any approval of an MAA or other approval, product, or establishment license, registration, or authorization required by Applicable Law for the commercial sale of a pharmaceutical, diagnostic, or biologic product in such country or other regulatory jurisdiction, excluding, in each case, Reimbursement Approval.

1.205 "**Regulatory Authority**" means, in a particular country or jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approval in such country or jurisdiction, including (a) in the U.S., the FDA and any other applicable Governmental Authority in the U.S. having jurisdiction over any pharmaceutical, diagnostic, or biologic product, (b) in the E.U., the EMA and any other applicable Governmental Authority in the E.U. having jurisdiction over any pharmaceutical, diagnostic, or biologic product, and (c) in other countries, other analogous Governmental Authorities having jurisdiction over any pharmaceutical, diagnostic, or biologic product.

1.206 "**Regulatory Exclusivity**" means, with respect to any Licensed Product in any country or jurisdiction in the Roche Territory, the period of time during which: (a) a Party or its Affiliate or Sublicensee has been granted the exclusive legal right by a Regulatory Authority, other than through a Patent Right, including orphan drug exclusivity, pediatric exclusivity, rights conferred in the U.S. under the FD&C Act, rights in the EU under Directive 2001/83/EC, or rights similar thereto in other countries or regulatory jurisdictions in the Roche Territory, or is otherwise entitled to the exclusive legal right by operation of Applicable Law in such country to market and sell such Licensed Product, and such right precludes the receipt of Regulatory Approval of any Third Party product that is deemed to be the same or a similar drug, in each case, under applicable orphan drug regulations; or (b) the data and information submitted by a Party or its Affiliate or Sublicensee to the relevant Regulatory Authority in such country or jurisdiction for purposes of obtaining Regulatory Approval of such Licensed Product may not be disclosed, referenced, or relied upon in any way by any Third Party or such Regulatory Authority to support the Regulatory Approval or marketing of any product by any Third Party in such country or jurisdiction, or if such data and information is disclosed, referenced, or relied upon to support a Regulatory Approval granted to any Third Party in such country or jurisdiction, then the product may not be placed on the market for any indication.

1.207 "**Regulatory Expert**" has the meaning set forth in Section 3.8.2(a) (Regulatory Expert Matters).

1.208 "**Regulatory Expert Matter**" has the meaning set forth in Section 4.3.1 (Joint Global Development Plan).

1.209 "**Regulatory Milestone Event**" has the meaning set forth in Section 9.4.1 (Regulatory Milestones).

1.210 "**Regulatory Milestone Payment**" has the meaning set forth in Section 9.4.1 (Regulatory Milestones).

1.211 "**Regulatory Responsible Party**" means, for each Sarepta Product in the Sarepta Territory or Roche Territory and any corresponding Sarepta Diagnostic Product, the Party designated under Section 5.2 (Regulatory Responsible Party).

1.212 "**Regulatory Submission**" means any filing, application, or submission with any Regulatory Authority in support of the Development, Manufacture, Commercialization, or other Exploitation of a pharmaceutical, diagnostic, or biologic product (including to obtain, support, or maintain Regulatory Approval from that Regulatory Authority), and all written or electronic correspondence or communication with or from the relevant Regulatory Authority, as well as minutes of any material meetings, telephone conferences, or discussions with the relevant Regulatory Authority. Regulatory Submissions include all INDs, MAAs, and other applications for Regulatory Approval and their equivalents.

1.213 "**Reimbursement Approval**" means any approval, agreement, determination, or other decision by the applicable Governmental Authority in a given country that establishes prices charged to end-users for pharmaceutical, diagnostic, or biologic products at which such pharmaceutical, diagnostic, or biologic products will be reimbursed by the Regulatory Authorities or other applicable Governmental Authorities in such country or any other approvals related to pricing, reimbursement, or access to a pharmaceutical, diagnostic, or biologic product (including all activities related to tenders and contracts).

1.214 "**Restricted Party**" means any individual or entity on one or more of the Restricted Party Lists.

1.215 "**Restricted Party List**" means the list of sanctioned entities maintained by the United Nations; the Specially Designated Nationals and Blocked Persons List, the Foreign Sanctions Evaders List and the Sectoral Sanctions Identifications List, all administered by OFAC; the U.S. Denied Persons List, the U.S. Entity List, and the U.S. Unverified List, all administered by the U.S. Department of Commerce; and the entities subject to restrictive measures and the consolidated list of Persons, Groups, and Entities Subject to E.U. Financial Sanctions, as implemented by the E.U. Common Foreign & Security Policy.

1.216 "**Right of Reference**" has the meaning set forth in Section 5.6 (Assignment of Regulatory Submissions and Regulatory Approvals to Roche).

1.217 "**Roche Background Know-How**" means any and all Know-How (excluding the Roche Collaboration Know-How and Roche's interest in Joint Collaboration Know-How) that is (a) Controlled by Roche or any of its Affiliates as of the Effective Date or during the Term and (b) (i) used by or on behalf of Roche or any of its Affiliates to Exploit one or more Licensed Products or corresponding Sarepta Diagnostic Products or (ii) otherwise disclosed to Sarepta or any of its Affiliates at any meeting of the JSC or any Subcommittee (as documented in the minutes of such JSC or Subcommittee meeting) or otherwise in writing, in each case, in the conduct of activities under this Agreement by or on behalf of Roche or any of its Affiliates.

1.218 "**Roche Background Patent Rights**" means any and all Patent Rights (excluding the Roche Collaboration Patent Rights and Roche's interest in the Joint Collaboration Patent Rights) that are (a) Controlled by Roche or any of its Affiliates as of the Effective Date or during the Term and (b) (i) used by or on behalf of Roche or any of its Affiliates to Exploit one or more Licensed Products or corresponding Sarepta Diagnostic Products and that Cover any Roche Background Know-How or (ii) that, without a license thereunder, would be infringed by the Exploitation of one or more Licensed Products or corresponding Sarepta Diagnostic Products in accordance with this Agreement.

1.219 "**Roche Background Technology**" means the Roche Background Know-How and Roche Background Patent Rights.

1.220 "**Roche Collaboration Know-How**" means any and all Collaboration Know-How developed or invented solely by Roche's or any of its Affiliates' or Sublicensees' employees, agents, or independent contractors, or any Persons contractually required to assign or license such Collaboration Know-How to Roche or any Affiliate or Sublicensee of Roche.

1.221 "**Roche Collaboration Patent Rights**" means any and all Collaboration Patent Rights that Cover any Roche Collaboration Know-How.

1.222 "**Roche Collaboration Technology**" means any and all Roche Collaboration Know-How, Roche Collaboration Patent Rights, and Roche's interest in the Joint Collaboration Technology.

1.223 "**Roche Housemarks**" means (a) all corporate logos of Roche or any of its Affiliates, (b) the trademark "Roche", (c) any other Mark (whether registered or unregistered) containing the word "Roche", (d) any other corporate logo or other Mark used by Roche or any of its Affiliates to identify Roche or its Affiliates, (e) all registrations and applications for registrations of the foregoing, and (f) all goodwill associated with any and all of the foregoing in clauses (a) through (e).

1.224 "**Roche Indemnitees**" has the meaning set forth in Section 13.1 (Indemnification by Sarepta).

1.225 "**Roche Major Country**" means, with respect to all Licensed Products, [**].

1.226 "**Roche Medical Affairs Plan**" has the meaning set forth in Section 7.1 (Medical Affairs Plans).

1.227 "**Roche Technology**" means Roche Background Technology and Roche Collaboration Technology.

1.228 "**Roche Territory**" means worldwide, excluding the Sarepta Territory.

1.229 "**Roche Territory Branding and Marketing Plan**" has the meaning set forth in Section 6.4 (Branding and Marketing Plans).

1.230 "**Roche Territory Development Plan**" means the plan setting forth (a) all Development activities, other than activities included in the Joint Global Development Plan, that are necessary or desirable to obtain and maintain Regulatory Approvals or Reimbursement Approvals of each Licensed Product and any corresponding Sarepta Diagnostic Product in the Roche Territory (including in each Roche Major Country for the applicable Licensed Product), including all proposed post-Regulatory Approval studies and all other non-clinical and pre-clinical studies and Clinical Trials, in each case, the data from which will be used solely for the Roche Territory and regulatory plans, and (b) the timelines for such activities, in each case ((a) and (b)), as the same may be amended from time-to-time in accordance with this Agreement.

1.231 "**Roche Territory Development Program**" means the program of Development activities conducted under the Roche Territory Development Plan, which will exclude any Development activities conducted under the Joint Global Development Program.

1.232 "**ROW Region**" means all countries and territories within the Roche Territory that are not included in Japan, the Asian Region, the Latin American Region, or the European Region.

1.233 "**Royalties**" has the meaning set forth in Section 9.5.2 (Royalty Payments for Licensed Products Other than the Lead Product).

1.234 "**Royalty-Bearing Patent Rights**" means, with respect to a Licensed Product in a country in the Roche Territory, [**].

1.235 "**Royalty Report**" has the meaning set forth in Section 9.5.4(a) (Royalty Report).

1.236 "**Royalty Term**" means, as applicable, the Lead Product Royalty Term or the Other Product Royalty Term.

1.237 "**Sales**" has the meaning set forth in Section 1.166 (Net Sales).

1.238 "**Sales Milestone Event**" has the meaning set forth in Section 9.4.2 (Sales Milestones).

1.239 "**Sales Milestone Payment**" has the meaning set forth in Section 9.4.2 (Sales Milestones).

1.240 "**Sarepta Collaboration Know-How**" means any and all Collaboration Know-How developed or invented solely by Sarepta's or any of its Affiliates' employees, agents, or independent contractors, or any Persons contractually required to assign or license such Collaboration Know-How to Sarepta or any Affiliate of Sarepta.

1.241 "**Sarepta Collaboration Patent Rights**" means any and all Collaboration Patent Rights that Cover any Sarepta Collaboration Know-How.

1.242 "**Sarepta Diagnostic Products**" means (a) any and all *in vitro* diagnostic tests or products that (i) are Controlled by Sarepta or its Affiliates at any time during the Term that are being developed, or have been indicated by the applicable Regulatory Authority, for use with any Licensed Products, and (ii) provide information essential to the safe and effective use of one or more Licensed Products or are otherwise necessary for the Regulatory Approval of any Licensed Products, and (b) [**].

1.243 "**Sarepta Housemarks**" means (a) the corporate logo of Sarepta or any of its Affiliates, (b) the trademark for "Sarepta," (c) any other Marks (whether registered or unregistered) containing the word "Sarepta," (d) any other corporate logo or other Mark used by Sarepta or any of its Affiliates to identify Sarepta or its Affiliates, (e) all registrations, applications for registrations, and other intellectual property rights associated with any of the foregoing, and (f) all goodwill associated with any and all of the foregoing in clauses (a) through (e). A list of all Sarepta Housemarks existing as of the Effective Date and Sarepta's form of trademark use authorization is set forth on **Schedule 1.243**.

1.244 "**Sarepta Inability to Supply**" means Roche's reasonable belief that Sarepta will be unable to deliver to Roche or its designee sufficient supply of Licensed Product to meet the quantities set forth in the then-current Demand Forecast Plan for the Licensed Product allocated for [**].

1.245 "**Sarepta Indemnitees**" has the meaning set forth in Section 13.2 (Indemnification by Roche).

1.246 "**Sarepta Know-How**" means any and all Know-How (excluding Sarepta's interest in Joint Collaboration Know-How) that is (a) Controlled by Sarepta or any of its Affiliates as of the Effective Date or at any time during the Term and (b) (i) necessary or useful to Exploit one or more Licensed Products or Sarepta Diagnostic Products in the Field or (ii) otherwise disclosed to Roche or any of its Affiliates at any meeting of the JSC or any Subcommittee (as documented in the minutes of such JSC or Subcommittee meeting) or otherwise in writing, in each case, in the conduct of activities under this Agreement by or on behalf of Sarepta or any of its Affiliates. Sarepta Know-How includes all Sarepta Collaboration Know-How.

1.247 "**Sarepta Manufacturing Know-How**" means, on a Licensed Product-by-Licensed Product basis, the Sarepta Know-How that is related to the Manufacture of the applicable Licensed Product that is the subject of a Supply Failure.

1.248 "**Sarepta Medical Affairs Plan**" has the meaning set forth in Section 7.1.3 (Sarepta Medical Affairs Plan).

1.249 "**Sarepta-Owned Marks**" has the meaning set forth in Section 10.16.2 (Ownership of Trademarks).

1.250 "**Sarepta Patent Rights**" means any and all Patent Rights (excluding Sarepta's interest in Joint Collaboration Patent Rights) that are (a) Controlled by Sarepta or any of its Affiliates as of the Effective Date or at any time during the Term and (b) necessary or useful (or, with respect to patent applications, would be necessary or useful if such patent applications were to issue as patents) to Exploit one or more Licensed Products or Sarepta Diagnostic Products in the Field in the Roche Territory. Sarepta Patent Rights include all Sarepta Collaboration Patent Rights. All Sarepta Patent Rights as of the Execution Date are set forth on **Schedule 1.250**(Sarepta Patent Rights).

1.251 "**Sarepta Product**" means any Licensed Product or Option Product.

1.252 "**Sarepta Technology**" means the Sarepta Know-How, the Sarepta Patent Rights, and Sarepta's interest in the Joint Collaboration Technology.

1.253 "**Sarepta Territory**" means the U.S.

1.254 "**Sarepta Territory Branding and Marketing Plan**" has the meaning set forth in Section 6.4 (Branding and Marketing Plans).

1.255 "**Seller**" has the meaning set forth in Section 1.166 (Net Sales).

1.256 "**Shortage**" means the inability of Sarepta and its CMOs to, or either Party's reasonable belief that Sarepta and its CMOs are reasonably likely to be unable to, Manufacture the quantities of conforming Licensed Product contemplated in the then-current Demand Forecast Plan that are in excess of the quantities set forth in the then-current Capacity Plan.

1.257 "**SRP-9001**" means a gene therapy product that delivers to cells as a therapeutic agent a transgene that encodes and directly expresses dystrophin or a derivative thereof (such as micro-dystrophin or mini-dystrophin) Controlled by Sarepta or any of its Affiliates having [**]. SRP-9001 includes the product known as SRP-9001 or rAAVrh74.MHCK7.micro-dystrophin.

1.258 "**Stock Purchase Agreement**" means that certain Stock Purchase Agreement dated as of the Execution Date between Roche Finance Ltd and Sarepta Therapeutics, Inc.

1.259 "**Subcommittee**" has the meaning set forth in Section 3.2.1 (Formation; Authority).

1.260 "**Subcontracting Party**" has the meaning set forth in Section 2.3.3 (Subcontracting).

1.261 "**Sublicense**" has the meaning set forth in Section 2.3 (Rights to Grant Sublicenses).

1.262 "**Sublicensee**" means any Third Party to which (a) Sarepta or any of its Affiliates grants a sublicense under any of the rights granted to Sarepta under this Agreement or (b) Roche or any of its Affiliates grants a sublicense under any of the rights granted to Roche under this Agreement.

1.263 "**Supply Agreements**" means the Development Supply Agreement and the Commercial Supply Agreement and the corresponding quality agreements fulfilling the requirements set forth in **Schedule 1.263**.

1.264 "**Supply Failure**" means (a) the failure of Sarepta or the CMOs engaged by Sarepta to [**].

1.265 "**Supply Price**" has the meaning set forth in Section 8.7 (Supply Price).

1.266 "**Term**" has the meaning set forth in Section 14.1 (Term).

1.267 "**Terminated Product**" has the meaning set forth in Section 14.1 (Effects of Termination).

1.268 "**Terminated Region**" means each Region in the Roche Territory with respect to which this Agreement has been terminated pursuant to Section 14.2 (Termination for Breach), Section 14.3 (Termination by Roche for Convenience), or Section 14.6 (Cessation of Development and Commercialization), and if this Agreement is terminated in its entirety, then all Regions in the Roche Territory will be Terminated Regions.

1.269 "**Territory**" means collectively the Roche Territory and the Sarepta Territory.

1.270 "**Third Party**" means any Person other than a Party and its Affiliates.

1.271 "**Third Party Claims**" has the meaning set forth in Section 13.1 (Indemnification by Sarepta).

1.272 "**Third Party Distributor**" means, with respect to any country, any Third Party that purchases any Licensed Products or Sarepta Diagnostic Products in such country from a Party or any of its Affiliates or Sublicensees and is appointed as a distributor to distribute, market, and resell such Licensed Products in such country directly to customers and does not Develop or Manufacture such product.

1.273 "**Third Party Patent Challenge**" has the meaning set forth in Section 10.10 (Defense of Third Party Patent Challenges).

1.274 "**Third Party Payment**" means any amount paid [**] pursuant to a Collaboration In-License.

1.275 "**Third Party Royalty Payments**" means, with respect to any Licensed Product, [**].

1.276 "**Upfront Payment**" has the meaning set forth in Section 9.1 (Upfront Payment).

1.277 "**U.S. Dollars**" or "**$**" means the legal tender of the U.S.

1.278 "**United States**" or "**U.S.**" means the United States of America (including all possessions and territories thereof, including Puerto Rico).

1.279 "**Valid Claim**" means: (a) any claim of an issued and unexpired patent (as may be adjusted through a patent term adjustment or extended through supplementary protection certificate or patent term extension or the like) that has not been revoked, held invalid, or held unenforceable by a patent office or other Governmental Authority of competent jurisdiction in a final and non-appealable judgment (or judgment from which no appeal was taken within the allowable time period); or (b) any pending claim of an unissued, pending patent application that (i) is being prosecuted in good faith and has not been abandoned or finally disallowed without the possibility of appeal or re-filing of the application and (ii) which application has not been pending for more than [**] since the earliest priority date of such application, unless and until such claim becomes an issued claim of an issued patent in which case it will again be considered a Valid Claim under the foregoing clause (a).

1.280 "**Withholding Party**" has the meaning set forth in Section 9.11 (Taxes).

ARTICLE 2
LICENSES

2.1 **Grant of Licenses to Roche**. Subject to the terms of this Agreement (including Section 2.4 (No Other Rights and Retained Rights)), Sarepta, on behalf of itself and its Affiliates, hereby grants to Roche an exclusive (even as to Sarepta and its Affiliates) license (with the right to grant Sublicenses through multiple tiers only as provided in Section 2.3.1 (Rights to Grant Sublicenses)) under the Sarepta Technology to (a) Develop Licensed Products and any corresponding Sarepta Diagnostic Products in the Field in the Roche Territory solely in accordance with the Roche Territory Development Plan solely for Commercialization of such Licensed Products in the Field in the Roche Territory, (b) Manufacture Licensed Products in the Territory for use in the Roche Territory in the Field in accordance with this Agreement as provided in Article 8 (Manufacturing and Supply), (c) perform Medical Affairs activities with respect to Licensed Products and any corresponding Sarepta Diagnostic Products in the Field in the Territory solely in accordance with the Roche Medical Affairs Plan and the Joint Global Medical Affairs Plan, and (d) Commercialize Licensed Products and any corresponding Sarepta Diagnostic Products in the Field in the Roche Territory and (e) otherwise perform Roche's obligations under this Agreement.

2.2 **Grant of License to Sarepta**. Subject to the terms of this Agreement (including Section 2.4 (No Other Rights and Retained Rights)), Roche, on behalf of itself and its Affiliates, hereby grants to Sarepta a royalty-free, fully paid-up license (with the right to grant Sublicenses through multiple tiers only as provided in Section 2.3.1 (Rights to Grant Sublicenses)) under the Roche Background Technology and the Roche Collaboration Technology to (a) Develop Licensed Products and any corresponding Sarepta Diagnostic Products in the Field worldwide solely in accordance with the Joint Global Development Plan, (b) perform Development activities with respect to Licensed Products, the data from which activities may be used solely to obtain or maintain Regulatory Approval for the Licensed Products in the Sarepta Territory, (c) perform Medical Affairs activities with respect to Licensed Products worldwide solely in accordance with the Joint Global Medical Affairs Plan and the Sarepta Medical Affairs Plan, (d) Manufacture the Licensed Products and any corresponding Sarepta Diagnostic Products worldwide in accordance with this Agreement, (e) Commercialize the Licensed Products and any corresponding Sarepta Diagnostic Products in the Sarepta Territory, and (f) otherwise perform Sarepta's obligations under this Agreement. The license granted by Roche to Sarepta under this Section 2.2 (Grant of License to Sarepta) (i) under the Roche Collaboration Technology will be exclusive in the Sarepta Territory and non-exclusive in the Roche Territory and, (ii) under the Roche Background Technology will be non-exclusive.

2.3 Sublicensing and Subcontracting Terms.

2.3.1 Rights to Grant Sublicenses. Subject to the terms of this Agreement (including Roche's rights of first negotiation set forth under Section 2.8 (Rights of First Negotiation)), each Party (the "**Sublicensing Party**") will have the right to grant to one or more of its Affiliates or any Third Party sublicenses of the rights granted to such Sublicensing Party under Section 2.1 (Grant of Licenses to Roche) or Section 2.2 (Grant of Licenses to Sarepta), as applicable (each, a "**Sublicense**"), without the other Party's consent (which rights may be further granted through multiple tiers, in each case, in accordance with this Agreement), except that with regards to any Sublicense of rights in any Roche Major Countries (other than the grant of a Sublicense to Chugai for rights in Japan), Roche may only grant Sublicenses upon receipt of Sarepta's prior written consent, such consent not to be unreasonably withheld, conditioned, or delayed. Subject to Section 2.3.2 (Termination of Sublicenses), each Sublicensee shall hold its rights subject to and contingent on the rights licensed to the applicable Sublicensing Party under the terms of this Agreement.

2.3.2 Termination of Sublicenses. If the licenses granted to the Sublicensing Party under Section 2.1 (Grant of Licenses to Roche) or Section 2.2 (Grant of Licenses to Sarepta) are terminated with respect to a particular Licensed Product in one or more countries, then all Sublicenses granted by such Sublicensing Party with respect to such Licensed Products in such country or countries shall automatically terminate; *provided, however*, that if (a) Sarepta terminates any licenses under Section 2.1 (Grant of Licenses to Roche) with respect to a particular Licensed Product in one or more countries pursuant to Section 14.2 (Termination for Breach) for material breach by Roche, then, upon the request of any Sublicensee of Roche that is not then in breach of its Sublicense or the terms of this Agreement applicable to such Sublicensee for the grant of a direct license from Sarepta to Exploit the applicable Licensed Products in the applicable country or countries, Sarepta will enter into a written agreement directly with such Sublicensee as soon as reasonably practicable after such termination on the same terms as this Agreement, taking into account any difference in license scope, territory, and duration of the sublicense grant.

2.3.3 Subcontracting. Each Party (the "**Subcontracting Party**") may engage one or more Affiliates or Third Party subcontractors to perform services in furtherance of the performance of the Subcontracting Party's obligations or exercise of the Subcontracting Party's rights under this Agreement; *provided* that (a) the Subcontracting Party will not engage any such Affiliate or Third Party that has been Debarred/Excluded; (b) no engagement of any such Affiliate or Third Party subcontractors will relieve the Subcontracting Party of its obligations under this Agreement or any liability hereunder, and (c) the Subcontracting Party will be liable for any act or omission of any Affiliate or Third Party subcontractor that is a breach of any of the Subcontracting Party's obligations under this Agreement as though the same were a breach by the Subcontracting Party, and the non-Subcontracting Party will have the right to proceed directly against the Subcontracting Party without any obligation to first proceed against such Affiliate or Third Party subcontractor.

2.3.4 **Sublicenses**. Prior to granting any Sublicenses to any Third Parties pursuant to Section 2.3.1 (Rights to Grant Sublicenses) and with regard to Roche for the Roche Major Countries only, the Sublicensing Party shall provide written notice to the other Party identifying (a) the Sublicensing Party's intention to grant a Sublicense to any Third Party of the rights granted to such Party under this Agreement, (b) the purpose of such Sublicense, and (c) the identity of such Third Party. Each Sublicense granted by a Sublicensing Party pursuant to Section 2.3.1 (Right to Grant Sublicenses) shall be made pursuant to a written agreement that is subject and subordinate to this Agreement. Each Sublicense agreement shall (i) be consistent with the terms of this Agreement, (ii) require that such Sublicensee undertake obligations of confidentiality and non-use regarding Confidential Information that are at least as protective as those undertaken by the Sublicensing Party with respect to Confidential Information pursuant to Article 12 (Confidentiality), and (iii) require that the Sublicensee assign or license to the Sublicensing Party all Patent Rights and Know-How developed or invented by the Sublicensee that are necessary or useful to Exploit the Licensed Products and corresponding Sarepta Diagnostic Products (such that the Sublicensing Party Controls such Patent Rights and Know-How for the purposes of this Agreement). As soon as reasonably practicable after execution by Roche or any of its Affiliates of any Sublicense agreement with a Third Party for a Sublicense Roche will provide Sarepta with a copy of such agreement (which copy may be redacted to remove provisions that are not necessary to monitor compliance with this Agreement, including this Section 2.3.4 (Sublicenses)). Notwithstanding any Sublicense, the Sublicensing Party will be liable for any act or omission of any Sublicensee that is a breach of any of the Sublicensing Party's obligations under this Agreement as though the same were a breach by the Sublicensing Party, and the non-Sublicensing Party will have the right to proceed directly against the Sublicensing Party without any obligation to first proceed against such Sublicensee.

2.4 **No Other Rights and Retained Rights**. Nothing in this Agreement will be interpreted to grant a Party any rights under any intellectual property rights owned or Controlled by the other Party or any of its Affiliates, including Sarepta Technology, Roche Background Technology, or Roche Collaboration Technology, in each case, that are not expressly granted herein, whether by implication, estoppel, or otherwise. Roche will not practice or otherwise Exploit the Sarepta Technology, and Sarepta will not practice or otherwise Exploit the Roche Background Technology or Roche Collaboration Technology, in each case, other than as expressly licensed and permitted under this Agreement. Any rights not expressly granted to a Party by the other Party under this Agreement are hereby retained by such other Party. Without limiting the foregoing, Sarepta hereby expressly retains the right to Exploit any Option Product in accordance with this Agreement (subject to Roche's exclusive rights under this Agreement upon exercise of the applicable Option for such Option Product) and to perform (a) Development activities for the Licensed Products and Sarepta Diagnostic Products worldwide in accordance with the Agreement; *provided* that the right to perform such Development activities for the Licensed Products and Sarepta Diagnostic Products in the Roche Territory shall be limited to the activities set forth in the Joint Global Development Plan, (b) Medical Affairs activities for the Licensed Products and Sarepta Diagnostic Products worldwide in accordance with the Joint Global Medical Affairs Plan and the Sarepta Medical Affairs Plan, (c) Commercialization activities for the Licensed Products and Sarepta Diagnostic Products in the Sarepta Territory, (d) Manufacturing activities worldwide in accordance with this Agreement, and (e) Sarepta's other obligations under this Agreement in accordance with this Agreement.

2.5 In-Licenses.

2.5.1 Existing In-Licenses. The agreements listed on **Schedule 2.5.1** (Existing In-Licenses) are Existing In-Licenses entered into by Sarepta prior to the Effective Date. Notwithstanding any provision to the contrary set forth in this Agreement, each Party stipulates and agrees that (a) the rights and licenses granted to the other Party under this Agreement are subject to the applicable terms of all Existing In-Licenses with respect to the Sarepta Technology or Roche Technology, as applicable, (b) each Party's ability to comply with its obligations, and grant rights and licenses to the other Party, under this Agreement may be limited by requirements and restrictions imposed on the other Party under the Existing In-Licenses with respect to the Sarepta Technology or Roche Technology, as applicable, that is being sublicensed under such Existing In-Licenses, and (c) neither Party will be required to take any action or inaction that would cause such Party to be in breach of any Existing In-License. Each Party shall maintain all Existing In-Licenses to which it is a Party in full force and effect and shall not, either directly or indirectly, (i) take or omit to take any action that would cause a termination of, or breach under, any such Existing In-Licenses, (ii) accept additional obligations to the extent such additional obligations would adversely impact the other Party or (iii) waive any of its rights under any such Existing In-Licenses. Sarepta acknowledges and agrees that it is solely responsible for ensuring its compliance (including any obligations to pay its counterparties any owed amounts) with such Existing In-Licenses and will give Roche notice of any material breach under any Existing In-License promptly upon receipt thereof from the applicable counterparty. In such case, if Sarepta has not cured, or put in place a plan to cure, such material breach within 30 days of the date of such notice from Sarepta (or such longer time as may be agreed by the Parties), then, to the extent practicable, Roche will have the right to cure any such uncured material breach of the applicable Existing In-License. If an Existing In-License is nonetheless terminated, then Sarepta shall use reasonable efforts to reasonably assist Roche in obtaining a direct license from the applicable counterparty to such Existing In-License as soon as reasonably practicable.

2.5.2 Potential In-Licenses. Either Party may determine that the Exploitation of a Licensed Product or a Sarepta Diagnostic Product in its Territory may require a grant of rights under either (a) additional Patent Rights or (b) Patent Rights together with Know-How, in each case, Controlled by Third Parties, to avoid infringement or misappropriation of the applicable Patent Rights or Know-How Controlled by such Third Party, whether by license or acquisition (each, a "**Potential In License**"). [**].

2.5.3 Collaboration In-Licenses. [**].

2.5.4 [**].

2.5.5 Scope of Sarepta Future In-Licenses. **[**]**.

2.6 Exclusivity.

2.6.1 Exclusivity Obligation. Subject to Section 2.5.5(a)(C) ([**]), Section 2.5.5(b)(B) ([**]), and Section 2.6.2 ([**]), Roche and its Affiliates will not, directly or indirectly by itself or in collaboration with a Third Party, perform any Clinical Trials that relate to, or Commercialize, any Gene Therapy Product, Gene Editing-Product, or antisense oligonucleotide product that targets the dystrophin gene to induce exon skipping, in each case, for the treatment, prevention, cure or amelioration of DMD ("**Competitive Product**") during the time period beginning on the Execution Date (to the extent permissible under Applicable Law) and continuing until the date that is five years following the Effective Date (the "**Exclusivity Period**"); *provided* that on an Option Product-by-Option Product basis:

(a) if Roche exercises an Option for a Gene Therapy Product, then the Exclusivity Period for Gene Therapy Products for the treatment, prevention, cure, or amelioration of DMD will extend from the date such Option is exercised until the fifth anniversary of such date;

(b) if Roche exercises an Option for a Gene-Editing Product, then the Exclusivity Period for Gene-Editing Products for the treatment, prevention, cure, or amelioration of DMD will extend from the date such Option is exercised until the fifth anniversary of such date; and

(c) if Roche exercises the Option for the Exon-Skipping Products, then the Exclusivity Period for antisense oligonucleotide product that targets the dystrophin gene to induce exon skipping will extend from the date such Option is exercised until the fifth anniversary of such date, and if Roche does not exercise the Option for the Exon-Skipping Products during the Option Exercise Period for the Exon-Skipping Products, then the Exclusivity Period for antisense oligonucleotide product that targets the dystrophin gene to induce exon skipping will end upon the expiration or termination of such Option Exercise Period.

For clarity, the exclusivity obligations set forth in this Section 2.6.1 (Exclusivity Obligation) does not apply to any Licensed Products under this Agreement.

2.6.2 [**].

2.7 Option.

2.7.1 Grant of Options. Sarepta hereby grants to Roche the exclusive option to be granted the exclusive license under the Sarepta Technology set forth in Section 2.1 (Grant of Licenses to Roche) (a) for, collectively, all Exon-Skipping Products together with any corresponding Sarepta Diagnostic Products, (b) on an Option Product-by-Option Product basis for Gene-Editing Option Products together with any corresponding Sarepta Diagnostic Products, and (c) on an Option Product-by-Option Product basis for Gene Therapy Option Products together with any corresponding Sarepta Diagnostic Products (each, an "**Option**").

2.7.2 Option Data Package.

(a) **Exon-Skipping Products Data Package**. With regard to the Exon-Skipping Products, Sarepta will deliver to Roche an Option Data Package for all Exon-Skipping Products [**].

(b) **Gene-Editing Option Products Data Package**. With regard to the Gene-Editing Option Products, on a Gene-Editing Option Product-by-Gene-Editing Option Product basis, [**], Sarepta will deliver to Roche an Option Data Package for such Gene-Editing Option Product.

(c) **Gene Therapy Option Product Data Packages**. With regards to Gene Therapy Option Products, on a Gene Therapy Option Product-by-Gene Therapy Option Product basis, [**], Sarepta will deliver to Roche an Option Data Package for such Gene Therapy Option Product.

(d) **Incomplete Option Data Packages and Right to Ask Questions**. Following receipt of an Option Data Package for the Exon-Skipping Products or any Gene-Editing Option Product or Gene Therapy Option Product, Roche will have 10 Business Days to notify Sarepta if such Option Data Package is missing any information that Roche reasonably needs in order to evaluate whether or not to exercise the Option for the Exon-Skipping Products or such Gene-Editing Option Product or Gene Therapy Option Product (as applicable), which notice will describe the information that Roche believes is missing from such Option Data Package. If and to the extent in Sarepta's possession and Control, Sarepta will provide Roche with the missing information identified in such notice no later than 10 Business Days after the date of Roche's request therefor and in such case, the Option Exercise Period will be extended to the extent necessary such that there are 10 days from the date of receipt of such information remaining prior to the expiration of the Option Exercise Period. In addition, until expiry of the applicable Option Exercise Period Roche shall have the right to ask questions to Sarepta relating to the Option Data Package, and Sarepta shall use reasonable efforts to respond to all such reasonable questions of Roche.

2.7.3 Exercise of Option. Roche may exercise the Option for the Exon-Skipping Products, or for any Gene-Editing Option Product or Gene Therapy Option Product at any time during the applicable Option Exercise Period by delivering to Sarepta written notice of such exercise (each, an "**Option Exercise Notice**"). Such Option shall become effective upon Sarepta's receipt of the applicable Option Exercise Fee paid in accordance with Section 9.3 (Option Exercise Fees), *provided*, *however*, if Roche exercises the Option for the Exon-Skipping Products, then such Option will become effective as of [**]. By way of illustration, if Roche exercises the Option for the Exon-Skipping Products between [**], then the Option will become effective as of [**].

2.7.4 Effect of Option Exercise.

(a) **For Exon-Skipping Products**. Upon Roche's exercise of the Option for the Exon-Skipping Products in accordance with Section 2.7.3 (Exercise of Option), from and after the effective date of the Option as set forth under Section 2.7.3 (Exercise of Option), all Exon-Skipping Products will be Licensed Products, and no longer Option Products, for all purposes of this Agreement. [**].

(b) **For Gene-Editing Option Products**. Upon Roche's exercise of the Option for any Gene-Editing Option Product in accordance with Section 2.7.3 (Exercise of Option), from and after the date of receipt of the Option Exercise Fee for each such Gene-Editing Option Product, such Option Product will be a Licensed Product, and no longer a Gene-Editing Option Product, for all purposes of this Agreement.

(c) **For Gene Therapy Option Products**. Upon Roche's exercise of the Option for any Gene Therapy Option Product in accordance with Section 2.7.3 (Exercise of Option), from and after the date of receipt of the Option Exercise Fee for each such Gene Therapy Option Product, such Option Product will be a Licensed Product, and no longer a Gene Therapy Option Product, for all purposes of this Agreement.

(d) **Sarepta Patent Rights and Patent Prosecution**. Upon the exercise of the Option for an Option Product by Roche in accordance with Section 2.7.3 (Exercise of Option), the Option Product Patent Rights that are necessary or useful to Exploit such Licensed Product in the Roche Territory will become Sarepta Patent Rights, and the prosecution of such Patent Rights shall be governed by Section 10.5 (Prosecution of Sarepta Patent Rights) thereafter.

(e) **Sarepta Know-How**. Upon the exercise of the Option for an Option Product by Roche in accordance with Section 2.7.3 (Exercise of Option), the Option Product Know-How that is necessary or useful to Exploit such Licensed Product will become Sarepta Know-How for all purposes under this Agreement.

(f) **Updates to the Development Plans**. No later than 30 days following Sarepta's receipt of the Option Exercise Notice for the Exon-Skipping Products or any Gene-Editing Option Product or Gene Therapy Option Product, Roche will provide to the JDC in accordance with Section 4.4 (Roche Territory Development Plan) an update to the Roche Territory Development Plan that includes such Option Products ([**]). In addition, following such exercise of the Option for such Option Products ([**]), in accordance with Section 4.3.1 (Joint Global Development Plan), the JDC will update the Joint Global Development Plan to include such Option Products ([**]) and until the JSC approves such an update, all activities relating to such Option Products ([**]) and any corresponding Sarepta Diagnostic Products under the Option Product Development Plan will be deemed to be included in the Joint Global Development Plan as activities relating to such Option Product and Sarepta Diagnostic Products.

(g) **Addition of [**] to the Development Plans**. Reasonably in advance of, but at least [**] prior to, the [**], Sarepta will provide written notice to Roche of the planned commencement of such activities. No later than [**] following Roche's receipt of such written notice from Sarepta, Roche will [**]. In addition, following such written notice from Sarepta to Roche, [**].

2.7.5 **Termination of Option**. If (a) Roche does not deliver to Sarepta the Option Exercise Notice for the Exon-Skipping Products or any Gene-Editing Option Product or Gene Therapy Option Product, as applicable, prior to the expiration of the Option Exercise Period for such Exon-Skipping Products or such other Gene-Editing Option Product or Gene Therapy Option Product, (b) Roche exercises the Option for the Exon-Skipping Products or any other Gene-Editing Option Product or Gene Therapy Option Product but does not pay to Sarepta the applicable Option Exercise Fee in accordance with Section 9.3 (Option Exercise Fees), or (c) Roche notifies Sarepta in writing that it does not wish to exercise the Option for the Exon-Skipping Products or any Gene-Editing Option Product or Gene Therapy Option Product, then in each case ((a) – (c)), the Option with respect to the Exon-Skipping Products or such other Gene-Editing Option Product or any Gene Therapy Option Product, as applicable, will terminate and Roche will no longer have any rights under this Agreement with respect to such Exon-Skipping Products or such other Gene-Editing Option Product or Gene Therapy Option Product, as applicable.

2.8 Rights of First Negotiation.

2.8.1 DMD ROFN. If, at any time during the Term, Sarepta seeks to offer to any Third Party any rights to Commercialize one or more Licensed Products in the Sarepta Territory, then Sarepta will provide to Roche notice of the proposed scope of, and the material terms that would apply to, such Commercialization rights that Sarepta proposes to grant with respect to the applicable Licensed Products (each, a "**DMD ROFN Notice**"). Thereafter, Roche will have a right, exercisable no later than [**] after receipt of any such DMD ROFN Notice from Sarepta, to notify Sarepta in writing as to whether Roche desires to negotiate for rights to Develop, perform Medical Affairs activities, and Commercialize the applicable Licensed Products and any corresponding Sarepta Diagnostic Products in the Sarepta Territory (each, a "**DMD ROFN Exercise Notice**"). If Roche provides a DMD ROFN Exercise Notice to Sarepta within such [**] period indicating its desire to negotiate for rights to Develop, perform Medical Affairs activities, and Commercialize such Licensed Product and any such corresponding Sarepta Diagnostic Product in the Sarepta Territory, then Roche will have a right for [**] from the date of Sarepta's receipt of the DMD ROFN Notice (each, a "**DMD ROFN Negotiation Period**") to negotiate with Sarepta in good faith the terms of a definitive agreement (or amendment to this Agreement) pursuant to which Sarepta would grant to Roche the rights to Develop, perform Medical Affairs activities, and Commercialize such Licensed Products and such corresponding Sarepta Diagnostic Products in the Sarepta Territory. Neither Party will have any obligation to enter into any agreement or amendment to this Agreement granting rights to Roche to Develop, perform Medical Affairs activities, or Commercialize any Licensed Product or corresponding Sarepta Diagnostic Product in the Sarepta Territory. If the applicable DMD ROFN Negotiation Period expires before the Parties have entered into an agreement or amendment to this Agreement with respect to Roche's Development, performance Medical Affairs activities, and Commercialization of the applicable Licensed Products and corresponding Sarepta Diagnostic Products in the Sarepta Territory, then for a period of [**] after the expiration of the DMD ROFN Negotiation Period Sarepta will have the right to negotiate and enter into a definitive agreement with any Third Party with respect to a grant of rights to Develop, perform Medical Affairs activities, or Commercialize the applicable Licensed Products and corresponding Sarepta Diagnostic Products in the Sarepta Territory. If Sarepta does not enter into any definitive agreement with any such Third Party as provided in the immediately preceding sentence during such [**] period, then with respect to one additional DMD ROFN Notice, Sarepta shall again be subject to Roche's rights under, and must comply with the procedures set forth in, this Section 2.8.1 (DMD ROFN) with respect to any proposed grant of rights to Commercialize the applicable Licensed Products in the Sarepta Territory. Following expiration of the second DMD ROFN Negotiation Period without the Parties having entered into an agreement or amendment to this Agreement with respect to Roche's Development, performance of Medical Affairs, and Commercialization of the applicable Licensed Products and corresponding Sarepta Diagnostic Products in the Sarepta Territory, Sarepta will have no further obligation to negotiate with Roche with respect to any grant of rights to Commercialize such Licensed Products in the Sarepta Territory and will be free to negotiate and enter into an agreement with a Third Party with respect to any grant of rights to Commercialize the applicable Licensed Products and corresponding Sarepta Diagnostic Products in the Sarepta Territory, *provided* that the agreement with such Third Party will be consistent with the then-current version of the Joint Global Branding and Marketing Strategy as reviewed by the JCC pursuant to Section 3.4.3(c).

2.8.2 **LGMD ROFN**. If, at any time during the Term, Sarepta seeks to offer to any Third Party rights to Commercialize one or more LGMD Products in any part of the Territory, then Sarepta will provide to Roche notice of the proposed scope of rights to be granted to such LGMD Products (the "**LGMD ROFN Rights**"), and all material terms that would apply to such LGMD ROFN Rights (each, a "**LGMD ROFN Notice**").

2.8.3 **LGMD ROFN Evaluation Period**. After receipt of a LGMD ROFN Notice, Roche will have the right, exercisable no later than [**] after receipt of any such LGMD ROFN Notice from Sarepta, to notify Sarepta in writing as to whether Roche desires to proceed with an evaluation of the LGMD Product that is the subject of such LGMD ROFN Notice (each, a "**LGMD Initial Response**"). If the LGMD Initial Response indicates that Roche is not interested in further evaluating such LGMD Product (or Roche fails to provide the LGMD Initial Response within such [**] period), then Roche shall be deemed to have declined the LGMD ROFN Rights with respect to such LGMD Product. If Roche provides a LGMD Initial Response within such [**] period indicating that Roche desires to evaluate such LGMD Product, then within [**] after receipt of such LGMD Initial Response, Sarepta shall make available to Roche the LGMD Diligence Package for such LGMD Product. For [**] after the date on which Roche receives such LGMD Diligence Package (the "**LGMD Evaluation Period**"), Roche shall have the right to review the information in such LGMD Diligence Package to evaluate such LGMD Product for the purpose of determining whether to negotiate with Sarepta with respect to the LGMD ROFN Rights for such LGMD Product.

Following receipt of the LGMD Diligence Package, Roche will have [**] to (a) notify Sarepta if such LGMD Diligence Package is missing any information that Roche reasonably needs in order to evaluate whether or not to exercise the DMD ROFN, which notice will describe the information that Roche believes is missing from such LGMD Diligence Package. If and to the extent in Sarepta's possession and Control, Sarepta will provide Roche with the missing information identified in such notice no later than [**] after the date of Roche's request therefor and in such case, the LGMD Evaluation Period will be extended to the extent necessary such that there are [**] from the date of receipt of such information remaining prior to the expiration of the LGMD Evaluation Period. In addition, until expiry of the applicable LGMD Evaluation Period Roche shall have the right to ask questions to Sarepta relating to the LGMD Diligence Package, and Sarepta shall use reasonable efforts to respond to all such reasonable questions of Roche.

2.8.4 **LGMD ROFN Exercise**. Prior to the expiration of the LGMD Evaluation Period, Roche shall notify Sarepta in writing as to whether Roche desires to negotiate the terms of a definitive agreement (or amendment to this Agreement) with respect to a grant to Roche of such LGMD ROFN Rights (each, a "**LGMD ROFN Exercise Notice**"). If Roche provides a LGMD ROFN Exercise Notice to Sarepta prior to the expiration of the LGMD Evaluation Period indicating its desire to so negotiate for a grant of such LGMD ROFN Rights, then for the [**] period beginning on the date of Sarepta's receipt of the LGMD ROFN Exercise Notice (each, a "**LGMD ROFN Negotiation Period**") the Parties will negotiate in good faith the terms of a definitive agreement (or amendment to this Agreement) pursuant to which Sarepta would grant to Roche rights that reasonably reflect the scope and material terms provided in such LGMD ROFN Notice. If the applicable LGMD ROFN Negotiation Period expires before the Parties have entered into an agreement or amendment to this Agreement with respect to a grant the applicable LGMD ROFN Rights, then for a period of [**] after the expiration of the LGMD ROFN Negotiation Period, Sarepta will have the right to negotiate and enter into a definitive agreement with any Third Party with respect to a grant of such LGMD ROFN Rights. If during such [**] period, Sarepta does not enter into any definitive agreement with such Third Party as provided in the immediately preceding sentence during such [**] period, then with respect to one additional LGMD ROFN Notice for the same LGMD Product Sarepta shall again be subject to Roche's LGMD ROFN Rights under, and must comply with the procedures set forth in, this Section 2.8.4 (LGMD ROFN Exercise) with respect to any proposed grant of such LGMD ROFN Rights to a Third Party. Following expiration of the second LGMD ROFN Negotiation Period without the Parties having entered into an agreement or amendment to this Agreement with respect to a grant of LGMD ROFN Rights from Sarepta to Roche, Sarepta will have no further obligation to negotiate with Roche with respect to any grant of LGMD ROFN Rights to Roche and will be free to negotiate and enter into an agreement with any Third Party granting the LGMD ROFN Rights to such Third Party.

ARTICLE 3
GOVERNANCE

3.1 **Joint Steering Committee**.

3.1.1 **Formation and Purpose of the JSC**. Within [**] days after the Effective Date, Sarepta and Roche will establish a Joint Steering Committee ("**JSC**"), which will have the responsibilities set forth in this Article 3 (Governance). The JSC will dissolve upon the expiration of the Term. The JSC shall have no responsibility and authority other than that which is expressly set forth in this Article 3 (Governance).

3.1.2 **Membership**. Each Party will designate up to [**] representatives with appropriate knowledge, expertise, and decision-making authority to serve as members of the JSC; *provided* that [**]. Each Party may replace its JSC representatives at any time upon written notice to the other Party. Sarepta will designate one of its JSC members as one of the co-chairpersons of the JSC and Roche will designate one of its members as the other co-chairperson of the JSC. For each Calendar Year, the Alliance Managers will alternate serving in the role of "lead Alliance Manager" with respect to the JSC. The lead Alliance Manager or his or her designee, in collaboration with the co-chairpersons, will be responsible for calling meetings, preparing and circulating an agenda in advance of each meeting, and preparing and issuing minutes of each meeting within 30 days thereafter. Such minutes will be finalized upon endorsement by all JSC members.

3.1.3 **Meetings**. The JSC will hold meetings at such times as it elects to do so, but in no event will such meetings be held less frequently than twice per Calendar Year, unless otherwise agreed by the Parties. Both Parties shall have the right to ask for ad-hoc meetings and the Party not requesting for such meeting shall be obliged to participate at such meeting as soon as feasible. The JSC will meet alternatively at Roche's facilities in Basel, Switzerland and Sarepta's facilities in Cambridge, MA, U.S. or at such locations as the Parties may otherwise agree, with the first JSC meeting to be held at Sarepta's offices in Cambridge, MA, U.S. Meetings of the JSC may be held by audio or video teleconference with the consent of each Party; *provided*, *however*, that at least one JSC meeting per Calendar Year will be held in-person. The Alliance Manager of each Party will attend each meeting of the JSC as a non-voting participant. Each Party will be responsible for all of its own expenses of participating in any JSC meeting.

3.1.4 **Meeting Agendas**. The JSC meeting agenda for each meeting of the JSC will be finalized at least [**] Business Days in advance of such meeting, or such other shorter time period as the circumstances allow in the case of an ad-hoc meeting.

3.1.5 **Specific Responsibilities of the JSC**. The responsibilities of the JSC will be to:

(a) manage the overall strategic alignment between the Parties under this Agreement and maintain the relationship between the Parties;

(b) [**];

(c) approve any material update to the Joint Global Development Plan or Joint Global Development Budget (as described in Section 4.3.1 (Joint Global Development Plans));

(d) review and discuss the initial Option Product Development Plan and any material update to the Option Product Development Plan (as described in Section 4.3.2 (Option Product Development Plans));

(e) approve the initial Roche Territory Development Plan and any material updates thereto (as described in Section 4.4 (Roche Territory Development Plan));

(f) approve any matters related to the Development of the Licensed Products or Medical Affairs activities with respect to the Licensed Products referred to the JSC by the JDC;

(g) approve the initial Joint Global Medical Affairs Plan, the initial Joint Global Medical Affairs Budget, the initial Roche Medical Affairs Plan, and the initial Sarepta Medical Affairs Plan, and any material updates to any of the foregoing (in each case, as described in Section 7.1 (Medical Affairs Plans));

(h) approve the initial Development Demand Forecast Plan created by the JMC and any material updates to the Development Demand Forecast Plans (as described in Section 8.1 (Forecast));

(i) approve the initial Capacity Plan and any material updates thereto (as described in Section 8.2 (Capacity Plan));

(j) approve the initial Manufacturing Plan and any material updates thereto (as described in Section 8.8 (Manufacturing Plan));

(k) approve, if applicable, the Manufacturing Transition Plan, as described in Section 8.11.2 (Manufacturing Transition Period);

(l) approve the Joint Global Branding and Marketing Strategy and any material updates thereto (as described in Section 6.4 (Branding and Marketing Plans));

(m) approve the initial Roche Territory Branding and Marketing Plan and initial Sarepta Territory Branding and Marketing Plan and any material updates thereto (as described in Section 6.4 (Brand Plans));

(n) approve any matters related to the Commercialization of the Licensed Products in the Roche Territory and the Sarepta Territory referred to the JSC by the JCC;

(o) approve any matters related to the Manufacture of the Licensed Products referred to the JSC by the JMC;

(p) approve the accepted objective measurement (and the related minimal outcome to be achieved) of a clinically relevant biomarker for purposes of defining Proof of Concept Trial Success for each Option Product (as described in Section 1.196 (Proof of Concept Trial Success));

(q) approve the initial Joint Publication Strategy and updates thereto (as described in Section 12.6 (Publications));

(r) establish and delegate specifically defined duties to the JDC, JCC, JMC, or IP Committee; and

(s) attempt to resolve any matters escalated to the JSC by the JDC, JCC, JMC or IP Committee.

3.2 Subcommittees.

3.2.1 Formation; Authority. The JSC will establish and delegate specifically-defined duties to the JDC, the JCC, the JMC, and the IP Committee (each a "**Subcommittee**"). Each Subcommittee and its activities will be subject to the oversight of, and will report to, the JSC. No Subcommittee may exceed its authorities specified for the JSC in this Article 3 (Governance). Any disagreement between the representatives of the Parties on a Subcommittee will be referred to the JSC for resolution in accordance with Section 3.7 (Decision-Making).

3.2.2 **Subcommittee Leadership and Meetings**. Sarepta will designate a co-chairperson of each Subcommittee and Roche will designate a co-chairperson of each Subcommittee, each of whom will be a Party's representative who is a member of such Subcommittee. Each Calendar Year, the co-chairpersons of each Subcommittee will alternate serving in the role of "lead co-chairperson." The lead co-chairperson or his or her designee will be responsible for calling meetings, preparing and circulating an agenda in advance of each meeting, and preparing and issuing minutes of each meeting within [**] days thereafter. Such minutes will be finalized upon endorsement of all Subcommittee members. Each Party may replace its representatives and co-chairpersons on each such Subcommittee at any time upon written notice to the other Party. Each Subcommittee will hold meetings at such times as it elects to do so and at such locations as the Parties may agree upon or, if agreed by the Parties, by audio or video teleconference. Each Party will be responsible for all of its own expenses of participating in any Subcommittee meeting.

3.3 **Joint Development Committee**.

3.3.1 **Formation and Purpose of the JDC**. Within [**] days after the Effective Date, Sarepta and Roche will establish a Joint Development Committee ("**JDC**"), which will be a Subcommittee of the JSC and will have the responsibilities set forth in this Article 3 (Governance). The JDC will dissolve upon completion of all Development activities and Medical Affairs activities with respect to the Licensed Products.

3.3.2 **Membership of the JDC**. Each Party will designate up to [**] representatives with appropriate knowledge, expertise, and decision-making authority to serve as members of the JDC; *provided* that [**]. Each Party may replace its JDC representatives and co-chairpersons at any time upon written notice to the other Party. The Alliance Manager of each Party (or his or her designee) may attend meetings of the JDC as a non-voting participant.

3.3.3 **Specific Responsibilities of the JDC**. The responsibilities of the JDC will be to:

(a) oversee all Development activities and Medical Affairs activities for the Licensed Products under this Agreement in the Territory;

(b) (i) review and discuss the initial Joint Global Development Plan, the initial Joint Global Development Budget (as described in Section 4.3.1 (Joint Global Development Plan)), (ii) prepare all updates to the Joint Global Development Plan (such as country and Clinical Trial site selection in the Roche Territory) and the Joint Global Development Budget (as described in Section 4.3.1 (Joint Global Development Plan)), and (iii) refer any material update to the Joint Global Development Plan or Joint Global Development Budget to the JSC to approve;

(c) incorporate a joint medical affairs team comprising of [**] of each Party ("**Joint Medical Affairs Team**") to (i) prepare the initial Joint Global Medical Affairs Plan (as described in Section 7.1 (Medical Affairs Plans)), (ii) prepare the initial Joint Global Medical Affairs Budget, (iii) review and discuss the initial Roche Medical Affairs Plan (as described in Section 7.1 (Medical Affairs Plans)), (iv) review and discuss the initial Sarepta Medical Affairs Plan (as described in Section 7.1 (Medical Affairs Plans)), (v) review and discuss all updates to the Joint Global Medical Affairs Plan, the Joint Global Medical Affairs Budget, the Roche Medical Affairs Plan, and the Sarepta Medical Affairs Plan, (vi) refer the initial Joint Global Medical Affairs Plan, the initial Joint Global Medical Affairs Budget, the initial Roche Medical Affairs Plan, the initial Sarepta Medical Affairs Plan, and all material updates to any of the foregoing to the JSC to approve.

The first such review and discussion by the Joint Medical Affairs Team shall occur no later than [**] following the Effective Date with respect to any Lead Product and no later than [**] following exercise of the Option with respect to the Exon-Skipping Products or any other Option Product. Any subsequent review and approval, to the extent required, will occur annually thereafter at an appropriate time as agreed by the JDC, or more frequently as may be required during the Term.

(d) review and discuss the initial Option Product Development Plan (as described in Section 4.3.2 (Option Product Development Plan));

(e) review and discuss the initial Roche Territory Development Plan and all updates to the foregoing (as described in Section 4.4 (Roche Territory Development Plan)), and (ii) refer the initial Roche Territory Development Plan and all material updates thereto to the JSC to approve;

(f) review and discuss the overall strategy regarding Regulatory Approval of each Licensed Product throughout the Sarepta Territory and Roche Territory, and oversee the implementation of, and discuss the progress regarding, the same;

(g) review and discuss principal issues raised in each Material Communication with Regulatory Authorities with respect to the Licensed Products throughout the Sarepta Territory and Roche Territory;

(h) share information related to, and review and discuss activities and progress under, the Joint Global Development Plan and the Roche Territory Development Plan, including through updates from each Party of the status of Development for the Licensed Products in each Party's Territory, as described in Section 4.6 (Development Reports);

(i) share information related to, and review and discuss activities and progress under, the Option Product Development Plan, including through updates from Sarepta of the status of Development for the Option Products, as described in Section 4.6 (Development Reports);

(j) review and discuss [**] and refer such matter to the JSC to approve;

(k) review and discuss updates provided by each Party regarding Medical Affairs conducted by such Party and progress under the Joint Global Medical Affairs Plan, the Roche Medical Affairs Plan, and the Sarepta Medical Affairs Plan (in each case, as described in Section 7.2 (Medical Affairs Activities)); and

(l) review and discuss the initial Joint Publication Strategy and updates thereto (as described in Section 12.6 (Publications)) and refer the initial Joint Publication Strategy and all updates thereto to the JSC to approve.

3.4 Joint Commercialization Committee.

3.4.1 Formation and Purpose of the JCC. Within [**] days following the Effective Date, the Parties will establish a Joint Commercialization Committee (the "**JCC**"), which will be a Subcommittee of the JSC and will have the responsibilities set forth in this Article 3 (Governance). The JCC will dissolve upon the expiration of the final Royalty Term in the Roche Major Countries.

3.4.2 **Membership of the JCC**. Each Party will designate up to [**] representatives with appropriate knowledge, expertise, and decision-making authority to serve as members of the JCC; *provided* that [**]. Each Party may replace its JCC representatives and co-chairpersons at any time upon written notice to the other Party. The Alliance Manager of each Party (or his or her designee) may attend meetings of the JCC as a non-voting participant.

3.4.3 **Specific Responsibilities of the JCC**. The responsibilities of the JCC will be to:

(a) oversee all Commercialization activities for the Licensed Products in the Territory;

(b) attempt to resolve any disputes or disagreements arising from matters within the jurisdiction of the IP Committee with respect to the Product Marks and associated usage instructions in the Roche Territory and escalate any such matters to the JSC for resolution if needed;

(c) review and discuss the Joint Global Branding and Marketing Strategy with respect to the Commercialization of the applicable Licensed Products in the Roche Territory and the Sarepta Territory (as described in Section 6.4 (Brand Plans));

(d) review and discuss the Roche Territory Branding and Marketing Plan and the Sarepta Territory Branding and Marketing Plan and all updates thereto;

(e) oversee the implementation of, and discuss the progress regarding, Commercialization of the Licensed Products in the Territory; and

(f) review and discuss updates provided by each Party regarding such Party's Commercialization activities for the Licensed Products in each Party's respective Territory, as described in Section 6.2 (Commercialization Reporting).

3.5 **Joint Manufacturing Committee**.

3.5.1 **Formation and Purpose of the JMC**. Within [**] days after the Effective Date, the Parties will establish a Joint Manufacturing Committee (the "**JMC**"), which will be a Subcommittee of the JSC and will have the responsibilities set forth in this Article 3 (Governance). The JMC will dissolve upon the completion or earlier termination of all Manufacturing activities under the Supply Agreements.

3.5.2 **Membership of the JMC**. Each Party will designate up to [**] representatives with appropriate knowledge, expertise, and decision-making authority to serve as members of the JMC; *provided* that [**]. Each Party may replace its JMC representatives and co-chairpersons at any time upon written notice to the other Party. The Alliance Manager of each Party (or his or her designee) may attend meetings of the JMC as a non-voting participant.

3.5.3 **Specific Responsibilities of the JMC**. The responsibilities of the JMC will be to:

(a) Oversee all aspects of the Manufacture of the Licensed Products under the Supply Agreements, including product specifications and quality;

(b) oversee interim supply arrangements for Licensed Products in the Roche Territory prior to the Parties' execution of the Supply Agreements;

(c) discuss planning, construction, qualification, and operating of manufacturing sites of the CMOs;

(d) (i) prepare the initial Development Demand Forecast Plan and all updates thereto (as described in Section 8.1 (Initial Forecast)), and (ii) refer the initial Development Demand Forecast Plan and any material update to the Development Demand Forecast Plan to the JSC to approve;

(e) (i) review the initial Capacity Plan and all updates thereto (as described in Section 8.2 (Capacity Plan)), and (ii) refer the initial Capacity Plan and any material update thereto to the JSC to approve.

(f) discuss, promptly after Roche's request under Section 8.11.1 (Request for Technology Transfer) to commence, itself or through one or more CMOs, Manufacturing Licensed Products, including any alternatives to transfer of Manufacturing Know-How from Sarepta that would be acceptable to Roche;

(g) prepare, if applicable, the Manufacturing Transition Plan, as described in Section 8.11.2 (Manufacturing Transition Period), and refer such Manufacturing Transition Plan to the JSC to approve; and

(h) (i) review the initial Manufacturing Plan and all updates thereto (as described in Section 8.8 (Manufacturing Plan)), and (ii) refer the initial Manufacturing Plan and any material update thereto to the JSC to approve.

3.6 Additional Participants. At the request of a Party, other employees of such Party or any of its Affiliates involved in the Exploitation of the Sarepta Products may attend meetings of the JSC or any Subcommittee as non-voting participants. In addition, with the consent of each Party, consultants, representatives, or advisors involved in the same activities and under written obligations of confidentiality and non-use applicable to the Confidential Information of each Party that are at least as stringent as those set forth in Article 12 (Confidentiality) may attend meetings of the JSC or any Subcommittee as non-voting observers.

3.7 Decision-Making.

3.7.1 General Decision-Making Process. Each Party's representatives on the JSC and each Subcommittee will, collectively, have one vote (the "**Party Vote**") on all matters brought before such committee for a decision by consensus. The JSC and each Subcommittee will make decisions as to matters within its jurisdiction by unanimous Party Vote, which will be reflected in the minutes of the committee meeting. Except as otherwise expressly set forth in this Agreement, the words "**determine**" or "**approve**" by the JSC or any Subcommittee and similar phrases used in this Agreement will mean approval in accordance with this Section 3.7 (Decision-Making) and Section 3.8 (Resolution of Committee Disputes). For the avoidance of doubt, matters that are specified in Section 3.1.5 (Specific Responsibilities of the JSC), Section 3.3.3 (Specific Responsibilities of the JDC), Section 3.4.3 (Specific Responsibilities of the JCC), or Section 3.5.3 (Specific Responsibilities of the JMC) to be reviewed and discussed (as opposed to approved) do not require any agreement by the JSC or any Subcommittee and are not subject to the voting and decision making procedures set forth in this Section 3.7 (Decision-Making) or Section 3.8 (Resolution of Committee Disputes).

3.7.2 **Decisions of the Subcommittees**. If any Subcommittee cannot reach unanimous agreement using good faith efforts on any matter within their respective scope of authority at the meeting at which such matter was discussed or if a meeting of such Subcommittee is not held within a reasonable period of time or the meeting minutes are not finalized in due time, then a Party may refer such matter to the JSC for resolution in accordance with Section 3.7.3 (Decisions of the JSC).

3.7.3 **Decisions of the JSC**. The JSC will use good faith efforts, in compliance with this Section 3.7.3 (Decisions of the JSC), to promptly resolve any such matter for which it has authority. If, after the use of good faith efforts, the JSC is unable to resolve any such matter referred to it by any Subcommittee or any matter with respect to the matters within the scope of the JSC's authority or any other disagreement between the Parties that may be escalated to the JSC, in each case, within a period of [**] days after the matter was escalated to the JSC, then a Party may refer such matter to the Parties' respective Executive Officers for resolution in accordance with Section 3.8.1 (Referral to Executive Officers).

3.8 **Resolution of Committee Disputes**.

3.8.1 **Referral to Executive Officers**. If a Party makes an election under Section 3.7.3 (Decisions of the JSC) to escalate for resolution by the Executive Officers a matter as to which the JSC cannot reach a consensus decision, then each Party will submit in writing the respective positions of the Parties to their respective Executive Officers. The Executive Officers will use good faith efforts to resolve any such matter so escalated to them as soon as practicable but in any event within [**] days after such matter is escalated to them, and any final decision that the Executive Officers agree to in writing will be conclusive and binding on the Parties.

3.8.2 **Final Decision Making Authority**. If the Executive Officers are unable to reach agreement on any such matter so referred within [**] days after such matter is referred to them (or such longer period as the Executive Officers may agree upon), then:

(a) **Regulatory Expert Matters**. If the matter is a Regulatory Expert Matter, then such matter will be resolved by the Regulatory Expert in accordance with the following procedure: (i) within [**] days following the Executive Officers' failure to reach agreement during the applicable [**]-day period, each Party will send to the other Party a list of [**] regulatory consulting firms that it proposes to nominate as the "**Regulatory Expert**", each of which must have sufficient expertise and experience and not have been engaged by such Party previously; (ii) if there are one or more common nominations, then [**] will select one of such common regulatory consulting firm nominees to serve as the regulatory expert to resolve the Regulatory Expert Matter (the "**Regulatory Expert**"); (iii) within [**] Business Days of selection of the Regulatory Expert in accordance with this Section 3.8.2(a) (Regulatory Expert Matters), the Parties will submit their written positions regarding the Regulatory Expert Matter to the Regulatory Expert; and (iv) the Regulatory Expert will render a decision in writing within [**] Business Days (or such other time period as the Parties may agree) after receipt of the last Party's submission of its written position and such decision will be conclusive and binding on the Parties. Notwithstanding the foregoing, if the Parties do not nominate any of the same regulatory consulting firms, then [**] will have the right to select the regulatory consulting firm to serve as the Regulatory Expert.

(b) **Sarepta Final Decision Making Authority**. Subject to Section 3.8.3 (Limitation on Decision-Making), Sarepta will have final decision making authority over [**].

(c) **Roche Final Decision Making Authority**. Subject to Section 3.8.3 (Limitation on Decision-Making), Roche will have final decision making authority over [**].

(d) **Matters Requiring Mutual Agreement**. Neither Party will have final decision-making authority over [**]. All such matters set forth in the foregoing clauses ([**]) must be decided by unanimous agreement of the Parties.

3.8.3 **Limitations on Decision-Making**. Notwithstanding anything to the contrary set forth in this Agreement, without the other Party's prior written consent, neither Party (in the exercise of a Party's final decision-making authority), the JSC, any Subcommittee, nor a Party's Executive Officer, in each case, may make a decision that could reasonably be expected to (i) require the other Party to take any action that such other Party reasonably believes would (A) require such other Party to violate any Applicable Law, the requirements of any Regulatory Authority, or any agreement with any Third Party entered into by such other Party (including any Collaboration In-License) or (B) require such other Party to infringe or misappropriate any intellectual property rights of any Third Party or (ii) conflict with, amend, interpret, modify, or waive compliance under this Agreement.

3.9 **Alliance Managers**. Each of the Parties will appoint a manager ("**Alliance Manager**") within [**] days after the Effective Date. The role of the Alliance Manager is to ensure a successful relationship under this Agreement. The Alliance Managers will attend all JSC meetings and will support the co-chairpersons of the JSC in the discharge of his or her responsibilities. Alliance Managers will be non-voting participants in all JSC meetings, but an Alliance Manager may bring any matter to the attention of the JSC or any Subcommittee if such Alliance Manager reasonably believes that such matter warrants such attention. Each Party may change its designated Alliance Manager at any time upon written notice to the other Party. Any Alliance Manager may designate a substitute to temporarily perform the functions of that Alliance Manager by written notice to the other Party. Each Alliance Manager will also: (a) be the point of first referral in all matters of conflict resolution; (b) provide a single point of communication for seeking consensus between the Parties regarding key strategy and plan issues; (c) identify and bring disputes to the attention of the JSC in a timely manner; (d) plan and coordinate cooperative efforts and internal and external communications; and (e) take responsibility for ensuring that governance activities, such as the conduct of required JSC meetings and production of meeting minutes, occur as set forth in this Agreement, and that the relevant action items resulting from such meetings are appropriately carried out or otherwise addressed.

ARTICLE 4
DEVELOPMENT

4.1 **Overview**. As between the Parties and in accordance with this Agreement, (a) Sarepta will be the Party that performs all Development activities set forth in the Joint Global Development Plan for the Licensed Products and all Development activities for all Option Products worldwide, and (b) Roche will be the Party that performs all Development activities set forth in the Roche Territory Development Plan for the Licensed Products. Each Party will conduct all Development activities for which it is responsible under this Agreement in a good scientific manner, in accordance with GLP and GCP, as applicable, and in compliance with Professional Requirements and Applicable Law.

4.2 Development Diligence Obligations.

4.2.1 Of Sarepta. Sarepta will use Commercially Reasonable Efforts to carry out the activities under the Joint Global Development Program in accordance with the Joint Global Development Plan.

4.2.2 Of Roche. Roche will use Commercially Reasonable Efforts to (a) obtain and maintain Regulatory Approval for each Licensed Product in each Roche Major Country, and (b) carry out the activities under the Roche Territory Development Program in accordance with the Roche Territory Development Plan.

4.2.3 Breach of Development Diligence Obligations. Any material breach by or on behalf of Sarepta of the diligence obligations set forth in Section 4.2.1 (Of Sarepta) or by or on behalf of Roche of the diligence obligations set forth in Section 4.2.2 (Of Roche) with respect to the Development of a Licensed Product will be a material breach of this Agreement and will be subject to the provisions of Section 14.2 (Termination for Breach).

4.2.4 Mitigation of Development Diligence Obligations. [**].

4.3 Global Development Plans.

4.3.1 Joint Global Development Plan.

(a) **Regulatory Guidance Requirements**. The Development activities set forth in the Joint Global Development Plan will be consistent with all guidances of the EMA, the health technology assessment bodies of any of the Roche Major Countries, the PMDA, and the MHLW, in each case, related to the use of data generated during any such Development such that the data generated in the performance of Development activities under the Joint Global Development Plan can be used to obtain and maintain Regulatory Approval in the European Union and the Roche Major Countries or to support one or more health technology assessments in any Roche Major Country. For clarity, the Joint Global Development Plan shall not include Clinical Trials or other studies required to obtain or maintain Regulatory Approval for a Licensed Product solely in Japan.

(b) **Initial Joint Global Development Plan and Updates**. The initial Joint Global Development Plan, including the initial Joint Global Development Budget, is set forth on **Schedule 4.3.1**. On or before March 31st of each Calendar Year during the Term (and more frequently as may be necessary and determined by the JDC during the Term), the JDC will prepare an update to the Joint Global Development Plan to include the Development activities within the Joint Global Development Program to be conducted during the following Calendar Year, together with the updated Joint Global Development Budget associated with such update to the Joint Global Development Plan. In addition, from time to time during the Term, either Party may submit to the JDC any proposed update to the Joint Global Development Plan to include additional Development activities within the Joint Global Development Program (or otherwise update such Development activities or propose updates to the applicable Joint Global Development Budget), including [**], a "**Regulatory Expert Matter**").

(c) **Updates Upon Option Exercise**. In addition, no later than 30 days following Roche's exercise of the Option for the Exon-Skipping Products or any other Option Product in accordance with Section 2.7 (Exercise of Option), the JDC will prepare an update to the Joint Global Development Plan for the Exon-Skipping Products ([**]) or other Option Products and corresponding Sarepta Diagnostic Products, as applicable, that includes all Development activities through the completion of Pivotal Clinical Trials and other Development activities necessary to obtain and maintain Regulatory Approvals for each such product in the U.S. and the European Union in accordance with Section 4.3.1(a) (Regulatory Guidance Requirements) and otherwise similar in scope as the activities conducted under the Joint Global Development Plan for the Lead Product, together with the Joint Global Development Budget associated with the performance of such activities. Within 30 days following Sarepta's written notice to Roche of the commencement of activities in furtherance of a Pivotal Clinical Trial for an [**], the JDC will prepare an update to the Joint Global Development Plan for the applicable [**] that includes all Development activities through the completion of Pivotal Clinical Trials and other Development activities necessary to obtain and maintain Regulatory Approvals for each such product in the U.S. and the European Union, together with the Joint Global Development Budget associated with the performance of such activities.

(d) **Review and Approval of Updates to the Joint Global Development Plan**. The JDC will review and discuss each update to the Joint Global Development Plan and will submit any such updates that are material (including any update that contemplates the initial Development activities to be performed thereunder for an Option Product that becomes a Licensed Product following Roche's exercise of the Option for such product and any material update proposed by either Party) to the JSC for approval. Once reviewed and discussed by the JDC and approved by the JSC, each update to the Joint Global Development Plan (including any update to the Joint Global Development Budget) will become effective and supersede the previous Joint Global Development Plan or Joint Global Development Budget, as applicable, as of the date of such approval or at such other time as decided by the JSC.

(e) **Day-to-Day Performance of Joint Global Development Activities**. Without limiting Roche's rights to review, discuss, and approve the Joint Global Development Plan through the JDC and the JSC, Sarepta will have the right, without seeking JDC review or JSC approval, to make operational decisions with respect to the performance of the Development activities within the Joint Global Development Program to the extent consistent with the then-current Joint Global Development Plan.

4.3.2 **Option Product Development Plan**. Sarepta may, from time to time, propose updates to the Option Product Development Plan, in which case Sarepta will submit any such updates that are material to the JDC to review and discuss. Each update to the Option Product Development Plan proposed by Sarepta will become effective and supersede the previous Option Product Development Plan as of the 10th day following the date of submission of such update to the JDC for review and discussion. Notwithstanding any provision to the contrary set forth in this Agreement, Sarepta will have the right, without seeking JDC or JSC review or approval, to make decisions with respect to the performance of the Development activities for the Option Products.

4.4 **Roche Territory Development Plan**. Within 120 days following the Effective Date, Roche will submit to the JDC to review and discuss, and following review and discussion by the JDC, to the JSC to approve, a proposed Roche Territory Development Plan. In addition, no later than 60 days following Roche's exercise of the Option for the Exon-Skipping Products ([**]) or any other Option Product in accordance with Section 2.7.3 (Exercise Notice and Option Fee), Roche will prepare an update to the Roche Territory Development Plan for such Exon-Skipping Products ([**]) or such other Option Products and corresponding Sarepta Diagnostic Products, as applicable, that includes all Development activities, other than the activities included in the Joint Global Development Plan, that are necessary or desirable to obtain and maintain Regulatory Approval or Reimbursement Approval of such Exon-Skipping Products ([**]) or other Option Products throughout the Roche Territory, including all proposed post-Regulatory Approval studies and all other non-clinical and pre-clinical studies and Clinical Trials, in each case, the data from which will be used solely for the Roche Territory, and regulatory plans. Within 60 days following Sarepta's written notice to Roche of the commencement of activities in furtherance of a Pivotal Clinical Trial for an [**], Roche will prepare an update to the Roche Territory Development Plan for the applicable [**] that includes all Development activities, other than the activities included in the Joint Global Development Plan, that are necessary or desirable to obtain and maintain Regulatory Approval or Reimbursement Approval of such [**] throughout the Roche Territory, including post-Regulatory Approval studies in the Roche Territory, the data from which will be used solely for the Roche Territory, and all proposed non-clinical and pre-clinical studies and Clinical Trials and regulatory plans. On or before March 31st of each Calendar Year during the Term (and more frequently as may be necessary during the Term), Roche will prepare an update to the Roche Territory Development Plan to include the Development activities within the Roche Territory Development Program to be conducted during the upcoming Calendar Year. In addition, from time to time during the Term, Roche may submit to the JDC any proposed update to the Roche Territory Development Plan to include additional Development activities within the Roche Territory Development Program (or otherwise update such Development activities). The JDC will review and discuss each update to the Roche Territory Development Plan and will submit any such update that is material (including any update that contemplates the initial Development activities to be performed thereunder for an Option Product that becomes a Licensed Product following Roche's exercise of the Option for such product) to the JSC for approval. Once reviewed and discussed by the JDC and approved by the JSC, the Roche Territory Development Plan and each update thereto will become effective and, in the case of an update, supersede the previous Roche Territory Development Plan as of the date of such approval or at such other time as decided by the JSC. Without limiting Sarepta's rights to review, discuss, and approve the Roche Territory Development Plan through the JDC and the JSC, Roche will have the right, without seeking JDC review or JSC approval, to make operational decisions with respect to the performance of the Development activities within the Roche Territory Development Program to the extent consistent with the then-current Roche Territory Development Plan.

4.5 Development Cost Sharing.

4.5.1 Eligible Global Development Costs. Commencing from and after the Execution Date and thereafter the Parties will equally share (50:50) all Eligible Global Development Costs in accordance with the procedures set forth in this Section 4.5.1 (Eligible Global Development Costs). Within (a) 10 days after the end of the first Calendar Quarter after the Effective Date, Sarepta will prepare and deliver to Roche a preliminary report detailing Sarepta's Eligible Global Development Costs incurred during the time period commencing as of the Execution Date and ending as of the end of first Calendar Quarter after the Effective Date and (b) within 30 days after the end of such Calendar Quarter, Sarepta will prepare and deliver to Roche a report, together with reasonable supporting documentation, detailing such Eligible Global Development Costs incurred during such period. Within (i) 10 days after the end of each Calendar Quarter thereafter, Sarepta will prepare and deliver to Roche a preliminary report detailing Sarepta's Eligible Global Development Costs incurred during such Calendar Quarter and (ii) within 30 days after the end of each such Calendar Quarter, Sarepta will prepare and deliver to Roche a report, together with reasonable supporting documentation, detailing such Eligible Global Development Costs incurred during such Calendar Quarter. Sarepta will submit any additional information reasonably requested by Roche related to the Eligible Global Development Costs included in Sarepta's report no later than 10 Business Days after its receipt of such request. Within 15 days after delivering the report and documentation set forth in clause (b) of this Section 4.5.1 (Eligible Global Development Costs), Sarepta will deliver an invoice to Roche and Roche will pay Sarepta all undisputed invoiced amounts no later than 30 days after Roche's receipt of each such invoice, and any disputed amounts within 30 days following resolution of the dispute.

4.5.2 Option Product Development Costs. Sarepta will be solely responsible for all costs and expenses incurred in connection with the performance of the Option Product Development Program.

4.5.3 Roche Territory Development Program Costs. Roche will be solely responsible for all costs and expenses incurred in connection with the performance of the Roche Territory Development Program.

4.6 Development Reports. At each JDC meeting, Sarepta and Roche will each provide the JDC with a written summary of the activities conducted by or on behalf of such Party under the Joint Global Development Program (in the case of Sarepta) and the Roche Territory Development Program (in the case of Roche) since the last JDC meeting, including patient enrollment and the ongoing status of all Clinical Trials under the applicable plan. Each Party will also promptly provide written notice to the other Party, through the JDC or Alliance Managers, of any significant Development events under the Joint Global Development Program (in the case of Sarepta) or the Roche Territory Development Program (in the case of Roche) that the reporting Party reasonably believes materially impacts the Development activities of the other Party under this Agreement or is otherwise of interest to the other Party. In addition, at each JDC meeting, Sarepta will provide to Roche a high-level summary of the activities conducted by or on behalf of Sarepta under the Option Product Development Plan.

4.7 **Development Records**. Each Party and its Affiliates will maintain written or electronic records, in sufficient detail, in a good scientific manner (in accordance with GLP, GCP, and GMP, as applicable), and appropriate for regulatory and patent purposes, and that are complete and accurate in all material respects and reflect all Development work performed and results achieved, in each case, by or on behalf of such Party and its Affiliates under the Global Development Program (in the case of Sarepta) and the Roche Territory Development Program (in the case of Roche).

ARTICLE 5
REGULATORY AFFAIRS

5.1 **Orphan Drug Designation**. To the extent permissible under Applicable Law, Roche shall have the right to have discussions with Regulatory Authorities in the Roche Territory relating to Orphan Drug Designation and to obtain Orphan Drug Designation for each Licensed Product in all countries of the Roche Territory eligible for Orphan Drug Designation, and in any case in the European Union and Japan. Sarepta shall use reasonable efforts to assist Roche in obtaining Orphan Drug Designation and have the above mentioned discussions with Regulatory Authorities for such products in such countries.

5.2 **Regulatory Responsible Party**. As between the Parties, Sarepta will be the Regulatory Responsible Party for all (a) Option Products and corresponding Sarepta Diagnostic Products worldwide, (b) Licensed Products and corresponding Sarepta Diagnostic Products in the Sarepta Territory, and (c) activities relating to the extent solely related to the conduct of preclinical studies and Clinical Trials conducted under the Joint Global Development Plan throughout the Roche Territory. Sarepta will be responsible for INDs and other Regulatory Submissions relating solely to preclinical studies and Clinical Trials conducted under the Joint Global Development Plan or Option Product Development Plan anywhere in the Territory, however excluding any activity relating to obtaining or maintaining any Regulatory Approval or Reimbursement Approval in the Roche Territory. Roche will be the Regulatory Responsible Party for all Licensed Products and corresponding Sarepta Diagnostic Products in the Roche Territory, including as it relates to any Regulatory Approval or Reimbursement Approval or any related strategy of Licensed Products and corresponding Sarepta Diagnostic Products, except to the extent related solely to the conduct of any preclinical studies and Clinical Trials conducted under the Joint Global Development Plan or Option Product Development Plan in any country or jurisdiction in the Roche Territory. The applicable Regulatory Responsible Party will be responsible for, and will have final decision-making authority on the strategy and content of, all Regulatory Submissions, communications, and other dealings with the Regulatory Authorities in the applicable jurisdictions relating to any Licensed Product or any Option Product (and any corresponding Sarepta Diagnostic Product). If any Licensed Product is denied Regulatory Approval due to the receipt of orphan drug exclusivity of a competing product, Roche shall have the right to challenge any such adverse determination in the Roche Territory and Sarepta shall use reasonable efforts to assist Roche as required.

5.3 **Collaboration With Respect to Regulatory Interactions**.

5.3.1 **Correspondence**. The Parties' regulatory teams will collaborate with respect to substantive correspondence in support of regulatory submissions. In addition, the Regulatory Responsible Party for each Licensed Product and corresponding Sarepta Diagnostic Product will provide the other Party with (a) copies (without translation) of any material written correspondence submitted to or received from (i) the FDA and the Regulatory Authorities in each Roche Major Country, and (ii) upon Sarepta's reasonable request to the extent necessary to satisfy its obligations under this Agreement or to comply with Applicable Law, Regulatory Authorities in other countries within the Roche Territory

(or summaries thereof), and (b) summaries of any material oral communications with (i) the FDA and the Regulatory Authorities in each Roche Major Country and (ii) upon Sarepta's reasonable request, Regulatory Authorities in other countries in the Roche Territory, in each case ((a) and (b)), relating to Regulatory Submissions for a Licensed Product or a corresponding Sarepta Diagnostic Product in such jurisdiction or country, reasonably promptly after receipt or delivery by such Regulatory Responsible Party of such correspondence or communication, as the case may be (but in any event, with respect to correspondence or communications with the EMA no later than ten Business Days after receipt or delivery).

5.3.2 **Regulatory Delays**. The Regulatory Responsible Party will not be required to delay any submission, correspondence, or communication with any Regulatory Authorities in its jurisdiction in a manner that affects such Regulatory Responsible Party's ability to comply with any Regulatory Authority requirement or deadline or Applicable Law in such jurisdiction.

5.4 **Regulatory Meetings**. The applicable Regulatory Responsible Party will invite one representative of the other Party with relevant experience and expertise (to be chosen by such other Party and at such other Party's expense) to attend as an observer all meetings relating to Regulatory Submissions for Licensed Products and corresponding Sarepta Diagnostic Products (to the extent such meetings are scheduled in advance) with (a) the FDA, (b) the EMA, and (c) upon Sarepta's request, other Regulatory Authorities in the Roche Major Countries, in each case ((a), (b), and (c)), to the extent not prohibited by Applicable Law or the applicable Regulatory Authority. In addition, the representatives of the non-Regulatory Responsible Party will be notified reasonably in advance of, and invited to attend, all substantive discussions (as determined by the Regulatory Responsible Party in its reasonable discretion) held by the Regulatory Responsible Party to prepare for any meetings with Regulatory Authorities that the non-Regulatory Responsible Party has the right to attend under this Section 5.4 (Regulatory Meetings). In addition, upon the request of the Regulatory Responsible Party, the non-Regulatory Responsible Party will review any preparatory documentation for any such meetings. The non-Regulatory Responsible Party will strictly follow the Regulatory Responsible Party's instructions with respect to any such meeting that it attends, and will not discuss the contents of any such meeting with any Third Party or Regulatory Authority except as required by Applicable Law or authorized by the Regulatory Responsible Party in writing. If either Party requires an interpreter or other translation services in connection with its participation in any such meeting with Regulatory Authorities, then the costs of such translation services will be borne solely by the requiring Party.

5.5 **Cooperation**. The Parties will cooperate with each other to achieve the regulatory objectives contemplated herein in a timely, accurate, and responsive manner. The non-Regulatory Responsible Party shall use reasonable efforts to assist the Regulatory Responsible Party, including through meetings between the Parties to prepare documents to be filed, in order for such Regulatory Responsible Party to obtain and maintain each applicable Marketing Authorization Application for each Licensed Product and corresponding Sarepta Diagnostic Products in the Regulatory Responsible Party's Territory, including in connection with the preparation, filing, and submission of all Regulatory Submissions by such Regulatory Responsible Party.

5.6 **Assignment of Regulatory Submissions and Regulatory Approvals to Roche**. On a Licensed Product-by-Licensed Product basis, upon last patient, last dosing of the final Clinical Trial under the Joint Global Development Program with respect to a Licensed Product, Sarepta will and hereby does assign and transfer to Roche all INDs and other Regulatory Submissions and Regulatory Approvals with respect to the applicable Licensed Product and corresponding Sarepta Diagnostic Products in the applicable countries in the Roche Territory that are in the possession and Control of Sarepta or any of its Affiliates or Sublicensees. In connection with the transfer of such Regulatory Submissions and Regulatory Approvals, Sarepta will provide to Roche copies (in electronic or other format) of the study reports that are Controlled by Sarepta or any of its Affiliates or Sublicensees (to the extent not previously provided to Roche) from all non-clinical and preclinical studies and Clinical Trials for the applicable Licensed Product and corresponding Sarepta Diagnostic Products relating to such Regulatory Submissions and Regulatory Approvals. For any such assignment and transfer, each Party will submit to the applicable Regulatory Authority all filings, letters, and other documentation necessary to effect such assignment and transfer as soon as practicable (or as soon as possible after the other Party's submission of any such filings, letters, or documentation to the extent required before such Party may take any such action).

5.7 **Cost of Regulatory Activities**. The Parties will share equally (50:50) all actual Internal Costs and actual External Costs relating to regulatory activities included within the Eligible Global Development Costs, and otherwise, the applicable Regulatory Responsible Party will be responsible for the costs and expenses incurred by each Party and its Affiliates in connection with the preparation or maintenance of Regulatory Submissions and Regulatory Approvals with respect to a Licensed Product and corresponding Sarepta Diagnostic Products in a given jurisdiction, including any filing fees.

5.8 **Right of Reference**. Subject to the rules of the relevant Regulatory Authority and the terms of this Agreement, each Party hereby grants to the other Party a "**Right of Reference**," as that term is defined in 21 C.F.R. § 314.3(b) (or any successor rule or analogous Applicable Law recognized outside of the United States) to, and a right to copy, access, and otherwise use, all information and data relating to the Licensed Products and corresponding Sarepta Diagnostic Products in any Regulatory Submission or Regulatory Approval Controlled by the grantor Party during the Term, solely for the other Party's or its Affiliates' use in the Development and Commercialization of the Licensed Products and Sarepta Diagnostic Products in the other Party's Territory in accordance with this Agreement. All such information and data contained in any such Regulatory Submissions or Regulatory Approvals will be considered Confidential Information of the grantor Party and subject to the terms of Article 12 (Confidentiality). If requested by the grantee Party, the grantor Party will provide a signed statement to this effect in accordance with 21 C.F.R. § 314.50(g)(3) (or any successor rule or analogous Applicable Law outside of the United States) to give effect to the intent of this Section 5.8 (Right of Reference).

5.9 **Pharmacovigilance and Adverse Event Reporting**. The Parties will cooperate with each other with regard to the reporting and handling of safety information involving the Licensed Products and Sarepta Diagnostic Products in accordance with Applicable Law, regulatory requirements, and regulations on pharmacovigilance and clinical safety. Prior to the commencement of any activities conducted by or on behalf of Roche or any of its Affiliates in furtherance of any Clinical Trial for any Licensed Product, the Parties will negotiate in good faith and enter into a Pharmacovigilance Agreement related to the Licensed Products and a quality agreement, or such other agreement as the Parties may agree, related to the Sarepta Diagnostic Products, which will define the pharmacovigilance responsibilities of the Parties and include safety data exchange procedures governing the exchange of information affecting the class and products (*e.g.*, Serious Adverse Events, emerging safety issues) to enable each Party to comply with all of its legal and regulatory obligations related to such Licensed Products and Sarepta Diagnostic Products. Sarepta will own and maintain the global safety database for all Sarepta Products and Sarepta Diagnostic Products.

5.10 Recall, Withdrawal, or Field Alerts.

5.10.1 Notification and Determination. If any Governmental Authority threatens in writing or initiates any action to remove a Licensed Product or Sarepta Diagnostic Product from the market (in whole or in part) in the Roche Territory, then the Party receiving notice thereof will notify the other Party of such communication immediately, but in no event later than two Business Days after receipt thereof. Notwithstanding the foregoing, in all cases the Regulatory Responsible Party for a Licensed Product in a given jurisdiction will determine whether to initiate any recall, withdrawal, or field alert of such Licensed Product or applicable Sarepta Diagnostic Product in such jurisdiction, including the scope of such recall or withdrawal (*e.g.*, a full or partial recall, or a temporary or permanent recall) or field alert. Before the Regulatory Responsible Party for a Licensed Product in a certain jurisdiction in the Roche Territory initiates a recall, withdrawal, or field alert for such Licensed Product or Sarepta Diagnostic Product in such jurisdiction, the Parties will use reasonable efforts to promptly meet and discuss in good faith the reasons therefor, *provided* that such discussions will not delay any action that such Regulatory Responsible Party reasonably believes should be taken in relation to any actual or potential recall, withdrawal, or field alert. In the event of any such recall, withdrawal, or field alert in the Roche Territory, the Regulatory Responsible Party for the applicable Licensed Product and the applicable jurisdiction will determine the necessary actions to be taken and will implement such action. Without limiting the foregoing, either Party will have the right to propose that a recall, withdrawal, or field alert for a Licensed Product or Sarepta Diagnostic Product should be initiated by such Party, but the Regulatory Responsible Party for the applicable Licensed Product in the applicable jurisdiction in the Roche Territory will have the right to make the final decision as to whether or not to initiate the recall, withdrawal, or field alert. Notwithstanding any provision to the contrary set forth in this Agreement, if Sarepta notifies Roche of a Manufacturing issue related to a Licensed Product that Sarepta reasonably believes could give rise to a recall, withdrawal, or field alert, then Roche, if it is the Regulatory Responsible Party for the applicable Licensed Product in the applicable jurisdiction in the Roche Territory, will assess such notification from Sarepta and initiate such recall, withdrawal, or field alert as appropriate. In all cases, Sarepta will determine whether to initiate any recall, withdrawal, or field alert of any Option Product, including the scope of such recall or withdrawal (*e.g.*, a full or partial recall, or a temporary or permanent recall) or field alert and will have sole control over and decision-making authority with respect thereto.

5.10.2 Cost Allocation. Sarepta will be responsible for all costs and expenses associated with implementing a recall, withdrawal, or field alert with respect to any Option Product or corresponding Sarepta Diagnostic Product. Sarepta will be responsible for all costs and expenses directly associated with implementing a recall, withdrawal, or field alert with respect to a Licensed Product or corresponding Sarepta Diagnostic Product in the Roche Territory in the event, and to the extent, that the recall, withdrawal, or field alert arises as a result of any breach by Sarepta or its Affiliates or CMOs of this Agreement or any Supply Agreement. Roche will be responsible for all costs and expenses associated with implementing a recall, withdrawal, or field alert with respect to a Licensed Product or corresponding Sarepta Diagnostic Product in the Roche Territory that does not result from any breach by Sarepta or its Affiliates or CMOs of this Agreement or any Supply Agreement.

To the extent necessary to effectuate the cost-sharing principles set forth in this Section 5.10.2 (Cost Allocation), either Party may deliver an invoice to the Party responsible for the applicable recall, withdrawal, or field alert for such Party's actual costs and expenses incurred in connection with such recall, withdrawal, or field alert, and the responsible Party will pay all undisputed invoiced amounts no later than 30 days after receipt of such invoice.

ARTICLE 6
COMMERCIALIZATION

6.1 Commercialization Responsibilities for Licensed Product.

6.1.1 Commercialization in the Sarepta Territory. Sarepta and its Affiliates will have sole control over and decision-making authority with respect to the Commercialization of the Licensed Products Sarepta in the Sarepta Territory, including, if applicable, seeking and maintaining any Reimbursement Approval for the Licensed Products in the Sarepta Territory, at its sole cost and expense.

6.1.2 Commercialization in the Roche Territory. Roche and its Affiliates will have sole control over and decision-making authority with respect to the Commercialization of the Licensed Products in the Roche Territory, including seeking and maintaining any Reimbursement Approval for the Licensed Products in the Roche Territory, at its sole cost and expense.

6.1.3 Coordination of Commercialization Activities. The Parties will coordinate global Commercialization activities, except pricing and reimbursement activities, with respect to Commercialization of Licensed Products in each Party's Territory through the JCC, as further set forth in Section 3.3.3(a) (Joint Commercialization Committee).

6.2 Commercialization Reporting.

6.2.1 Sarepta Obligations. No later than 45 days following the end of each Calendar Year, Sarepta will provide to the JCC a high-level summary of the material Commercialization activities, except pricing and reimbursement activities, conducted by Sarepta or its Affiliates or Sublicensees for each Licensed Product in the Sarepta Territory during such Calendar Year and the material Commercialization activities expected to be conducted by Sarepta or its Affiliates or Sublicensees in the Sarepta Territory during the upcoming Calendar Year.

6.2.2 Roche Obligations. No later than 45 days following the end of each Calendar Year, Roche will provide to the JCC a high-level summary of the material Commercialization activities, except pricing and reimbursement activities, conducted by Roche or its Affiliates or Sublicensees for such Licensed Product in the Roche Territory during such Calendar Year and the material Commercialization activities expected to be conducted by Roche or its Affiliates or Sublicensees in the Roche Territory during the upcoming Calendar Year. In addition, no later than 45 days prior to the end of each Calendar Year, Roche will provide to the JCC a report of the forecasted Net Sales anticipated to be generated by Roche or its Affiliates or Sublicensees in the Roche Territory during the upcoming Calendar Year.

6.3 Pricing. Notwithstanding any provision to the contrary set forth in this Agreement, all decisions for each Licensed Product related to any pricing matter, including list price, targeted net pricing, sales-weighted average discounts and rebates, pricing strategy (including the approach to pricing with different types of accounts and plans, including types of discounts and rebates), and modifications to any of the foregoing, will be solely made by (a) Sarepta for the Sarepta Territory and (b) Roche for the Roche Territory.

6.4 **Branding and Marketing Plans**. Within 90 days following (a) the formation of the JCC with respect to any Lead Product, and (b) the exercise of the Option with respect to each of the Exon-Skipping Products and any other Option Product, in each case ((a) and (b)), the JCC will prepare, review, and discuss, and following review and discussion by the JCC, submit to the JSC to approve, a joint global branding and marketing strategy with respect to the Commercialization of the applicable Licensed Products throughout the Roche Territory and the Sarepta Territory (the "**Joint Global Branding and Marketing Strategy**"). The Joint Global Branding and Marketing Strategy will include, in reasonable detail, the Product Marks, trade dress, positioning, detailing, market access planning, and marketing messages with respect to the Licensed Products that each Party will use under its own branding and marketing plan. The Joint Global Branding and Marketing Strategy will not include information related to pricing or reimbursement for any Licensed Product. Based on the Joint Global Branding and Marketing Strategy, Roche shall develop a branding and marketing plan that is applicable for the Licensed Products in the Roche Territory (the "**Roche Territory Branding and Marketing Plan**") and Sarepta shall develop a branding and marketing plan that is applicable for the Licensed Products in the Sarepta Territory (the "**Sarepta Territory Branding and Marketing Plan**"). Each of the Roche Territory Branding and Marketing Plan and the Sarepta Territory Branding and Marketing Plan will, at all times during the Term, be consistent with, and not conflict with, the Joint Global Branding and Marketing Strategy.

6.5 **Roche Commercialization Diligence Obligations**. Following receipt of Regulatory Approval for a Licensed Product in a country in the Roche Territory, Roche will use Commercially Reasonable Efforts to obtain Reimbursement Approval for and subsequently Commercialize each Licensed Product for which it has obtained Regulatory Approval in such country.

6.5.1 **Notice to JCC**. If Roche determines not to (a) seek Reimbursement Approval for a Licensed Product in a country in the Roche Territory in which Roche or its Affiliates or Sublicensees has obtained Regulatory Approval or (b) Commercialize a Licensed Product in a country in the Roche Territory in which Roche or its Affiliates or Sublicensees has obtained Reimbursement Approval, in each case ((a) and (b)), then Roche will promptly inform Sarepta, through the JCC, of such decision and explain its rationale for such decision in reasonable detail at the next meeting of the JCC.

6.5.2 **Breach of Commercialization Diligence Obligation**. Any material breach by or on behalf of Roche of the diligence obligations set forth in this Section 6.5 (Roche Commercialization Diligence Obligations) with respect to the Commercialization of a Licensed Product will be a material breach of this Agreement and will be subject to the provisions of Section 14.2 (Termination for Breach).

6.5.3 **Mitigation of Commercialization Diligence Obligations**. Notwithstanding any provision to the contrary set forth in this Agreement, any failure of Roche to comply with its obligations under this Section 6.5 (Roche Commercialization Diligence Obligations) with respect to a particular Licensed Product will be excused only to the extent that and for so long as such failure results from the failure of Sarepta or any of its Affiliates, Sublicensees, or subcontractors to supply such Licensed Product in accordance with its obligations under this Agreement or any of the Supply Agreements or to satisfy its obligations to Develop such Licensed Product in accordance with Section 4.2.1 (Of Sarepta).

6.6 **Standards of Conduct; Compliance**. Each Party will perform, or will ensure that each of its Affiliates, Sublicensees, and subcontractors perform, all Commercialization activities in a professional and ethical business manner and in compliance with Applicable Law and applicable Professional Requirements.

6.7 **Diversion**. Notwithstanding any provision to the contrary set forth in this Agreement, either Party will have the right to attend, or have its designees attend, conferences and meetings of congresses inside and outside of such Party's Territory, subject to this Section 6.7 (Diversion). As applicable, (a) in the case of Roche, in any country or jurisdiction outside of the Roche Territory, or (b) in the case of Sarepta, in any country or jurisdiction outside of the Sarepta Territory:

6.7.1 such Party will inform the other Party timely in advance of any marketing, promotion, or attendance at conferences and such activities must comply with Applicable Law and the Joint Global Medical Affairs Plan, Roche Medical Affairs Plan, and Sarepta Medical Affairs Plan;

6.7.2 such Party and its Affiliates will not engage, nor permit its Third Party Sublicensees and subcontractors to engage, in any advertising or promotional activities relating to any Licensed Product for use directed primarily to customers or other buyers or users of the Licensed Product located in any such country or jurisdiction;

6.7.3 such Party and its Affiliates will not solicit orders from any prospective purchaser located in any such country or jurisdiction;

6.7.4 such Party and its Affiliates will use reasonable efforts not to, and will take reasonable measures to cause its Third Party Sublicensees and subcontractors to not, deliver or tender (or cause to be delivered or tendered) any Licensed Product to Third Parties for use in such country or jurisdiction; and

6.7.5 if either Party or its Affiliates or Sublicensees receive any order for any Licensed Product from a prospective purchaser located in any such country or jurisdiction, then such Party will use reasonable efforts to refer that order to the other Party or its designee.

ARTICLE 7
MEDICAL AFFAIRS

7.1 **Medical Affairs Plans**.

7.1.1 **Joint Global Medical Affairs Plan**. The JDC, through the Joint Global Medical Affairs Team, will prepare a reasonably detailed, annual plan for Medical Affairs activities to be performed jointly by the Parties for the Licensed Products and any corresponding Sarepta Diagnostic Product, including a Joint Global Medical Affairs Budget (the "**Joint Global Medical Affairs Plan**").

7.1.2 **Roche Medical Affairs Plan**. Roche will prepare a reasonably detailed, annual plan for Medical Affairs activities to be performed for the Licensed Products and any corresponding Sarepta Diagnostic Product by or on behalf of Roche or its Affiliates that are not included in the Joint Global Medical Affairs Plan (the "**Roche Medical Affairs Plan**"), in each case, no later than 120 days following the Effective Date.

7.1.3 **Sarepta Medical Affairs Plan**. Sarepta will prepare a reasonably detailed, annual plan for Medical Affairs activities to be performed for the Licensed Products and any corresponding Sarepta Diagnostic Product by or on behalf of Sarepta or its Affiliates that are not included in the Joint Global Medical Affairs Plan (the "**Sarepta Medical Affairs Plan**"), in each case, no later than 120 days following the Effective Date.

7.1.4 **Addition of Option Products to Medical Affairs Plans**. Following exercise of the Option for each of the Exon-Skipping Products or any other Option Product, the JDC will prepare an update to the Joint Global Medical Affairs Plan, Roche will prepare an update to the Roche Medical Affairs Plan, and Sarepta will prepare an update to the Sarepta Medical Affairs Plan, in each case, to include the Exon-Skipping Products or any other Option Product, as applicable, and any corresponding Sarepta Diagnostic Product.

7.1.5 **Alignment of Medical Affairs Plans**. The strategic objectives in the Roche Medical Affairs Plan and the Sarepta Medical Affairs Plan, respectively, will be consistent with the activities and strategic objectives set forth in the Joint Global Medical Affairs Plan, unless otherwise agreed by the Parties. In order to ensure consistency between the Joint Global Medical Affairs Plan and each of the Roche Medical Affairs Plan and the Sarepta Medical Affairs Plan, and coordination and alignment between the Parties with respect to the Medical Affairs to be conducted by each Party pursuant to the Joint Global Medical Affairs Plan, by Roche in the Roche Territory pursuant to the Roche Medical Affairs Plan, and by Sarepta in the Sarepta Territory pursuant to the Sarepta Medical Affairs Plan (including with respect to each Party's communications with key opinion leaders in each Party's Territory), the JDC will review and discuss each such plan and any update thereto and submit the initial Joint Global Medical Affairs Plan and any update that is material to the JSC to approve.

7.2 **Medical Affairs Activities**. Roche will conduct Medical Affairs activities in accordance with the Joint Global Medical Affairs Plan and the Roche Medical Affairs Plan. Sarepta will conduct Medical Affairs activities in accordance with the Joint Global Medical Affairs Plan and the Sarepta Medical Affairs Plan. In addition, each Party will conduct all Medical Affairs activities under this Agreement in a professional and ethical business manner and in compliance with Applicable Law and applicable Professional Requirements. Each Party will provide the other Party with reasonable cooperation, support, and assistance with respect to preparing such Party's Medical Affairs plans, and conducting activities under each such plan, in order to coordinate Medical Affairs under this Agreement. In addition, each Party will provide to the JDC an update (by means of a slide presentation or otherwise) summarizing the Medical Affairs activities conducted by such Party and progress under the Joint Global Medical Affairs Plan (with respect to each Party), the Roche Medical Affairs Plan (with respect to Roche), and the Sarepta Medical Affairs Plan (with respect to Sarepta), during the period since the last JDC meeting, as provided in Section 3.3.3(k) (Specific Responsibilities of the JDC).

7.3 **Medical Affairs Cost Sharing**.

7.3.1 **Eligible Medical Affairs Costs**. The Parties will equally share all Eligible Medical Affairs Costs in accordance with the procedures set forth in this Section 7.3.1 (Eligible Medical Affairs Costs). Within 30 days after the end of each Calendar Quarter, each Party will prepare and deliver to the other Party a report, together with reasonable supporting documentation, detailing such Party's Eligible Medical Affairs Costs incurred during such Calendar Quarter. Each Party will submit any additional information reasonably requested by the other Party related to the Eligible Medical Affairs Costs included in such Party's report no later than 10 Business Days after its receipt of such request. The Party that

incurred greater Eligible Medical Affairs Costs than the other Party during such Calendar Quarter will prepare and deliver to the other Party an invoice for a balancing payment between the Parties, which will be equal to the amount that is 50% of the difference between the Parties' Eligible Medical Affairs Costs incurred during such Calendar Quarter. The other Party will pay the invoicing Party all undisputed invoiced amounts no later than 30 days after the date of each such invoice, and any disputed amounts within 30 days following resolution of the dispute.

7.3.2 **Other Medical Affairs Costs**. Other than as set forth in Section 7.3.1 (Eligible Medical Affairs Costs), each Party will be responsible for all costs and expenses related to the performance of Medical Affairs activities under this Agreement by or on behalf of such Party or any of its Affiliates or Sublicensees, including the costs of performing Medical Affairs activities under (a) the Roche Medical Affairs Plan (with respect to Roche) and (b) the Sarepta Medical Affairs Plan (with respect to Sarepta).

ARTICLE 8
MANUFACTURING AND SUPPLY

8.1 **General**. This Article 8 (Manufacturing and Supply) shall apply with respect to the Lead Product and all Exon-Skipping Products together with any corresponding Sarepta Diagnostic Products, but shall only apply with respect to other Option Products together with any corresponding Sarepta Diagnostic Products, if the Parties have not agreed otherwise in good faith discussion.

8.2 **Capacity Plan**. Within 60 days following the Effective Date, the Parties will agree upon an initial plan setting forth the quantities of Sarepta's or its CMOs' [**] (the "**Capacity Plan**"). The JMC will update the Capacity Plan on an annual basis contemporaneously with updates to the Manufacturing Plan based on updates to the Parties' Demand Forecast Plans (if any); *provided* that [**].

8.3 **Initial Forecasts**.

8.3.1 **Commercial Demand Forecast Plan**. Each Party will prepare an initial good faith five-year rolling forecast of its demand in the Sarepta Territory or the Roche Territory (as applicable) for each Licensed Product for Commercialization purposes (a) with respect to the Lead Product, within six months after the Effective Date, and (b) with respect to each other Licensed Product, within six months following Roche's Exercise of Option pursuant to Section 2.7.3 (Exercise of Option) for such Licensed Product (each, a "**Commercial Demand Forecast Plan**").

8.3.2 **Development Demand Forecast Plan**. The JMC will prepare an initial good faith five-year rolling forecast of the demand of both Parties throughout the Territory for each Licensed Product for Development purposes (a) with respect to the Lead Product, within 60 days following the formation of the JMC, or such other time as agreed by the Parties, and (b) with respect to each other Licensed Product, within 60 days following the JSC's approval of the applicable updated Roche Territory Development Plan that includes activities for such Licensed Product (each, a "**Development Demand Forecast Plan**", together with the Commercial Demand Forecast Plan, the "**Demand Forecast Plan**").

8.3.3 **Allocation of Supply**. Each Demand Forecast Plan shall allocate the supply of each Licensed Product needed to meet the expected demand of each Party for Development and Commercialization in the Sarepta Territory and the Roche Territory in accordance with this Agreement. [**]. The JMC will review each initial Demand Forecast Plan for each Licensed Product and submit each initial Demand Forecast Plan to the JSC to approve.

8.4 Demand Forecast Plans.

8.4.1 **Details**.

(a) [**]

(b) [**].

8.4.2 **Updates**. Each Demand Forecast Plan will be subsequently updated every Calendar Quarter for the upcoming five year period by the JMC and submitted for approval by the JSC.

8.4.3 **Supply Agreements**. The principles set forth in Section 8.4 (Demand Forecast Plans) shall be further detailed in the Supply Agreements established under Section 8.6 (Supply Agreement).

8.5 Purchase and Supply Obligation.

8.5.1 **Roche Purchase Obligation**. Roche shall purchase from Sarepta the following (as may be adjusted through agreement of the Parties) (a) [**] of the quantities of Licensed Product (drug product bulk) set forth for the first year of (i) the Development Demand Forecast Plan allocated for Development purposes under the Roche Territory Development Plan in such year and (ii) Roche's Commercial Demand Forecast Plan for such Licensed Product in such year; and (b) [**] of the quantities of Licensed Product (drug product bulk) set forth for the second year of (i) the Development Demand Forecast Plan allocated for Development purposes under the Roche Territory Development Plan in such year and (ii) Roche's Commercial Demand Forecast Plan for such Licensed Product in such year.

8.5.2 **Sarepta Supply Obligation**. Sarepta will use Commercially Reasonable Efforts to Manufacture itself or have Manufactured on its behalf through its network of CMOs the Licensed Products for Development purposes in accordance with the applicable Demand Forecast Plans and the Development Supply Agreement and the Commercial Supply Agreement to be negotiated in good faith by the Parties pursuant to Section 8.6 (Supply Agreements), in each case, to the extent such Demand Forecast Plans are not in excess of the Manufacturing capacity set forth in the Capacity Plan. Sarepta will not be responsible for the storage of any inventory of Licensed Products for the Roche Territory, all of which inventory will be held by or on behalf of Roche or its Affiliates.

8.6 Supply Agreements.

8.6.1 **Development Supply Agreement**. Unless otherwise agreed by the Parties, no later than [**] following (a) the Effective Date with regards to the Lead Product, and (b) the effective date of exercise of the Option with regards to every other Licensed Product, (or such other time as agreed by each Party), the Parties will negotiate in good faith and enter into a supply agreement on reasonable and customary terms for the supply of the Licensed Products by Sarepta to Roche in the Roche Territory at the Supply Price (the "**Development Supply Agreement**"), and a related quality agreement, which agreements will govern the terms and conditions of the Manufacturing the Licensed Products for Development purposes.

8.6.2 **Commercial Supply Agreement**. Unless otherwise agreed by the Parties, no later than [**] following (a) the Effective Date with regards to the Lead Product, and (b) the effective date of exercise of the Option with regards to every other Licensed Product, (or such other time as agreed by each Party), the Parties will negotiate in good faith and enter into a commercial supply agreement on reasonable and customary terms for the commercial-grade supply of the Licensed Products by Sarepta to Roche in the Roche Territory at the Supply Price, including customary remedies for Sarepta or its CMOs' failure to deliver quantities of Licensed Product consistent with the applicable quantities under properly submitted and accepted orders (the "**Commercial Supply Agreement**" and together with the Development Supply Agreement, the "**Supply Agreements**"), and a related quality agreement, which agreements will govern the terms and conditions of the Manufacturing and supply of the Licensed Products for Commercialization purposes.

8.6.3 **Consistency with Contract Manufacturing Agreements**. The Parties shall endeavor to agree on such operational terms in the Supply Agreements that are as closely aligned as possible with the terms of the agreements between Sarepta and its CMOs. Notwithstanding the above, Sarepta will be liable for any act or omission of any CMO that is a breach of any Sarepta's obligations under this Agreement as though the same were a breach by Sarepta, and Roche will have the right to directly proceed against Sarepta without any obligation to first proceed against such CMO.

8.7 **Supply Price**. The Parties agree that Roche will pay a supply price to Sarepta under the Supply Agreements that is equal to [**] (the "**Supply Price**"). The average Supply Price shall represent the price per drug product dose needed to treat one kilogram-equivalent patient over a particular Calendar Quarter (the "**Average Supply Price**"). The Parties agree that the Supply Price of a Licensed Product will be [**].

8.8 **Manufacturing Plan**. Within a period of time after the Effective Date to be agreed by the Parties, but in no case later than [**] days following the formation of the JMC, Sarepta will prepare a reasonably detailed annual plan for the Manufacture and supply of the Licensed Products throughout the Territory, which plan will include (a) the current Capacity Plan, (b) a plan to reduce Manufacturing Costs, (c) an annual plan for capital expenditure by Sarepta and its network of Third Party contract manufacturers in connection with such Manufacture and supply of the Licensed Products, and (d) each Party's good faith long-term, five-year rolling Development Demand Forecast Plans for its requirements of each Licensed Product (the proposed "**Manufacturing Plan**"). [**] after the Effective Date with respect to the Lead Product and [**] following Roche's Exercise of Option with respect to each other Licensed Product, Sarepta will prepare an update to the Manufacturing Plan including the Parties' Commercial Demand Forecast Plan. On or before [**] of each Calendar Year during the Term after the approval of the initial Manufacturing Plan (and more frequently as may be necessary during the Term), Sarepta will prepare an update to the Manufacturing Plan. The JMC will review and discuss the initial Manufacturing Plan and each update thereto, and submit the initial plan and any material update thereto to the JSC to approve. Once approved by the JSC, the initial Manufacturing Plan and each update to the Manufacturing Plan will become effective and, with respect to any update, supersede the previous Manufacturing Plan as of the date of such approval or at such other time as decided by the JMC. Notwithstanding any provision to the contrary set forth in this Agreement or in any Supply Agreement, Sarepta will have the right, without seeking JMC approval, to make operational decisions with respect to performance of the Manufacturing activities within the Manufacturing Plan that do not require a material update to the Manufacturing Plan.

8.9 **Audit**. Sarepta shall, and shall use reasonable efforts to ensure that its CMOs, maintain full and accurate records for the Licensed Products related to GMP and safety, health, and environmental protection standards. Roche shall have the right, upon reasonable advance notice during regular business hours, to audit the facilities and records of any of Sarepta's or any Affiliates' CMOs, including to perform audits related to GMP and safety, health, and environmental protection standards. Such audit will not be performed more frequently than once per Calendar Year for each facility of any such CMO. To the extent Sarepta is not able to facilitate such audits as set forth in this Section 8.9 (Audit), the Parties shall agree upon alternative measures to provide Roche with equivalent information.

8.10 **Shortage and Supply Failure**.

8.10.1 **Mitigation**. Each Party will promptly inform the other Party and the JMC if (a) the Demand Forecast Plans indicate that the Parties' demand for Licensed Products will outstrip the Manufacturing capacity set forth in the Capacity Plan, (b) it becomes aware of any issues relating directly or indirectly to planning, construction, qualification, and operating of Sarepta or a CMOs' manufacturing sites that could lead to a Shortage or Supply Failure, or (c) it otherwise believes that there is a reasonable risk of Shortage or Supply Failure of a Licensed Product for Development or Commercialization purposes in the Roche Territory in accordance with this Agreement. In such event, the JMC will meet to discuss potential remedies or mitigation strategies, including whether the Parties should invest in or otherwise procure such additional capacity and how such investments should be financed.

8.10.2 **Additional Audit**. To the extent agreed by the CMOs (which agreement Sarepta will use reasonable efforts to secure), in the event of a Supply Failure under clause (b) of Section 1.264 (Supply Failure), Roche will have the right to perform an additional audit in accordance with Section 8.9 (Audit) sufficient to verify the existence of such Supply Failure.

8.10.3 **Insufficient Supply**.

(a) **Insufficient Quantities; Shortages**. As will be more fully set forth in the applicable Supply Agreement, in the event of a Shortage of any Licensed Product for Development or Commercialization purposes in the Territory in accordance with this Agreement, until such Shortage is resolved, Sarepta will allocate available supply of the affected Licensed Product according to the allocation principles set forth in this Section 8.10.3(a) (Insufficient Quantities; Shortages). [**].

(b) **Insufficient Quantities; To Meet Demand Under Capacity Plan**. As will be more fully set forth in the applicable Supply Agreement, in the event that available supply of Licensed Product for Development or Commercialization purposes in the Territory falls below the total amount allocated to both Parties' Territories under the then-current Capacity Plan in an applicable year ("**Insufficient Supply Event**"), Sarepta will (i) investigate the cause(s) of such Insufficient Supply Event and report the result of such investigation to the JMC, (ii) use Commercially Reasonable Efforts to remedy the Insufficient Supply Event, and (iii) until such Insufficient Supply Event is resolved, allocate available supply of the affected Licensed Product in accordance with the allocation principles set forth in this Section 8.10.3(b) (Insufficient Quantities; To Meet Demand Under Capacity Plan). [**].

8.10.4 **Supply Failure**. As will be more fully set forth in the applicable Supply Agreement, in the event of a Supply Failure of any Licensed Product for Development or Commercialization purposes in the Territory in accordance with this Agreement, Sarepta will (a) investigate the cause(s) of such Supply Failure and report the result of such investigation to the JMC, and (b) use Commercially Reasonable Efforts to remedy such Supply Failure. In addition, in the event of a Supply Failure, Roche shall have the right to terminate the Agreement pursuant to Section 14.3 (Supply Failure).

8.10.5 **Sarepta Inability to Supply**. In the event of a Sarepta Inability to Supply, following discussion between the Parties, solely during the pendency of such Sarepta Inability to Supply, [**].

8.11 Technology Transfer.

8.11.1 **Request for Technology Transfer**. At any time, irrespective of any actual or imminent Shortage or Supply Failure, Roche shall have the right to request that Sarepta transfer the Sarepta Manufacturing Know-How to Roche or one or more Roche CMOs. In such event, no later than [**] after Roche's request, the JMC will discuss in good faith such request, including any alternatives that would be acceptable to Roche. Following such JMC discussion, Roche may provide written notice of its intention to, itself or through one or more CMOs, Manufacture Licensed Products in accordance with this Agreement (the "**Manufacturing Transition Notice**"). Subject to Section 8.11.2 (Manufacturing Transition Period), following Roche's delivery of the Manufacturing Transition Notice to Sarepta, (a) Roche may Manufacture the Licensed Product for Development and Commercialization purposes in accordance with this Agreement for the purpose of satisfying demand for Licensed Product in the Roche Territory and (b) Sarepta will use reasonable efforts to transfer to Roche or its CMOs copies of the Sarepta Manufacturing Know-How in electronic form or such other form maintained by Sarepta. To facilitate such transfer set forth in the foregoing clause (b), upon Roche's reasonable request, Sarepta will use reasonable efforts to make available to Roche or its selected Roche CMO a reasonable number of Sarepta's technical personnel with appropriate skill and experience at times to be agreed by the Parties. Unless such request is made following a Supply Failure, Roche will be responsible for all Internal Costs and External Costs incurred by or on behalf of Sarepta or its Affiliates in connection with such transfer of Know-How. Accordingly, Sarepta may invoice Roche for such costs and expenses, and Sarepta will pay the undisputed invoiced amounts within 30 days after the date of the invoice. If such request is made following a Supply Failure, then Sarepta will be responsible for all Internal Costs and External Costs incurred by or on behalf of Sarepta or its Affiliates in connection with such transfer of Know-How.

8.11.2 **Manufacturing Transition Period**. For a period of years to be agreed by the JMC following delivery to Sarepta of the Manufacturing Transition Notice in accordance with Section 8.11.1 (Request for Technology Transfer) (such period, the "**Manufacturing Transition Period**"), Roche will continue to order Licensed Products from Sarepta or Sarepta's CMOs in the quantities set forth in a manufacturing transition plan proposed by the JMC and approved by the JSC (the "**Manufacturing Transition Plan**"), which quantities in any event will not be less than the Manufacturing capacity of Sarepta or any of its Affiliates or CMOS, in each case, that was reserved in accordance with the Demand Forecast Plan at the applicable time for any Licensed Product, which capacity Sarepta or any of its Affiliates cannot, using reasonable efforts, use itself, cancel (free of charge), or allocate to any product that is not a Licensed Product or to any Third Party. During the Manufacturing Transition Period, the JMC will regularly update the Demand Forecast Plans in accordance with Section 8.4.2 (Updates).

ARTICLE 9
PAYMENTS

9.1 **Upfront Payment**. No later than [**] days after the Effective Date, Roche will pay to Sarepta by wire transfer of immediately available funds a payment of $750,000,000 (the "**Upfront Payment**") in consideration for the rights granted by Sarepta and for prepaid funding for Development activities.

9.2 **Equity Investment**. Roche Finance Ltd will purchase shares of common stock of Sarepta Therapeutics, Inc. in accordance with the terms set forth in the Stock Purchase Agreement.

9.3 **Option Exercise Fees**. No later than 15 days following Roche's delivery to Sarepta of an Option Exercise Notice with respect to the exercise of the Option for the Exon-Skipping Products or any other Option Product and receipt of a corresponding invoice from Sarepta, Roche will pay to Sarepta by wire transfer of immediately available funds a payment of (a) for the exercise of the Option for the Exon-Skipping Products: $[**], (b) for the exercise of the Option for any Gene-Editing Option Product: (i) $[**] for the exercise of the Option for the first Gene-Editing Option Product; and (ii) $[**] for the exercise of the Option for each of the [**] Gene-Editing Option Product, (c) subject to any reduction permitted under Section 2.5.5(a)(C) ([**]), for each exercise of the Option for any Gene Therapy Option Product: $[**] (each, an "**Option Exercise Fee**"). If Roche fails to pay any Option Exercise Fee when due under this Section 9.3 (Option Exercise Fees), then Sarepta will notify Roche of such failure in writing and, to avoid termination of the applicable Option with respect to such Option Product, Roche will pay to Sarepta the applicable Option Exercise Fee within 15 days after receipt of such notice. Roche will not owe any Option Exercise Fee with respect to the exercise of the Option for any Gene-Editing Option Product after the [**] Gene-Editing Option Product. [**].

9.4 **Milestone Payments**.

9.4.1 **Regulatory Milestones for Lead Product**. No later than 30 days after receipt of an invoice from Sarepta for the first achievement of each regulatory milestone event set forth in Table 9.4.1 below for the Lead Product in each of [**], Roche will pay to Sarepta the corresponding regulatory milestone payment set forth in Table 9.4.1 (the regulatory milestone events set forth in Table 9.4.1, the "**Lead Product Regulatory Milestone Events**" and the regulatory milestone payments set forth in Table 9.4.1, the "**Lead Product Regulatory Milestone Payments**"). If the Lead Product receives Regulatory Approval in [**] for a label that includes more than one Lead Product Regulatory Milestone Events set forth in Table 9.4.1, then all applicable Lead Product Regulatory Milestone Payments corresponding to the Regulatory Milestone Events achieved will be due and payable. By way of illustration, upon receipt of Regulatory Approval in [**] for the Lead Product that [**] in Lead Product Regulatory Milestone Payments will be due and payable.

Table 9.4.1 – Lead Product Regulatory Milestones		
Lead Product Regulatory Milestone Event	**Lead Product *Regulatory Milestone Payment (in U.S. Dollars)***	
	Achievement of the Lead Product Regulatory Milestone Event in [**]	***Achievement of the Lead Product Regulatory Milestone Event in [**]***
[**]	$[**]	$[**]
[**]	$[**]	$[**]
[**]	$[**]	$[**]
[**]	$[**]	$[**]
[**]	$[**]	$[**]
[**]	$[**]	$[**]

9.4.2 **Clinical and Regulatory Milestones for Exon-Skipping Products that are Licensed Products**. On a Licensed Product-by-Licensed Product basis, no later than 30 days after receipt of an invoice from Sarepta for the first achievement of each clinical and regulatory milestone event set forth in Table 9.4.2 below for a Licensed Product that is an Exon-Skipping Product in [**], Roche will pay to Sarepta the corresponding clinical and regulatory milestone payment set forth in Table 9.4.2 (the clinical and regulatory milestone events set forth in Table 9.4.2, the "**Exon-Skipping Product Clinical Milestone Events**", the "**Exon-Skipping Product Clinical Milestone Payments**", the "**Exon-Skipping Product Regulatory Milestone Events**" and "**Exon-Skipping Product Regulatory Milestone Payments**").

Exon-Skipping Product Clinical Milestone Payments and Exon-Skipping Product Regulatory Milestone Payments are due only for Exon-Skipping Product Clinical Milestone Events and Exon-Skipping Product Regulatory Milestone Events that occur after delivery of the Option Exercise Notice for the Exon-Skipping Products. Each Exon-Skipping Product Clinical Milestone Payment and each Exon-Skipping Product Regulatory Milestone Payment is payable only once with respect to each Exon-Skipping Product and each such milestone payment is due for achievement of the same Exon-Skipping Product Clinical Milestone Event or Exon-Skipping Product Regulatory Milestone Event for a maximum of [**] distinct Exon-Skipping Products. For clarity, the maximum aggregate amount of Exon-Skipping Product Clinical Milestone Payments and Exon-Skipping Product Regulatory Milestone Payments is $[**].

Table 9.4.2 – Exon-Skipping Product Clinical Milestones and Regulatory Milestones	
Exon-Skipping Product Clinical Milestone Event	***Exon-Skipping Product Clinical Milestone Payment (in U.S. Dollars)***
[**]	$[**]
Exon-Skipping Product Regulatory Milestone Event in [**]	***Exon-Skipping Product Regulatory Milestone Payment in [**] (in U.S. Dollars)***
[**]	$[**]
[**]	$[**]

9.4.3 **Regulatory Milestones for Gene Therapy Products that are Licensed Products other than Lead Product**. On a Gene Therapy Product-by-Gene Therapy Product basis, no later than 30 days after receipt of an invoice from Sarepta for the first achievement of each regulatory milestone event set forth in Table 9.4.3 below for a Gene Therapy Product that is a Licensed Product (other than the Lead Product) in each of [**], Roche will pay to Sarepta the corresponding regulatory milestone payment set forth in Table 9.4.3 (the regulatory milestone events set forth in Table 9.4.3, the "**Gene Therapy Product Regulatory Milestone Events**" and the regulatory milestone payments set forth in Table 9.4.3, the "**Gene Therapy Product Regulatory Milestone Payments**"), subject to any reduction permitted under [**]. For clarity, each Gene Therapy Product Regulatory Milestone Payment is payable only once per Licensed Product.

Table 9.4.3 – Gene Therapy Product Regulatory Milestones (other than for Lead Product)		
Gene Therapy Product Regulatory Milestone Event	***Gene Therapy Product Regulatory Milestone Payment (in U.S. Dollars)***	
	Gene Therapy Product Regulatory Milestone Event in [**]	***Gene Therapy Product Regulatory Milestone Event in [**]***
[**]	$[**]	$[**]
[**]	$[**]	$[**]

9.4.4 **Clinical and Regulatory Milestones for Gene-Editing Licensed Products.** On a Gene-Editing Licensed Product-by-Gene-Editing Licensed Product basis, no later than 30 days after receipt of an invoice from Sarepta for the first achievement of each regulatory milestone event set forth in Table 9.4.4 below for a Gene-Editing Licensed Product in each of [**], Roche will pay to Sarepta the corresponding regulatory milestone payment set forth in Table 9.4.4 (the regulatory milestone events set forth in Table 9.4.4, the "**Gene-Editing Licensed Product Regulatory Milestone Events**" and the regulatory milestone payments set forth in Table 9.4.4, the "**Gene-Editing Licensed Product Regulatory Milestone Payments**"). For clarity, each Gene-Editing Licensed Product Regulatory Milestone Payment is payable only once per Gene-Editing Licensed Product.

Gene-Editing Licensed Product Regulatory Milestone Payments and Gene-Editing Licensed Product Regulatory Milestone Payments are due only for Gene-Editing Licensed Product Regulatory Milestone Events and Gene-Editing Licensed Product Regulatory Milestone Events that occur after delivery of the Option Exercise Notice for the Gene-Editing Licensed Products. Each Gene-Editing Licensed Product Regulatory Milestone Payment and each Gene-Editing Licensed Product Regulatory Milestone Payment is payable only once for the [**] Gene-Editing Licensed Product (as applicable). If Roche or its Affiliates or Sublicensees files for Regulatory Approval for a Gene-Editing Licensed Product prior to Roche paying Sarepta any Gene-Editing Licensed Product Milestone Payment that is due upon Initiation of a Pivotal Clinical Trial for such Gene-Editing Licensed Product (*e.g.*, because the Pivotal Clinical Trial was the same Clinical Trial as the Proof of Concept Trial for such Gene-Editing Licensed Product), then Roche will promptly pay to Sarepta such unpaid Gene-Editing Licensed Product Milestone Payment for Initiation of such Pivotal Clinical Trial. For clarity, the maximum aggregate amount of Gene-Editing Licensed Product Regulatory Milestone Payments and Gene-Editing Licensed Product Regulatory Milestone Payments is $[**].

Table 9.4.4– Gene-Editing Licensed Product Clinical Milestones and Regulatory Milestones		
Gene-Editing Licensed Product Regulatory Milestone Event	***Gene-Editing Licensed Product Regulatory Milestone Payment (in U.S. Dollars)***	
	Gene-Editing Licensed Product Regulatory Milestone Event in [**]	***Gene-Editing Licensed Product Regulatory Milestone Event in [**]***
[**]	$[**]	$[**]
[**]	$[**]	$[**]
[**]	$[**]	$[**]
[**]	$[**]	$[**]
[**]	$[**]	$[**]
[**]	$[**]	$[**]

9.4.5 **Sales Milestones with respect to Lead Product**. With respect to the Lead Product, no later than 60 days after the end of the first Calendar Quarter in which for the first time either [**] crosses each of the thresholds set forth in Table 9.4.5, Roche will pay to Sarepta the corresponding sales milestone payment set forth in Table 9.4.5 below (the sales milestone events set forth in Table 9.4.5, the "**Lead Product Sales Milestone Events**" and the sales milestone payments set forth in Table 9.4.5, the "**Lead Product Sales Milestone Payments**").

Table 9.4.5 – Lead Product Sales Milestones	
One-time Lead Product Sales Milestone Event	***Sales Milestone Payment (in U.S. Dollars)***
[**]	$[**]
[**]	$[**]
[**]	$[**]
[**]	$[**]

9.4.6 **Sales Milestones for Gene-Editing Licensed Products**. With respect to all Gene-Editing Licensed Products in aggregate, no later than 60 days after the end of the first Calendar Quarter in which for the first time either [**] crosses each of the thresholds set forth in Table 9.4.6, Roche will pay to Sarepta the corresponding sales milestone payment set forth in Table 9.4.6 below (the sales milestone events set forth in Table 9.4.6, the "**Gene-Editing Sales Milestone Events**" and the sales milestone payments set forth in Table 9.4.6, the "**Gene-Editing Sales Milestone Payments**").

Table 9.4.6 – Gene-Editing Licensed Products Sales Milestones	
One-time Gene-Editing Licensed Products Sales Milestone Event	***Sales Milestone Payment (in U.S. Dollars)***
[**]	$[**]
[**]	$[**]
[**]	$[**]
[**]	$[**]

9.4.7 **Notification of Milestone Events**. Roche will promptly notify Sarepta in writing, but in no event later than 30 days after, the achievement of each Regulatory Milestone Event or Sales Milestone Event (collectively, the "**Milestone Events**"). However, in no event will a failure by Roche to deliver such notice of achievement of a Milestone Event relieve Roche of its obligation to pay Sarepta the corresponding Regulatory Milestone Payment or Sales Milestone Payment (collectively, the "**Milestone Payments**") for achievement of the applicable Milestone Event.

9.5 **Royalties**.

9.5.1 **Royalty Payments for Lead Product**. With respect to the Lead Product, Roche will pay to Sarepta, on a country-by-country basis, royalties at the applicable royalty rate set forth in Table 9.5.1 (the "**Lead Product Royalty Rates**") on Net Sales of Lead Product by Roche and its Affiliates and Sublicensees in each country in the Roche Territory (the "**Lead Product Royalties**") beginning with First Commercial Sale until the later to occur of (a) [**] years after First Commercial Sale of the Lead Product in such country, (b) the expiration of the last Valid Claim in the Royalty-Bearing Patent Rights that Covers the Lead Product in such country, and (c) loss of Regulatory Exclusivity of the Lead Product in such country (the "**Lead Product Royalty Term**"). [**].

Table 9.5.1 – Lead Product Royalty Rates	
[**]	***Lead Product Royalty Rate***
[**]	[**]%
[**]	[**]%
[**]	[**]%
[**]	[**]%
[**]	[**]%

9.5.2 **Royalty Payments for Licensed Products Other than the Lead Product**. For Licensed Products other than the Lead Product, Roche will pay to Sarepta, on a Licensed Product-by-Licensed Product and country-by-country basis, royalties during the Term at a royalty rate of [**]% on the Net Sales of each such Licensed Product sold by Roche and its Affiliates and Sublicensees in each country in the Roche Territory (the "**Other Product Royalties**" and together with the Lead Product Royalties, the "**Royalties**") beginning at First Commercial Sale until the latest to occur of (a) 12 years after First Commercial Sale of such Licensed Product in such country, (b) the expiration of the last Valid Claim in the Royalty-Bearing Patent Rights that Covers such Licensed Product in such country, and (c) loss of Regulatory Exclusivity of such Licensed Product in such country (the "**Other Product Royalty Term**").

9.5.3 Royalty Reduction.

(a) **Step-Down for no Valid Claim of Royalty-Bearing Patent Rights**. Subject to Section 9.5.3(e) (Royalty Reductions Floor), on a Licensed Product-by-Licensed Product and country-by-country basis, the Royalties payable by Roche with respect to the Net Sales of an applicable Licensed Product in a country in the Roche Territory will be reduced by [**]% during each Calendar Quarter in which there exists no Valid Claim within the Royalty-Bearing Patent Rights that Cover such Licensed Product thereof in such country.

(b) **Biosimilar Competition Royalty Reduction for Licensed Products**. Subject to Section 9.5.3(e) (Royalty Reductions Floor), on a Licensed Product-by-Licensed Product and country-by-country basis, in the event of Biosimilar Competition with respect to a Licensed Product in a given country in the Roche Territory, the applicable Royalties in such country for such Licensed Product shall be reduced as follows:

(A) [**].

(B) [**].

(c) **Apportionment of Compulsory Sublicensee Consideration**. The Parties will [**] all consideration from Compulsory Sublicensees received by Roche or its Affiliates or Sublicensees for a Licensed Product in a country in the Roche Territory from a Compulsory Sublicensee.

(d) **Royalty Stacking**. Subject to Section 9.5.3(e) (Royalty Reductions Floor), Roche may credit [**]% of any Third Party Payments and Third Party Royalty Payments with respect to a Licensed Product in a country in the Roche Territory in a Calendar Quarter against the Royalties due and payable by Roche to Sarepta on the Net Sales for such Licensed Product in such country in such Calendar Quarter; *provided* that the terms of this Section 9.5.3(d) (Royalty Stacking) will not apply to any license agreement entered into in violation of the terms of Section 10.11.3 (Settlement).

(e) **Royalty Reductions Floor; Carry Forward**. In no event will the Royalties due to Sarepta for a Licensed Product in a country in the Roche Territory in any given Calendar Quarter during the Royalty Term for such Licensed Product in such country be reduced by more than [**]% of the amount that otherwise would have been due and payable to Sarepta in such Calendar Quarter for such Licensed Product in such country but for the reductions set forth in this Section 9.5.3 (Royalty Reduction). Roche may carry forward any such reductions permitted under this Section 9.5.3 (Royalty Reduction) that are incurred or accrued in a Calendar Quarter but that are not creditable in such Calendar Quarter as a result of the foregoing floor and apply such amounts in any subsequent Calendar Quarter (subject to the minimum floor set forth in this Section 9.5.3(e) (Royalty Reductions Floor; Carry Forward)) until the amount of such reductions have been fully applied.

9.5.4 Royalty Payments and Reports.

(a) **Royalty Report**. Within 45 days after the end of each Calendar Quarter during the applicable Royalty Term, Roche will provide to Sarepta a written report (each, a "**Royalty Report**") setting forth in reasonable detail, on a country-by-country basis, (i) the Sales of the Licensed Products by Roche or its Affiliate or Sublicensee in the Roche Territory in such Calendar Quarter; (ii) the aggregate Net Sales of the Licensed Products sold by Roche or its Affiliates or Sublicensees in the Roche Territory in such Calendar Quarter; (iii) all deductions and reductions from Sales used to determine the Net Sales of the Licensed Products for such Calendar Quarter or the Royalties payable with respect to the Licensed Products for such Calendar Quarter, including any reductions pursuant to Section 9.5.2 (Royalty Reduction); (iv) the exchange rates used to calculate the Royalties payable in U.S. Dollars; and (v) the Compulsory Sublicense Consideration due in such Calendar Quarter. The Parties will seek to resolve any questions or issues related to a Royalty Report within five days following receipt by Sarepta of each Royalty Report.

(b) **Royalty Payments**. The information contained in each Royalty Report will be considered Confidential Information of Roche. Within 60 days after the end of each Calendar Quarter, Roche will make the Royalty payment due hereunder for such Calendar Quarter covered by the applicable Royalty Report.

9.6 Accounting; Audit. Each Party agrees to keep full, clear, and accurate records in accordance with the applicable Accounting Standard for such Party, for a period of at least three years after the relevant payment is owed pursuant to this Agreement, setting forth (as applicable) Eligible Global Development Costs, Eligible Medical Affairs Costs, Royalties, sales of the Licensed Products (including all calculations of Net Sales), and other amounts payable to the other Party hereunder, in each case, in sufficient detail to enable amounts owed or payable to the other Party hereunder to be determined. Each Party further agrees to permit its books and records to be examined by an independent accounting firm selected by the auditing Party and reasonably acceptable to the audited Party to verify the accuracy of any of the foregoing; *provided* that such independent accounting firm is subject to written obligations of confidentiality and non-use applicable to each Party's Confidential Information that are at least as stringent as those set forth described in Article 12 (Confidentiality). Such audit will not be (a) performed more frequently than once per Calendar Year, (b) conducted for any Calendar Year more than three years after the end of such year, or (c) repeated for any Calendar Year or with respect to the same set of records (unless a discrepancy with respect to such records is discovered during a prior audit). Such examination is to be made at the expense of the auditing Party, except in the event that the results of the audit reveal an underpayment, or overcharge in the case of Manufacturing Costs charged, by the audited Party of [**]% or more during the period being audited, in which case reasonable audit fees for such examination will be paid by the audited Party. The underpaid Party will be entitled to recover any shortfall in payments as determined by such audit, plus interest thereon, calculated in accordance with Section 9.12 (Late Payments; Disputed Payments). If such examination of records reveals any overpayment by a Party, then the other Party will credit the amount overpaid against future amounts due to the other Party by the overpaying Party.

9.7 No Refunds. Except as expressly provided herein, all payments under this Agreement will be irrevocable, non-refundable, and non-creditable.

9.8 **Currency Conversion**. Any Net Sales that are invoiced or incurred in a currency other than U.S. Dollars, and all other payments by Roche to Sarepta, will be converted into Swiss Francs and then into U.S. Dollars using Roche's then-current internal foreign currency translation method actually used on a consistent basis in preparing its audited financial statements, which as of the Effective Date, uses the year-to-date average conversion rate reported by Reuters.

9.9 **Blocked Payments**. If, in a given country, proceeds related to Net Sales are received in a local currency that cannot be removed from such country as a result of Applicable Law, then Roche will promptly notify Sarepta of the conditions preventing such transfer and such payments will be deposited in local currency in the relevant country to the credit of Sarepta in a recognized banking institution designated by Sarepta or, the Royalties for such Net Sales in such country shall continue to be accrued and shall continue to be reported, but not paid to Sarepta until the sales proceeds related to such Net Sales are permitted to be removed from such country under Applicable Law. At such time as Roche or its Affiliates or Sublicensees, as the case may be, is able to remove the sales proceeds related to such Net Sales from such country under Applicable Law, Roche will pay such accrued Royalties in accordance with Section 9.10 (Method of Payment) using the actual exchange rate that is used to remove such sales proceeds from such country (it being understood that such Royalties shall not be deemed to be a late payment or subject to any interest under Section 9.12 (Late Payments)).

9.10 **Method of Payment**. All payments due to a Party under this Agreement will be made in U.S. Dollars by wire transfer to a U.S. bank account of such Party designated from time-to-time in writing by the relevant Party.

9.11 **Taxes**. If under any law or regulation of any country of the Territory withholding of taxes of any type, levies or other charges is required with respect to any amounts payable hereunder to a Party, the other Party ("**Withholding Party**") will apply the withholding or deduction as so required and will promptly pay such tax, levy, or charge to the proper Governmental Authority, and will promptly furnish the Party with proof of such payment. The Withholding Party will have the right to withhold or deduct any such tax, levy, or charge actually paid from payment due the Party or be promptly reimbursed by the Party if no further payments are due the Party. Any amounts so withheld or deducted from the payment due the Party pursuant to the relevant law or regulation will be deemed paid to such Party for all purposes of this Agreement. Each Withholding Party agrees to assist the other Party in claiming exemption from (or reduction in) such deductions or withholdings under double taxation or similar agreement or treaty from time-to-time in force and in minimizing the amount required to be so withheld or deducted. Notwithstanding the foregoing, all sums payable by either Party hereunder are stated exclusive of any sales tax, value added tax, or other similar taxes, assessments, and charges imposed by the jurisdiction of the Withholding Party or the payee and any such taxes will be paid by the Withholding Party.

9.12 **Late Payments; Disputed Payments**. Any amount owed by a Party to the other Party under this Agreement that is not paid within the applicable time period set forth herein will accrue interest at [**]. If a Party disputes an invoice or other payment obligation under this Agreement, then such Party will timely pay the undisputed amount of the invoice or other payment obligation, and the Parties will resolve such dispute in accordance with Article 15 (Effectiveness). For clarity, no interests shall accrue for any payment that is successfully disputed, and accordingly not due, in accordance with this Agreement.

ARTICLE 10
INTELLECTUAL PROPERTY

10.1 **Patent Filing**. To the extent that prosecution of applicable Patent Rights are within Sarepta's responsibility as set forth in this Article 10 (Intellectual Property), Sarepta shall use reasonable efforts to obtain and maintain patent protection for the Licensed Product in the Roche Major Countries.

10.2 **Ownership**.

10.2.1 **Sarepta Technology**. As between the Parties, ownership of the Sarepta Know-How, Sarepta Patent Rights, the Option Product Know-How, and Option Product Patent Rights, in each case, will be and remain vested at all times in Sarepta. To the extent that Roche or any of its Affiliates or Sublicensees acquires any rights, title, or interests in or to any Sarepta Collaboration Know-How or Sarepta Collaboration Patent Rights, Roche for itself and on behalf of its Affiliates and Sublicensees, hereby irrevocably assigns to Sarepta all such rights, title, and interests in and to all such Sarepta Collaboration Know-How and Sarepta Collaboration Patent Rights.

10.2.2 **Roche Technology**. As between the Parties, ownership of the Roche Collaboration Technology and Roche Background Technology will be and remain vested at all times in Roche. To the extent that Sarepta or any of its Affiliates or Sublicensees acquires any rights, title, or interests in or to any Roche Collaboration Technology or Roche Background Technology, Sarepta for itself and on behalf of its Affiliates and Sublicensees, hereby irrevocably assigns to Roche all such rights, title, and interests in and to all such Roche Collaboration Technology and Roche Background Technology.

10.2.3 **Joint Collaboration Technology**. All Joint Collaboration Technology will be jointly owned by the Parties, with each Party holding an equal and undivided joint ownership interest therein, and each Party for itself and on behalf of its Affiliates and Sublicensees, hereby assigns to the other Party an equal and undivided joint ownership interest in and to all Joint Collaboration Technology to be held in accordance with this Section 10.2.1 (Joint Collaboration Technology). Each Party is and will be entitled to practice the Joint Collaboration Technology for all purposes on a worldwide basis and to license such Joint Collaboration Technology through multiple tiers and transfer its ownership interest in such Joint Collaboration Technology, in each case without the consent of the other Party (and where consent is required by Applicable Law, such consent is deemed hereby granted) and without a duty of accounting or compensation to the other Party, but in each case subject to the terms and conditions of this Agreement, including the license grants under Article 2 (Licenses). Each Party will grant and hereby does grant to the other Party all further permissions, consents, waivers with respect to, and all licenses under the Joint Collaboration Technology throughout the world, necessary to provide the other Party with full rights of use and Exploitation of the Joint Collaboration Technology in accordance with the terms of this Agreement. Without limiting the foregoing, each Party will cooperate with the other Party through the IP Committee pursuant to Section 10.6 (Prosecution of Joint Collaboration Patent Rights) in the filing and prosecution of Joint Collaboration Technology.

10.3 Disclosure; Inventorship.

10.3.1 Invention Disclosure. Each Party will promptly disclose to the other Party through the IP Committee any Inventions within the Collaboration Know-How developed or invented during the Term by or on behalf of such Party, in each case, no later than 30 days after the applicable Party's intellectual property department receives notice of such Invention and in any event as soon as practicable prior to an intended public disclosure of such Invention and prior to the filing of a patent application thereon.

10.3.2 Inventions by a Party. Inventorship for Inventions and discoveries (including Know-How) first invented or developed during the course of the performance of activities under this Agreement will be determined in accordance with United States Patent Laws for determining inventorship.

10.3.3 CREATE Act. Notwithstanding any provision to the contrary set forth in this Agreement, neither Party may invoke the Cooperative Research and Technology Enhancement Act, 35 U.S.C. § 102(c) (the "**CREATE Act**") when exercising its rights under this Agreement without prior notice to the IP Committee and the prior written approval of the other Party. If a Party intends to invoke the CREATE Act, then it will notify the other Party through the IP Committee and if agreed by the Parties the other Party will cooperate and coordinate its activities with such Party with respect to any filings or other activities in support thereof. The Parties acknowledge and agree that this Agreement is a "**joint research agreement**" as defined in the CREATE Act.

10.4 IP Committee.

10.4.1 Membership. Within [**] days following the Effective Date, the Parties will establish a committee (the "**IP Committee**") comprised of at least [**] senior patent attorneys and one senior trademark attorney from each Party (*provided* that [**]) to (a) manage, review, and discuss the patent strategy for the preparation, filing, prosecution, and maintenance of (i) Collaboration Patent Rights, other than Joint Collaboration Patent Rights, (ii) Inventions within the Collaboration Know-How, other than Inventions within the Joint Collaboration Know-How, and (iii) any Patent Rights Controlled pursuant to a Collaboration In-License, (b) review, discuss, and, as provided in this Article 10 (Intellectual Property), comment on the preparation, filing, prosecution, and maintenance of Sarepta Patent Rights as provided under Section 10.5.2 (Status Updates), Joint Collaboration Patent Rights as provided under Section 10.6.3 (Status Updates), Option Product Patent Rights as provided under Section 10.7.2 (Status Updates), and Roche Collaboration Patent Rights as provided under Section 10.8.2 (Status Updates), (c) review, discuss, and, as provided in this Article 10 (Intellectual Property), comment on any Third Party Patent Challenges under Section 10.10 (Defense of Third Party Patent Challenges) or Third Party infringement claims or Patent Challenges as provided under Section 10.11 (Third Party Infringement Claims) or Section 10.12 (Patent Challenges of Third Party Patent Rights), as applicable, (d) review, discuss, and, as provided in this Article 10 (Intellectual Property), comment on the preparation, filing, prosecution, and maintenance of Sarepta-Owned Marks as provided under Section 10.16.3(b) (Status Updates) and review, discuss, and determine whether to approve the Product Marks and associated usage instructions in the Roche Territory under Section 10.16 (Marks), and (e) perform such other activities as may be delegated to the IP Committee from time to time during the Term by the JSC or otherwise by agreement of the Parties.

10.4.2 **Meetings**. The IP Committee will hold meetings at such times as it elects to do so, but in no event will such meetings be held less frequently than once per Calendar Quarter. The IP Committee will meet alternatively at Roche's facilities in Basel, Switzerland and Sarepta's facilities in Cambridge, MA, U.S., or at such locations as the Parties may otherwise agree, with the first IP Committee meeting to be held at Sarepta's offices in Cambridge, MA, U.S. Meetings of the IP Committee may be held by audio or video teleconference with the consent of each Party; *provided, however*, that at least one IP Committee meeting per Calendar Year will be held in-person. In between such meetings, the IP Committee will receive updates from the Parties regarding the prosecution and maintenance of Sarepta Patent Rights, Roche Collaboration Patent Rights and Joint Collaboration Patent Rights as set forth in this Agreement and will discuss such updates as well as day-to-day activities regarding the preparation, filing, prosecution and maintenance of Sarepta Patent Rights, Roche Collaboration Patent Rights and Joint Collaboration Patent Rights by audio or video teleconference.

10.4.3 **Decision-Making**. All decisions of the IP Committee will be made by consensus, with each Party's representatives on the IP Committee having collectively one vote on all matters that are within the responsibility of the IP Committee. If the members of the IP Committee are unable to agree on any such matter after a period of [**] days, then, except as otherwise agreed by the Parties, the matter will be escalated to the JDC, JCC or JMC, as appropriate.

10.5 Prosecution of Sarepta Patent Rights.

10.5.1 **Sarepta First Right to Prosecute**. Sarepta will have the first right, but not the obligation, to file, prosecute, and maintain the Sarepta Patent Rights using internal counsel and external counsel mutually agreed to by the Parties. Upon the reasonable request of Sarepta, Roche will at Sarepta's own cost and expense cooperate with and assist Sarepta as needed in connection with the filing, prosecution, and maintenance of all Sarepta Patent Rights.

10.5.2 **Status Updates; Comments**. Upon Roche's request, but no more than once per month, Sarepta will provide to the IP Committee a written summary of the status of all Sarepta Patent Rights (including patent applications) being prosecuted and maintained by Sarepta in the Roche Territory and will provide updates to the IP Committee by audio or video teleconference regarding Sarepta Patent Rights being prosecuted and maintained by Sarepta in the Roche Territory, including the strategies for the filing, prosecution, and maintenance of such Sarepta Patent Rights in the Roche Territory. Through the IP Committee, Sarepta will reasonably discuss and consult with Roche regarding the prosecution and maintenance of the Sarepta Patent Rights. Sarepta will consider in good faith the comments provided by Roche's representatives on the IP Committee, but will retain final decision-making authority regarding the prosecution and maintenance of all Sarepta Patent Rights.

10.5.3 **Assistance; Costs**. Subject to Section 10.5.4 (Abandonment in Roche Territory), [**] will be responsible for [**] of the actual External Costs incurred by Sarepta with respect to the filing, prosecution, and maintenance of the Sarepta Patent Rights in the Roche Territory. Sarepta will invoice Roche quarterly for such External Costs incurred by Sarepta. Roche will pay Sarepta the undisputed invoiced amount within 30 days after the date of Sarepta's invoice therefor, and any disputed amount within 30 days following the resolution of the dispute.

10.5.4 **Abandonment in Roche Territory**. If Sarepta decides that it is no longer interested in prosecuting or maintaining a particular Sarepta Patent Right in any country in the Roche Territory during the Term such that there would be an irrevocable loss of such Sarepta Patent Right (including the ability to file a new Patent Right claiming benefit of priority to such Patent Right) in such country, then Sarepta will promptly, and in any event at least [**] prior to the date any such Sarepta Patent Right would become abandoned, no longer available or otherwise forfeited, provide written notice to Roche of such decision. Roche may, upon written notice to Sarepta no later than [**] after Roche's receipt of the applicable notice from Sarepta, assume such prosecution and maintenance in Sarepta's name at Roche's sole cost and expense. Notwithstanding any provision to the contrary, such Sarepta Patent Right shall remain exclusively licensed to Roche with rights to sublicense without requiring Sarepta's approval, cease to be a Royalty-Bearing Patent Right for the purposes of this Agreement, and may be abandoned by Roche without permission of, but with notice to, Sarepta.

10.6 Prosecution of Joint Collaboration Patent Rights.

10.6.1 **Filing of Joint Collaboration Patent Rights**. Sarepta will have the first right, but not the obligation, to file, prosecute, and maintain Patent Rights that claim any Invention included in the Joint Collaboration Know-How using internal counsel and external counsel mutually agreed to by the Parties. If Sarepta declines to file such Patent Rights, then Sarepta will promptly, and in any event no later than 30 days after the applicable decision, provide written notice to Roche of such decision and Roche may, upon written notice to Sarepta within 30 days after Roche's receipt of the applicable notice from Sarepta, elect to do so using such external counsel. Whichever Party files patent applications claiming Joint Collaboration Know-How in accordance with this Section 10.6.1 (Filing of Joint Collaboration Patent Rights) will be responsible for prosecuting and maintaining such Joint Collaboration Patent Rights (such Party, the "**Prosecuting Party**").

10.6.2 **Prosecuting Party's First Right to Prosecute**. The Prosecuting Party will have the first right, but not the obligation, to prosecute and maintain the Joint Collaboration Patent Rights using internal counsel and external counsel mutually agreed to by the Parties. On the reasonable request of the Prosecuting Party, the non-Prosecuting Party will at its own cost and expense cooperate with and assist the Prosecuting Party as needed in connection with the prosecution and maintenance of all Joint Collaboration Patent Rights.

10.6.3 **Status Updates**. Upon the other Party's request, but no more than once per month, the Prosecuting Party will provide to the IP Committee a written summary of the status of all Joint Collaboration Patent Rights, including patent applications, being prosecuted and maintained by the Prosecuting Party. Furthermore, upon the other Party's request, but no more than once per Calendar Quarter, the Prosecuting Party will reasonably discuss and consult with the IP Committee and will provide updates to the IP Committee by audio or video teleconference regarding Joint Collaboration Patent Rights being prosecuted and maintained by the Prosecuting Party, including the strategies for the preparation, filing, prosecution, and maintenance of such Joint Collaboration Patent Rights.

10.6.4 **Assistance; Costs**. The Parties will cooperate in obtaining any necessary assignment documents for the Prosecuting Party with respect to prosecution and maintenance of Joint Collaboration Patent Rights, rendering all signatures that will be necessary for Joint Collaboration Patent Right filings, and assisting the Prosecuting Party in all other reasonable ways that are necessary for the issuance of the Joint Collaboration Patent Rights as well as for the prosecution and maintenance of such Patent Rights. Subject to Section 10.5.2 (Filing of Joint Collaboration Patent Rights) and Section 10.5.2 (Abandonment), [**] will be responsible for [**] of the actual External Costs incurred by the other Party with respect to the filing, prosecution, and maintenance of such Joint Collaboration Patent Rights. [**] will invoice [**] quarterly for the other Party's [**] share of such External Costs. Both Parties agree that each Party will pay the other Party the undisputed invoiced amount within 30 days after the date of the invoice therefor, and any disputed amount within 30 days following the resolution of the dispute.

10.6.5 **Abandonment**. If the Prosecuting Party decides that it is no longer interested in prosecuting or maintaining a particular Joint Collaboration Patent Right in any country during the Term such that there would be an irrevocable loss of such Joint Collaboration Patent Right (including the ability to file a new Patent Right claiming benefit of priority to such Patent Right) in such country, then it will promptly, and in any event at least [**] prior to the date any such Joint Collaboration Patent Right would become abandoned, no longer available or otherwise forfeited, provide written notice to the non-Prosecuting Party of such decision. The non-Prosecuting Party may, upon written notice to the Prosecuting Party within [**] following the non-Prosecuting Party's receipt of the applicable notice from the Prosecuting Party, assume such prosecution and maintenance at such non-Prosecuting Party's sole cost and expense, in which case, it may prosecute and maintain (or abandon) such Patent Right in the name of the Parties jointly and such Joint Collaboration Patent Right will cease to be a Royalty-Bearing Patent Right for the purposes of this Agreement. Subject to the terms and conditions of this Agreement, including the terms of Article 2 (Licenses), the non-Prosecuting Party shall have the sole right to grant licenses under such Joint Collaboration Patent Right, and where required, the Prosecuting Party agrees to join in the granting of such licenses.

10.7 **Prosecution of Option Product Patent Rights**.

10.7.1 **Sarepta's Right to Prosecute**. Sarepta will have the sole right, but not the obligation, to file, prosecute, and maintain the Option Product Patent Rights.

10.7.2 **Status Updates**. Upon Roche's request, but no more than once per Calendar Quarter, Sarepta will provide to the IP Committee a written summary of the status of all Option Product Patent Rights (including patent applications) being prosecuted and maintained by Sarepta in the Roche Territory and will provide updates to the IP Committee by audio or video teleconference regarding Option Product Patent Rights being prosecuted and maintained by Sarepta in the Roche Territory, including the strategies for the filing, prosecution, and maintenance of such Sarepta Patent Rights in the Roche Territory.

10.7.3 **Costs**. Sarepta will be responsible for the External Costs incurred by it with respect to the filing, prosecution, and maintenance of the Option Product Patent Rights in the Roche Territory.

10.8 Prosecution of Roche Collaboration Patent Rights.

10.8.1 Filing of Roche Patent Rights. Except as provided in Section 10.8.4 (Abandonment), Roche will have the sole right to file, prosecute, and maintain the Roche Background Patent Rights and the Roche Collaboration Patent Rights, *provided* that Roche will file, prosecute, and maintain the Roche Collaboration Patent Rights using internal counsel and external counsel mutually agreed to by the Parties.

10.8.2 Status Updates. Upon Sarepta's request, but no more than once per month, Roche will provide to the IP Committee a written summary of the status of all Roche Collaboration Patent Rights being prosecuted and maintained by Roche. Furthermore, upon Sarepta's request, but no more than once per Calendar Quarter, Roche will reasonably discuss and consult with the IP Committee and will provide updates to the IP Committee by audio or video teleconference regarding Roche Collaboration Patent Rights being prosecuted and maintained by Roche, including the strategies for the filing, prosecution, and maintenance of such Roche Collaboration Patent Rights.

10.8.3 Assistance; Costs. Roche will be responsible for 100% of the External Costs incurred by it with respect to the filing, prosecution, and maintenance of the Roche Background Patent Rights and the Roche Collaboration Patent Rights.

10.8.4 Abandonment. If Roche decides that it is no longer interested in maintaining or prosecuting a particular Roche Collaboration Patent Right in any country during the Term such that there would be an irrevocable loss of such Roche Collaboration Patent Right (including the ability to file a new Patent Right claiming benefit of priority to such Patent Right) in such country, then Roche will promptly, and in any event at least [**] prior to the date any such Roche Collaboration Patent Right would become abandoned, no longer available or otherwise forfeited, provide written notice to Sarepta of such decision. In such case, Sarepta may, upon written notice to Roche within [**] following Sarepta's receipt of the applicable notice from Roche, assume such prosecution and maintenance in Roche's name at Sarepta's sole expense. In such event, such Roche Collaboration Patent Right shall remain exclusively licensed to Sarepta with rights to sublicense without requiring Roche's approval and may be abandoned by Sarepta without permission of, but with notice to, Roche.

10.9 Enforcement Against Third Party Infringement or Misappropriation.

10.9.1 Notice of Infringement or Misappropriation. Each Party will promptly notify the other of any apparent, threatened, or actual Competitive Infringement of which it becomes aware.

10.9.2 Enforcement in Roche Territory. Subject to the terms of Section 10.9.5 (Abbreviated Applications) and of any applicable license pursuant to which Sarepta Controls any Patent Right or Know-How included within the Sarepta Patent Rights or Sarepta Know-How, and except as may be otherwise agreed by the Parties, Roche will have the first right, but not the obligation, to enforce any Sarepta Patent Rights, Sarepta Know-How, Roche Collaboration Patent Rights, Roche Collaboration Know-How, Joint Collaboration Patent Rights, or Joint Collaboration Know-How against any Competitive Infringement in the Roche Territory, in each case, at its own cost and expense and using counsel reasonably acceptable to Sarepta; *provided* that Sarepta will be entitled to attend any substantive meetings, hearings, or other proceedings related to such infringement or misappropriation suit (together with its own counsel, at its own expense) and to review and comment on all

substantive documents related to such Competitive Infringement suit prior to filing or submission of such documents. If Roche fails to initiate a suit or take other action to terminate any such Competitive Infringement within [**] after the notice provided under Section 10.9.1 (Notice of Infringement or Misappropriation) (or such shorter period of time as is required to comply with the provisions of Section 10.9.5 (Abbreviated Applications)), then Sarepta will have the second right, but not the obligation, to attempt to resolve such Competitive Infringement, as applicable, at its own expense, including the filing of an infringement or misappropriation suit, as applicable, to enforce the applicable Patent Rights or Know-How using counsel of its own choice.

10.9.3 **Enforcement in Sarepta Territory**. Subject to the terms of Section 10.9.5 (Abbreviated Applications), Sarepta will have the sole right, but not the obligation, to enforce any Sarepta Patent Rights, Sarepta Know-How, Roche Collaboration Patent Rights, Roche Collaboration Know-How, Joint Collaboration Patent Rights, or Joint Collaboration Know-How against any Competitive Infringement in the Sarepta Territory, in each case, at its own cost and expense, and, solely with respect to the enforcement of Roche Collaboration Patent Rights, Roche Collaboration Know-How, Joint Collaboration Patent Rights and Joint Collaboration Know-How, using counsel reasonably acceptable to Roche. Roche will be entitled to attend any substantive meetings, hearings, or other proceedings related to any such infringement or misappropriation suit enforcing Roche Collaboration Patent Rights, Roche Collaboration Know-How, Joint Collaboration Patent Rights, or Joint Collaboration Know-How, (together with its own counsel, at its own expense) and to review and comment on all substantive documents related to such Competitive Infringement suit prior to filing or submission of such documents to the extent related to the enforcement of the Roche Collaboration Patent Rights, Roche Collaboration Know-How, Joint Collaboration Patent Rights or Joint Collaboration Know-How.

10.9.4 **Allocation of Recoveries**. Any amounts recovered by a Party as a result of an action pursuant to this Section 10.9 (Enforcement Against Third Party Infringement or Misappropriation), whether by settlement or judgment, will be allocated as follows: (a) first each Party will be reimbursed its actual External Costs incurred in conducting, or cooperating with, such action, and (b) second, (i) in the event of any amount awarded by a court, the balance of such recovered amounts will be split as follows: (A) to the extent the Competitive Infringement occurs in the Sarepta Territory, Sarepta will receive the balance of such recoveries (unless the recoveries result from a judgment of infringement of only Roche Collaboration Patent Rights or Roche Collaboration Know-How and no other Patent Rights or Know-How, in which case [**]), and (B) to the extent the Competitive Infringement occurs in the Roche Territory, Roche will receive [**] of the balance of such recoveries and Sarepta will receive the remainder (unless the recoveries result from a judgment of infringement of only Roche Collaboration Patent Rights or Roche Collaboration Know-How and no other Patent Rights or Know-How, in which case [**]); and (ii) in the event of any amount awarded by a settlement, [**].

10.9.5 **Cooperation; Procedures**. In any event, at the request and expense of the Party bringing an infringement or misappropriation action under this Section 10.9 (Enforcement Against Third Party Infringement or Misappropriation), the other Party will provide reasonable assistance and cooperation in any such action (including entering into a common interest agreement if reasonably deemed necessary by any Party) and agrees to be joined as a party to the suit if necessary for the initiating Party to bring or continue an infringement or misappropriation action hereunder. In addition, the Party bringing an infringement or misappropriation action under this Section 10.9 (Enforcement Against Third Party

Infringement or Misappropriation) will provide the other Party with copies of all pleadings and other documents in advance of filing with the court and will consider reasonable input from the other Party during the course of the action. Neither Party may settle any action or proceeding brought under this Section 10.9 (Enforcement Against Third Party Infringement or Misappropriation) or knowingly take any other action in the course thereof (a) without Sarepta's prior written consent with respect to the Sarepta Territory and (b) without Roche's prior written consent with respect to the Roche Territory. The Parties will reasonably assist each other and cooperate with each other, at their own expense, in any such investigation, pre-litigation preparation, or litigation to ensure that there is an aligned global litigation and enforcement strategy.

10.9.6 **Abbreviated Applications**. Notwithstanding Section 10.9.2 (Enforcement in Roche Territory) or Section 10.9.3 (Enforcement in Sarepta Territory), if either Party or their Affiliate or Sublicensee receives a copy of an Abbreviated Application naming a Licensed Product as a reference product or otherwise becomes aware that such an Abbreviated Application has been filed (such as in an instance described in Section 351(1)(9)(C) of the PHSA), then such Party will promptly notify the other Party. If either Party receives any equivalent or similar certification or notice in the United States or any other jurisdiction, then such Party will promptly notify and provide the other Party copies of such communication. The Parties will comply with all Applicable Laws in the Roche Territory in connection with the actions taken by the Parties in exercising their rights and obligations with respect to Abbreviated Applications under this Section 10.9.6 (Abbreviated Applications). Other than any actions and procedures that would not comply with such Applicable Law, the Parties will pursue any legal actions they may have against the applicant of an Abbreviated Application in accordance with the provisions of Section 10.9.2 (Enforcement in Roche Territory), Section 10.9.3 (Enforcement in Sarepta Territory) and Section 10.9.5 (Cooperation; Procedures).

10.10 **Defense of Third Party Patent Challenges**. Each Party will promptly notify the other Party in writing of its becoming aware of an actual or threatened Patent Challenge by a Third Party of any Sarepta Patent Right or Collaboration Patent Right (each, a "**Third Party Patent Challenge**").

10.10.1 **Defense of Third Party Patent Challenges in the Roche Territory**. Subject to the terms of Section 10.9.5 (Abbreviated Applications) and Section 10.10.2 (Cooperation; Procedures) and of any applicable license pursuant to which Sarepta Controls any Patent Right, and except as may be otherwise agreed by the Parties, Roche will have the first right, but not the obligation, to control the defense of any Third Party Patent Challenge relating to a Sarepta Patent Right or Collaboration Patent Right in the Roche Territory and to compromise, litigate, settle, or otherwise dispose of any such challenge, in each case at its own expense using counsel of its own choice; *provided* that Sarepta will be entitled to attend any substantive meetings, hearings, or other proceedings related to such Third Party Patent Challenge (together with its own counsel, at its own expense) and to review and comment on all substantive documents related to such Third Party Patent Challenge, and if Roche fails to initiate or continue the defense of such Third Party Patent Challenge of a Sarepta Patent Right or Collaboration Patent Right within [**] after the notice provided under Section 10.10 (Defense of Third Party Patent Challenges) (or such shorter period of time as is required to comply with the provisions of Section 10.9.5 (Abbreviated Applications)), or otherwise abandons or elects not to continue any such defense once initiated, then Sarepta will have the second right, but not the obligation, to control the defense of such Third Party Patent Challenge at its own expense using counsel of its own choice.

10.10.2 **Defense of Third Party Patent Challenges in the Sarepta Territory**. Subject to the terms of Section 10.9.5 (Abbreviated Applications) and Section 10.10.2 (Cooperation; Procedures), Sarepta will have the sole right, but not the obligation, to control the defense of any Third Party Patent Challenge relating to a Sarepta Patent Right or Collaboration Patent Right in the Sarepta Territory and to compromise, litigate, settle, or otherwise dispose of any such challenge, in each case, at its own expense using counsel of its own choice; *provided* that, to the extent practicable and such actions will not compromise any privilege available to Sarepta, (a) Sarepta will keep Roche reasonably informed with respect to any such defense of any Third Party Patent Challenge relating to a Sarepta Patent Right or Collaboration Patent Right in the Sarepta Territory, and (b) Roche will be entitled to attend any substantive meetings, hearings, or other proceedings related to such Third Party Patent Challenge (together with its own counsel, at its own expense) and to review and comment on all substantive documents related to such Third Party Patent Challenge. If Sarepta fails to (i) initiate or continue the defense of such Third Party Patent Challenge of a Roche Collaboration Patent Right or Joint Collaboration Patent Right or (ii) commit to do so within a reasonable period of time, in each case ((i) and (ii)), within [**] after the notice provided under Section 10.10 (Defense of Third Party Patent Challenges) (or such shorter period of time as is required to comply with the provisions of Section 10.9.5 (Abbreviated Applications)), or otherwise abandons or elects not to continue any such defense once initiated, then Roche, will have the second right, but not the obligation, to control the defense of such Third Party Patent Challenge at its own expense using counsel of its own choice.

10.10.3 **Cooperation; Procedures**. In any event, at the request and expense of the Party controlling the defense of any Third Party Patent Challenge under this Section 10.10 (Defense of Third Party Patent Challenges), the other Party will provide reasonable assistance and cooperation in any such action. In addition, the Party controlling the defense of any Third Party Patent Challenge under this Section 10.10 (Defense of Third Party Patent Challenges) will provide the other Party with copies of all pleadings and other documents to be filed with the court and will consider reasonable input from the other Party during the course of the action. Roche may not settle any action or proceeding brought or defended under this Section 10.10 (Defense of Third Party Patent Challenges) or knowingly take any other action in the course thereof without Sarepta's prior consent. Sarepta may not settle any action or proceeding brought or defended under this Section 10.10 (Defense of Third Party Patent Challenges) or knowingly take any other action in the course thereof without Roche's prior written consent with respect to the Roche Territory. The Parties will reasonably assist each other and cooperate with each other, at their own expense, in any such investigation, pre-litigation preparation, or litigation to ensure that there is an aligned global litigation strategy.

10.11 **Third Party Infringement Claims**.

10.11.1 **Infringement Claim; Patent Challenges of Third Party IP**. If a Third Party asserts that a Patent Right controlled by it is, or will be, infringed by the Exploitation of a Licensed Product in the Roche Territory in accordance with this Agreement, then the Party first obtaining knowledge of such claim will promptly provide the other Party and the IP Committee with prompt written notice thereof and the related facts in reasonable detail.

10.11.2 **Responsibility to Defend**. During the Term of this Agreement, if a Third Party asserts that a Patent Right controlled by such Third Party is infringed, or will be infringed, by the Exploitation of a Licensed Product, then [**].

10.11.3 Settlement. [**].

10.12 Patent Challenges of Third Party Patent Rights.

10.12.1 Notice of Third Party Patent Right. If either Party becomes aware of a Third Party Patent Right that might form the basis for a claim that the Exploitation of a Licensed Product anywhere in the world infringes, or will infringe, such Patent Right, then [**].

10.12.2 Patent Challenges of Third Party Patent Rights. [**].

10.12.3 Restrictions on Settlement. [**].

10.13 Patent Term Extensions. Each Party will be solely responsible for making all decisions regarding patent term extensions in its respective Territory, including supplementary protection certificates and any other extensions that are now or become available in the future, in all cases, that are applicable to Sarepta Patent Rights or Collaboration Patent Rights licensed hereunder and that become available directly as a result of the Regulatory Approval of a Licensed Product; *provided*, *however*, that such Party will consult with the other Party with respect to such decisions and will consider the comments and concerns of the other Party in good faith. [**].

10.14 Unified Patent Court. If the Unified Patent Court Agreement enters into force during the Term of this Agreement, then Roche will be solely responsible for making all decisions regarding Patent Rights, including decisions regarding the opting-out or opting-in of existing Patent Rights into the jurisdiction of the Unified Patent Court or the registration of Patent Rights with Unitary Effect; *provided* that Roche will consult with Sarepta with respect to such decisions and will consider the comments and concerns of Sarepta in good faith.

10.15 Common Interest. All information exchanged between the Parties regarding the prosecution, maintenance, enforcement, and defense of Patent Rights or a Patent Challenge with respect to a Third Party's Patent Rights under this Article 10 (Intellectual Property) will be the Confidential Information of the disclosing Party. In addition, the Parties stipulate and agree that, with regard to such prosecution, maintenance, enforcement, and defense the interests of the Parties as collaborators and licensor and licensee are to obtain the strongest patent protection possible, and as such, are aligned and are legal in nature. The Parties stipulate and agree that they have not waived, and nothing in this Agreement constitutes a waiver of, any legal privilege concerning the Patent Rights under this Article 10 (Intellectual Property), including privilege under the common interest doctrine and similar or related doctrines. Notwithstanding any provision to the contrary set forth in this Agreement, to the extent a Party has a good faith belief that any information required to be disclosed by such Party to the other Party under this Article 10 (Intellectual Property) is protected by attorney-client privilege or any other applicable legal privilege or immunity, such Party will not be required to disclose such information and the Parties will in good faith cooperate to agree upon a procedure (including entering into a specific common interest agreement, disclosing such information on a "for counsel eyes only" basis or similar procedure) under which such information may be disclosed without waiving or breaching such privilege or immunity.

10.16 Marks.

10.16.1 Product Mark. All Licensed Products will be sold in the Roche Territory solely under the Product Marks selected by the IP Committee with advice from the Parties' intellectual property counsel and the Sarepta Housemarks and Roche Housemarks as provided in this Agreement. No such Mark will be used by Roche outside of the country as to which it has been approved for use by the IP Committee, unless otherwise agreed by the Parties in writing.

10.16.2 **Ownership of Marks**. Ownership of all Product Marks as well as all Sarepta Housemarks (together, the "**Sarepta-Owned Marks**") will be and remain vested at all times in Sarepta. To the extent that Roche acquires any rights, title, or interests in any Product Mark in the Territory, or any registration or application therefore or any goodwill associated therewith, Roche will, and hereby does, assign the same to Sarepta.

10.16.3 **Prosecution of Trademarks**.

(a) **Sarepta's First Right to Prosecute**. Sarepta will have the first right, but not the obligation, to file, prosecute, and maintain all Sarepta-Owned Marks. Upon the reasonable request of Sarepta, Roche will [**] cooperate with and assist Sarepta in connection with the filing, prosecution, and maintenance of all Sarepta-Owned Marks in the Roche Territory.

(b) **Status Updates**. Upon Roche's request, but no more than once per month, Sarepta will provide to the IP Committee a written summary of the status of all Product Marks being prosecuted and maintained by Sarepta in the Roche Territory and reasonably discuss and consult with the IP Committee and will provide updates to the IP Committee by audio or video teleconference regarding the Sarepta-Owned Marks being prosecuted and maintained by Sarepta in the Roche Territory, including the strategies for the filing, prosecution, and maintenance of such Sarepta-Owned Marks in the Roche Territory.

(c) **Assistance; Costs**. Subject to Section 10.16.3(d) (Abandonment in Roche Territory), [**] will be responsible for all actual External Costs incurred by or on behalf of Sarepta or its Affiliates in connection with the filing, prosecution, maintenance, and defense of the Product Marks in the Roche Territory.

(d) **Abandonment in Roche Territory**. If [**] decides that it is no longer interested in prosecuting or maintaining a particular Product Mark in any country in the Roche Territory during the Term such that there would be an irrevocable loss of such Product Mark in such country, then [**] will promptly, and in any event no later than [**] days following the applicable decision, provide written notice to [**] of such decision. [**] may, upon written notice to [**] within [**] days following [**] receipt of the applicable notice from [**], assume such prosecution and maintenance at [**] sole expense, and promptly following the date of [**] notice, [**] will assign such [**] to [**] at [**]. Following such assignment, such Product Mark will no longer be considered a [**] for any purposes of this Agreement. In such event, [**] will be responsible for [**] of the External Costs incurred in connection with the prosecution and maintenance of such Product Mark in the [**] Territory.

10.16.4 **Trademark License**. To effectuate the purposes of this Agreement, Sarepta hereby grants to Roche a royalty-free license to use and display the Sarepta-Owned Marks, in each case, solely for the Commercialization of a Licensed Product in the Field in the Roche Territory and solely in accordance with this Agreement. All goodwill arising from the use of such Sarepta-Owned Marks will inure to the benefit of Sarepta.

10.16.5 **Trademark Use**. The manner of use of the Product Marks selected by the IP Committee in the Roche Territory will be subject to periodic review by the IP Committee. Neither Party nor its Affiliates will use such Product Marks in a way that is inconsistent with the usage instructions approved by the IP Committee, and neither Party nor its Affiliates will (a) use, file, register, or maintain any registrations for any trademarks or trade names that are confusingly similar to one of such Product Marks with any of its other products, (b) except as otherwise provided herein, use such Product Marks in combination with its other trademarks in a manner which would create combination marks, or (c) authorize or assist any Third Party to do the foregoing. The Parties will utilize such Product Marks within the Sarepta Territory and the Roche Territory only in accordance with this Agreement. In addition, Roche will not, and will cause its Affiliates and Sublicensees to not, attack, challenge, oppose, petition to cancel, or initiate legal action or proceedings in connection with any Sarepta-Owned Mark during the Term, or challenge the registration of any Sarepta-Owned Mark in any country, or authorize or assist any Third Party to do any of the foregoing. Roche will maintain the quality standards of Sarepta with respect to use of the Sarepta-Owned Marks and will assure at all times that the quality of the products sold under the Sarepta-Owned Marks are of a standard of quality consistent with Licensed Products in the Sarepta Territory.

10.16.6 **Enforcement of Product Marks in Roche Territory**. Except as may be otherwise agreed by the Parties, Roche will have the first right, but not the obligation, to enforce any Product Mark in the Roche Territory against any infringement or threatened infringement by any Third Party with respect to any Product Mark by reason of the sale or marketing of any product that would be competitive with any Licensed Product in the Field in the Roche Territory, in each case, at its own cost and expense and using counsel reasonably acceptable to Sarepta. Sarepta will be entitled to attend any substantive meetings, hearings, or other proceedings related to such infringement or misappropriation suit (together with its own counsel, at its own expense) and to review and comment on all substantive documents related to such infringement suit prior to filing or submission of such documents. If Roche fails to initiate a suit or take other action to terminate any such infringement within [**] after receiving notice thereof from Sarepta, then Sarepta will have the second right, but not the obligation, to attempt to resolve such infringement, at its own expense, including the filing of an infringement suit, as applicable, to enforce the applicable Product marks using counsel of its own choice. In such case, Roche will be entitled to attend any substantive meetings, hearings, or other proceedings related to such infringement suit (together with its own counsel, at its own expense) and to review and comment on all substantive documents related to such infringement suit prior to filing or submission of such documents. Any amounts recovered in any such suit enforcing the Product Marks in the Roche Territory will be allocated between the Parties in the same manner as a suit regarding Competitive Infringement of the Sarepta Patent Rights would be allocated pursuant to Section 10.9.4 (Allocation of Recoveries). Each Party will provide the other Party with reasonable assistance and cooperating, at its own expense, in any such action (including entering into a common interest agreement if reasonably deemed necessary by any Party) and agrees to be joined as a party to the suit if necessary for the initiating Party to bring or continue a trademark infringement action hereunder.

10.16.7 **Party Name on Product Promotional Material**. Subject to Applicable Law, Roche will exercise commercially reasonable efforts to include a notice on all Product Materials in the Roche Territory indicating that the applicable Product Mark included in such Product Materials is a Mark of Sarepta.

ARTICLE 11
REPRESENTATIONS, WARRANTIES, AND COVENANTS

11.1 **Mutual Representations and Warranties**. Each of Roche and Sarepta hereby represents and warrants to the other Party as of the Execution Date that:

11.1.1 It is a corporation or entity duly organized and validly existing under the laws of the state, municipality, provinces, administrative division, or other jurisdiction of its incorporation or formation.

11.1.2 It has full power and authority and the legal right to own and operate property and assets and to carry on its business as it is now being conducted and as it is contemplated to be conducted by this Agreement.

11.1.3 The execution, delivery, and performance of this Agreement by it has been duly authorized by all requisite corporate action.

11.1.4 This Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid, and binding obligation of such Party and is enforceable against it in accordance with its terms, subject to the effects of bankruptcy, insolvency, or other laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity.

11.1.5 It has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder.

11.1.6 It has obtained all necessary consents, approvals, and authorizations of all Regulatory Authorities and other Third Parties required to be obtained in connection with the execution and delivery of this Agreement and the performance of its obligations hereunder, including, for the avoidance of doubt, to grant the licenses granted by it under this Agreement.

11.1.7 The execution and delivery of this Agreement and the performance of its obligations hereunder (a) do not conflict with or violate any requirement of Applicable Law or any provision of its articles of incorporation, bylaws, limited partnership agreement, or any similar instrument, as applicable, in any material way, and (b) do not conflict with, violate, or breach or constitute a default or require any consent under, any Applicable Law or any contractual obligation or court or administrative order by which it or any of its Affiliates are bound.

11.1.8 To its Knowledge, it has not, directly or indirectly, offered, promised, paid, authorized, or given to any Government Official or Other Covered Party for the purpose, pertaining to this Agreement, of: (a) influencing any act or decision of the Government Official or Other Covered Party; (b) inducing the Government Official or Other Covered Party to do or omit to do an act in violation of a lawful duty; (c) securing any improper advantage; or (d) inducing the Government Official or Other Covered Party to influence the act or decision of a government or government instrumentality, in order to obtain or retain business, or direct business to, any Person, in each case in any way related to this Agreement.

11.1.9 It is not aware of any Government Official or Other Covered Party having any financial interest in the subject matter of this Agreement or in any way personally benefiting, directly, or indirectly, from this Agreement.

11.1.10 It is in compliance with all applicable global trade laws (including the Global Trade Control Laws), including those related to import controls, export controls, or economic sanctions. It is not, nor is any of its Affiliates or its or their respective directors, officers, employees, agents, or representatives, or in the last five years was, a Restricted Party.

11.1.11 It and its Affiliates have not been debarred or suspended under 21 U.S.C. §335(a) or (b), are not the subject of a conviction described in Section 306 of the FD&C Act, have not been and are not excluded from a federal or governmental health care program, debarred from federal contracting, convicted of or pled nolo contendere to any felony, or to any federal or state legal violation (including misdemeanors) relating to prescription drug products or fraud, is not subject to OFAC sanctions or on the OFAC list of specially designated nationals, and is not subject to any similar sanction of any Governmental Authority, in the Territory ("**Debarred/Excluded**"), and no proceeding that could result in it or any of its Affiliates being Debarred/Excluded is pending, and neither it nor any of its Affiliates has used, in any capacity in the performance of obligations relating to any Licensed Product any employee, subcontractor, consultant, agent, representative, or other Person who has been Debarred/Excluded.

11.2 **Additional Sarepta Warranties**. Except as disclosed in the disclosure letter dated as of the Execution Date delivered by Sarepta to Roche, Sarepta hereby represents and warrants as of the Execution Date to Roche that:

11.2.1 Sarepta solely and exclusively owns or Controls the Sarepta Technology, including all Sarepta Patent Rights set forth on **Schedule 1.250** (Sarepta Patent Rights) and licensed to Roche pursuant to Section 2.1 (Grant of Licenses to Roche), and it has not assigned, transferred, conveyed, or granted any right, title or interest in any of the Sarepta Technology in any manner that is inconsistent with the licenses granted to Roche with respect to the Licensed Product under, or any other terms and conditions of, this Agreement.

11.2.2 Sarepta has provided Roche with redacted and otherwise true copies of each Existing In-License entered into by Sarepta and listed on **Schedule 2.5.1** (Existing In-Licenses).

11.2.3 Sarepta possesses, under the Existing In-Licenses or otherwise, all rights necessary to grant to Roche an exclusive license under Sarepta Technology with respect to Licensed Products pursuant to Section 2.1 (License Grants to Roche) and the right to grant sublicenses to one or more of its Affiliates or any Third Party sublicenses (which may be further granted through multiple tiers) as set forth in this Agreement, including Section 2.3.1 (Right to Grant Sublicenses).

11.2.4 The Sarepta Patent Rights set forth on **Schedule 1.250** (Sarepta Patent Rights) have been duly filed and maintained in the Roche Territory and, to Sarepta's Knowledge, are (a) being diligently prosecuted in the Roche Territory and (b) are valid and enforceable.

11.2.5 Other than routine patent prosecution, (a) there is no pending, or to Sarepta's Knowledge threatened, litigation or claims relating to it or any Affiliate that seeks to invalidate or challenge the enforceability of any of the Sarepta Patent Rights, (b) no Sarepta Patent Right is the subject of any declaratory judgment, interference, reissue, derivation, opposition, revocation, cancellation, inter partes review, post grant review, re-examination or other similar proceeding, (c) no Third Party has challenged in writing, or, to the Knowledge of Sarepta, has threatened to challenge, Sarepta's or any of its Affiliates' right to use and license the Sarepta Know-How, and (d) there are no claims asserted in writing, judgments, or settlements in effect against Sarepta or any of its Affiliates relating to the Sarepta Technology.

11.2.6 Sarepta has obtained the written assignment of the entire right, title, and interest of all Third Parties who have or have had any rights in or to any of the Sarepta Patent Rights that are owned by Sarepta or any of its Affiliates, and, to Sarepta's Knowledge, the applicable Third Party licensor under each Existing In-License has obtained the assignment of all interests and all rights of all Third Parties who has or has had any rights in or to any of the Sarepta Patent Rights that are licensed by Sarepta or any of its Affiliates from such Third Party licensor.

11.2.7 There are no investigations, inquiries, actions, or other proceedings pending, or, to Sarepta's Knowledge, threatened by any Person, disputing the Sarepta Technology.

11.2.8 To Sarepta's Knowledge, no Third Party is infringing, misappropriating, or otherwise violating any Sarepta Technology.

11.2.9 There are no investigations, inquiries, actions, or other proceedings pending before or, to Sarepta's Knowledge, threatened by any Regulatory Authority or other Governmental Authority in the Territory with respect to any Licensed Product in the Roche Territory arising from any violation of Applicable Law by Sarepta or any of its Affiliates or any Third Party acting on behalf of Sarepta or any of its Affiliates in the Exploitation of any Licensed Product, and Sarepta and its Affiliates have not received written notice threatening any such investigation, inquiry, action, or other proceeding, and to Sarepta's Knowledge, there are no circumstances currently existing that, in Sarepta's reasonable discretion, would reasonably be expected to lead to or result in an investigation, corrective action, or enforcement action by any other Regulatory Authority with respect to any Licensed Product.

11.2.10 There are no investigations, inquiries, actions or other proceedings pending, or, to Sarepta's Knowledge, threatened in writing alleging that any Exploitation of any Licensed Product in the manner contemplated in this Agreement, infringes, misappropriates or otherwise violates, or would infringe, misappropriate or otherwise violate, any Patent Right or Know-How of any Third Party in the Roche Territory.

11.2.11 To Sarepta's Knowledge, it, its Affiliates and its contractors and consultants, have complied in all material respects with all Applicable Law, including GLP, GCP, and the requirements of informed consent and institutional review boards (as those terms are defined by the FDA or other relevant Regulatory Authorities), and in accordance with its or their standard operating procedures for the conduct of Clinical Trials at the time such tests were conducted, in the Exploitation of the Licensed Products prior to the Execution Date.

11.2.12 All personal data collected, processed or disclosed by Sarepta or any of its Affiliates in connection with any Licensed Product have been, and are being, collected, processed, and disclosed in compliance, in all material respects, with all Applicable Laws that were in effect at the time such data was collected, processed or disclosed, or currently stored, including the Health Insurance Portability and Accountability Act of 1996 and the implementing regulations of the United States Department of Health and Human Services,; and neither Sarepta nor any of its Affiliates has received any: (a) written notice or complaint alleging non-compliance with any Applicable Law relating to the collection, processing, and disclosure of information or data; (b) written claim for compensation for loss or unauthorized collection, processing, or disclosure of data; or (c) written notification of an application for rectification, erasure or destruction of information or data that is still outstanding, in each case ((a) through (c)), in connection with any Licensed Product; Sarepta and its Affiliates have documented and stored all material data, documents, and reports resulting from the Exploitation of each Licensed Product in accordance with Sarepta's practices and standards in place for its own activities at the time such data, documents, and reports were documented or stored.

11.3 **Additional Roche Warranties**. Roche hereby represents and warrants as of the Execution Date that Roche has immediately available funds sufficient to cover Roche's financial obligations under this Agreement.

11.4 **Additional Covenants**. Each of Roche and Sarepta hereby covenant to the other:

11.4.1 **Assignment of Inventions**. Each Party will require all of its and its Affiliates' employees to assign all Inventions that are developed or invented by such employees according to the ownership principles described in Section 10.1 (Ownership).

11.4.2 **Compliance with Law**. It will, and will cause its Affiliates and its and its Affiliates' employees and contractors to, comply with all Applicable Laws (including anti-corruption and anti-slavery and anti-human trafficking laws, statutes, regulations, and codes) and, to the extent applicable, Professional Requirements, with respect to the performance of its obligations under this Agreement.

11.4.3 **No Bribery**. It will not, and will cause its Affiliates and its and its Affiliates' employees and contractors not to, directly or indirectly, in the future offer, promise, pay, authorize, or give, money or anything of value, directly or indirectly, to any Government Official or Other Covered Party for the purpose, pertaining to this Agreement, of: (a) influencing any act or decision of the Government Official or Other Covered Party; (b) inducing the Government Official or Other Covered Party to do or omit to do an act in violation of a lawful duty; (c) securing any improper advantage; or (d) inducing the Government Official or Other Covered Party to influence the act or decision of a government or government instrumentality, in order to obtain or retain business, or direct business to, any Person, in each case, in any way related to this Agreement.

11.4.4 **Restricted Countries**. Neither it nor its Affiliates will knowingly export, transfer, or sell any Licensed Product or corresponding Sarepta Diagnostic Product (a) to any country or territory that is subject to comprehensive economic sanctions administered by OFAC, unless the sale of such Licensed Product or corresponding Sarepta Diagnostic Product would be permissible if Roche or its Affiliates or Sublicensees were subject to OFAC's jurisdiction, (b) to any Restricted Party unless the sale of such Licensed Product or corresponding Sarepta Diagnostic Product would be permissible if Roche or its Affiliates or Sublicensees was subject to OFAC's jurisdiction, or (c) in such a manner that would violate the Global Trade Control Laws.

11.4.5 **Debarred/Excluded Persons**. Neither it nor any of its Affiliates will engage, in any capacity in connection with this Agreement or any ancillary agreements, any officer, employee, contractor, consultant, agent, representative, or other Person who has been Debarred/Excluded. Each Party will inform the other Party in writing promptly if it or any Person engaged by it or any of its Affiliates who is performing any obligations under this Agreement or any ancillary agreements is Debarred/Excluded, or if any action, suit, claim, investigation, or legal or administrative proceeding is pending or, to each Party's Knowledge, is threatened, pursuant to which a Party, any of its Affiliates or any such Person performing obligations hereunder or thereunder may become Debarred/Excluded, and such Party shall cease employing, contracting with, or retaining any such Person to perform any such services.

11.5 **Additional Covenants of Sarepta**. Sarepta will not assign, transfer, convey, or grant any rights, licenses and title, or interests in or to any of the Sarepta Technology in any manner that is inconsistent with the rights and licenses granted to Roche hereunder, including the Options, DMD ROFN, and LGMD ROFN, or any other terms and conditions of, this Agreement.

11.6 **Additional Covenants of Roche**.

11.6.1 **Diagnostic Tests**. Roche will not Develop any *in vitro* diagnostic tests or products for use with any Licensed Product except as set forth in the Joint Global Development Plan or as otherwise agreed in writing by the Parties.

11.6.2 **Anti-Corruption; Integrity**. In performing under this Agreement, Roche and its Affiliates will maintain and comply with Roche's "Directive on Integrity in Business" and the "Roche Group Code of Conduct," copies of which are attached as **Schedule 11.6.2.**, as such policies may be updated from time to time.

11.7 **Time For Claims**. Except in the case of any fraud or intentional misrepresentation by a Party: (a) no claim may be made or suit instituted alleging breach or seeking indemnification pursuant to Article 13 (Indemnification) for any breach of, or inaccuracy in, any representation or warranty contained in Section 11.1 (Mutual Representations and Warranties), Section 11.2 (Additional Sarepta Warranties), and Section 11.3 (Additional Roche Warranties) unless a written notice is provided to the Indemnifying Party at any time prior to the date that is [**] following the Effective Date, and (b) after such [**] period, no Party may bring any claim against the other Party arising from or relating to such other Party's breach of such representations and warranties.

11.8 **Disclaimer**. EXCEPT AS EXPRESSLY SET FORTH HEREIN, THE INTELLECTUAL PROPERTY RIGHTS PROVIDED BY SAREPTA ARE PROVIDED "**AS IS**" AND WITHOUT WARRANTY. EXCEPT AS EXPRESSLY SET FORTH HEREIN, EACH OF THE PARTIES EXPRESSLY DISCLAIMS ANY AND ALL REPRESENTATIONS AND WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE REPRESENTATIONS AND WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY, OR ENFORCEABILITY OF THEIR RESPECTIVE INTELLECTUAL PROPERTY RIGHTS, AND NONINFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, ARISING FROM A COURSE OF DEALING, USAGE, OR TRADE PRACTICES, IN ALL CASES WITH RESPECT THERETO.

11.9 **Limitation of Liability**. NEITHER OF THE PARTIES WILL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, INDIRECT, CONSEQUENTIAL, OR PUNITIVE DAMAGES OR DAMAGES FOR LOSS OF PROFIT, LOSS OF REVENUE, OR LOST OPPORTUNITY IN CONNECTION WITH THIS AGREEMENT, ITS PERFORMANCE OR LACK OF PERFORMANCE HEREUNDER, OR ANY LICENSE GRANTED HEREUNDER, EXCEPT TO THE EXTENT THE DAMAGES RESULT FROM A BREACH OF THE OBLIGATIONS OF A PARTY UNDER ARTICLE 12 (CONFIDENTIALITY), A VIOLATION BY ROCHE OF THE PROVISIONS IN SECTION 2.6 (EXCLUSIVITY COVENANT), MISAPPROPRIATION, INFRINGEMENT OR OTHER VIOLATION OF INTELLECTUAL PROPERTY OWNED OR CONTROLLED BY THE OTHER PARTY, OR AMOUNTS REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF A CLAIM FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER ARTICLE 13 (INDEMNIFICATION). NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 11.9 (LIMITATION OF LIABILITY) IS INTENDED TO OR SHALL LIMIT OR RESTRICT ANY DAMAGES TO THE EXTENT ARISING FROM OR RELATING TO WILLFUL MISCONDUCT OR FRAUDULENT ACTS OR FRAUDULENT OMISSIONS OF EITHER PARTY.

ARTICLE 12
CONFIDENTIALITY

12.1 **Duty of Confidence**. Subject to the other provisions of this Article 12 (Confidentiality):

12.1.1 except to the extent expressly authorized by this Agreement, all Confidential Information of a Party (the "**Disclosing Party**") will be maintained in confidence and otherwise safeguarded, and not published or otherwise disclosed, by the other Party (the "**Receiving Party**") and its Affiliates for the Term and for 10 years thereafter;

12.1.2 the Receiving Party will treat all Confidential Information provided by the Disclosing Party with the same degree of care as the Receiving Party uses for its own similar information, but in no event less than a reasonable degree of care;

12.1.3 the Receiving Party may only use any Confidential Information of the Disclosing Party for the purposes of performing its obligations or exercising its rights under this Agreement;

12.1.4 a Receiving Party may only disclose Confidential Information of the Disclosing Party to: (a) such Receiving Party's Affiliates and Sublicensees; and (b) employees, directors, officers, agents, contractors, consultants, attorneys, accountants, banks, investors, and advisors of the Receiving Party and its Affiliates and Sublicensees, in each case ((a) and (b)), to the extent reasonably necessary for the purposes of, and for those matters undertaken pursuant to, this Agreement; *provided* that such Persons are bound by legally enforceable obligations of confidentiality and non-use with respect to the Disclosing Party's Confidential Information no less stringent than the confidentiality and non-use obligations set forth in this Agreement. Each Party will remain responsible for any failure by its Affiliates and Sublicensees, and its and its Affiliates' and Sublicensees' respective employees, directors, officers, agents, consultants, attorneys, accountants, banks, investors, advisors, and contractors, in each case, to treat such Confidential Information as required under this Section 12.1 (Duty of Confidence) (as if such Affiliates, Sublicensees, employees, directors, officers agents, consultants, advisors, attorneys, accountants, banks, investors, and contractors were Parties directly bound to the requirements of this Section 12.1 (Duty of Confidence)); and

12.1.5 each Party will promptly notify the other Party of any misuse or unauthorized disclosure of the other Party's Confidential Information.

12.2 **Confidential Information**. The Sarepta Know-How, each Option Data Package, each LGMD Diligence Package, and each DMD ROFN Notice and LGMD ROFN Notice will be the Confidential Information of Sarepta. The Joint Collaboration Know-How and the terms of this Agreement will be the Confidential Information of both Parties. The Roche Collaboration Know-How and Roche Background Know-How will be the Confidential Information of Roche. Except as provided in Section 12.4 (Authorized Disclosures) and Section 12.8 (Publicity; Use of Names), neither Party nor its Affiliates may disclose the existence or the terms of this Agreement. In addition, any report regarding the Exploitation of any Sarepta Product provided by a Party to the other Party under this Agreement will be the Confidential Information of the providing Party.

12.3 **Exemptions**. Information of a Disclosing Party will not be Confidential Information of such Disclosing Party to the extent that the Receiving Party can demonstrate through competent evidence that such information:

12.3.1 is known by the Receiving Party or any of its Affiliates without an obligation of confidentiality at the time of its receipt from the Disclosing Party, and not through a prior disclosure by or on behalf of the Disclosing Party, as documented by the Receiving Party's business records;

12.3.2 is generally available to the public before its receipt from the Disclosing Party;

12.3.3 became generally available to the public or otherwise part of the public domain after its disclosure by the Disclosing Party and other than through any act or omission of the Receiving Party or any of its Affiliates or disclosees in breach of this Agreement;

12.3.4 is subsequently disclosed to the Receiving Party or any of its Affiliates without obligation of confidentiality by a Third Party who may rightfully do so and is not under a conflicting obligation of confidentiality to the Disclosing Party; or

12.3.5 is developed by the Receiving Party or any of its Affiliates independently and without use of or reference to any Confidential Information received from the Disclosing Party, as documented by the Receiving Party's business records.

No combination of features or disclosures will be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the Receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the Receiving Party.

12.4 Authorized Disclosures.

12.4.1 **Permitted Circumstances**. Notwithstanding the obligations set forth in Section 12.1 (Duty of Confidence) and Section 12.7 (Publication and Listing of Clinical Trials), a Party may disclose the other Party's Confidential Information (including this Agreement and the terms herein) to the extent such disclosure is reasonably necessary in the following situations:

(a) (i) the filing and prosecution of Sarepta Patent Rights, Joint Collaboration Patent Rights, or Roche Collaboration Patent Rights, in each case, as contemplated by this Agreement; or (ii) Regulatory Submissions and other filings with Governmental Authorities (including Regulatory Authorities), as necessary for the Exploitation of a Sarepta Product as contemplated by this Agreement;

(b) disclosure of this Agreement, its terms, and the status and results of Exploitation of one or more Sarepta Products or Sarepta Diagnostic Products to actual or *bona fide* potential investors, acquirors, Sublicensees, lenders, and other financial or commercial partners (including in connection with any royalty financing transaction), and their respective attorneys, accountants, banks, investors, and advisors, solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition, Sublicense, debt transaction, or collaboration; *provided* that, in each such case, on the condition that such Persons are bound by obligations of confidentiality and non-use at least as stringent as those set forth Article 12 (Confidentiality) or otherwise customary for such type and scope of disclosure any such disclosure is limited to the maximum extent practicable for the particular context in which it is being disclosed;

(c) such disclosure is required to comply with Applicable Law (whether generally or in pursuit of an application for listing of securities) including the United States Securities and Exchange Commission or equivalent foreign agency or regulatory body, or otherwise required by judicial or administrative process, *provided* that in each such event, as promptly as reasonably practicable and to the extent not prohibited by Applicable Law or judicial or administrative process, such Party will notify the other Party of such required disclosure and provide a draft of the disclosure to the other Party reasonably in advance of such filing or disclosure for the other Party's review and comment. The non-disclosing Party will provide any comments as soon as practicable, and the disclosing Party will consider in good faith any timely comments provided by the non-disclosing Party; *provided* that the disclosing Party may or may not accept such comments in its sole discretion. Confidential Information that is disclosed in order to comply with Applicable Law or by judicial or administrative process pursuant to this Section 12.4.1(c) (Permitted Circumstances), in each case, will remain otherwise subject to the confidentiality and non-use provisions of this Article 12 (Confidentiality) with respect to the Party disclosing such Confidential Information, and such Party will take all steps reasonably necessary, including seeking of confidential treatment or a protective order for a period of at least 10 years (to the extent permitted by Applicable Law or Governmental Authority), to ensure the continued confidential treatment of such Confidential Information, and each Party will be responsible for its own legal and other External Costs in connection with any such filing or disclosure pursuant to this Section 12.4.1(c) (Permitted Circumstances); or

(d) disclosure pursuant to Section 12.7 (Publication and Listing of Clinical Trials) and Section 12.8 (Publicity; Use of Name).

12.4.2 **Confidential Treatment**. Notwithstanding any provision to the contrary set forth in this Agreement, if a Party is required or permitted to make a disclosure of the other Party's Confidential Information pursuant to Section 12.4.1 (Permitted Circumstances), then it will, to the extent not prohibited by Applicable Law or judicial or administrative process, except where impracticable, give reasonable advance notice to the other Party of such proposed disclosure and use reasonable efforts to secure confidential treatment of such information and will only disclose that portion of Confidential Information that is legally required to be disclosed as advised by its legal counsel. In any event, each Party agrees to take all reasonable action to avoid disclosure of Confidential Information of the other Party hereunder.

12.5 **Tax Treatment**. Nothing in Section 12.1 (Duty of Confidence) or 12.4 (Authorized Disclosures) will limit either Party in any way from disclosing to any Third Party such Party's U.S. or foreign income tax treatment and the U.S. or foreign income tax structure of the transactions relating to such Party that are based on or derived from this Agreement, or materials of any kind (including opinions or other tax analyses) relating to such tax treatment or tax structure, except to the extent that nondisclosure of such matters is reasonably necessary in order to comply with applicable securities laws.

12.6 **Publications**. Within 90 days following the Effective Date, the JDC (or other assigned subcommittee, such as the Joint Medical Affairs Team) will prepare a written joint publication strategy for the Licensed Products (the "**Joint Publication Strategy**"). During the Term, each Party may present or publish any Clinical Trial data, non-clinical or preclinical data, or any associated results or conclusions generated by or on behalf of either Party pursuant to this Agreement (each such proposed presentation or publication, a "**Publication**") only in accordance with the Joint Publication Strategy and subject to the limitations set forth in this Section 12.6 (Publications) and Section 12.7 (Publication and Listing of Clinical Trials).

(a) Both Parties acknowledge that it is their policy for the studies and results thereof to be registered and published in accordance with their internal guidelines.

(b) A Party ("**Publishing Party**") shall provide the other Party with a copy of any proposed Publication at least 30 days prior to submission for publication so as to provide such other Party with an opportunity to recommend any changes it reasonably believes are necessary to continue to maintain the Confidential Information disclosed by the other Party to the Publishing Party in accordance with the requirements of this Agreement. The implementation of such recommended changes shall not be unreasonably refused by the Publishing Party. If such other Party notifies ("**Publishing Notice**") the Publishing Party in writing, within 30 days after receipt of the copy of the proposed publication or presentation, that such publication or presentation in its reasonable judgment (i) contains an invention, solely or jointly conceived or reduced to practice by the other Party, for which the other Party reasonably desires to obtain patent protection or (ii) could be expected to have a material adverse effect on the commercial value of any Confidential Information disclosed by the other Party to the Publishing Party, the Publishing Party shall prevent such publication or delay such publication for a mutually agreeable period of time. In the case of inventions, a delay shall be for a period reasonably sufficient to permit the timely preparation and filing of a patent application(s) on such invention, and in no event less than 90 days from the date of the Publishing Notice.

(c) Each Party will provide the other Party a copy of the Publication at the time of the submission or presentation thereof.

(d) Each Party agrees to determine the authorship of all Publications in accordance with all applicable International Committee of Medical Journal Editors (ICMJE) guidelines, and, in addition, to acknowledge the contributions of the other Party and its employees, in each case, as scientifically appropriate.

12.7 Publication and Listing of Clinical Trials. With respect to the listing of Clinical Trials or the publication of Clinical Trial results for the Licensed Products and to the extent applicable to a Party's activities conducted under this Agreement, each Party will comply with (a) the Pharmaceutical Research and Manufacturers of America (PhRMA) Guidelines on the listing of Clinical Trials and the Publication of Clinical Trial results, and (b) any Applicable Law or applicable court order, stipulations, consent agreements, and settlements entered into by such Party. The Parties agree that any such listings or publications made pursuant to this Section 12.7 (Publication and Listing of Clinical Trials) will be considered a Publication for purposes of this Agreement and will be subject to Section 12.6 (Publications).

12.8 Publicity; Use of Names.

12.8.1 Press Release. Roche will be permitted to issue the initial press release regarding the execution of this Agreement and the Stock Purchase Agreement as set forth in **Schedule 12.8.1(a)**. Roche shall otherwise issue press releases in accordance with its internal policy that typically does not issue a second press release until proof of concept has been achieved for a compound. Following such initial press release, Roche shall provide Sarepta with a copy of any draft press release related to the activities contemplated by this Agreement and Stock Purchase Agreement at least two weeks prior to its intended publication for Sarepta's review. Sarepta may provide Roche with suggested modification to the draft press release. Roche shall consider Sarepta's suggestions in good faith in issuing its press release. Sarepta

will be permitted to issue the initial press release regarding the execution of this Agreement and the Stock Purchase Agreement as set forth in **Schedule 12.8.1(b)**. Following such initial press release, Sarepta may issue additional press releases and other public announcements related to the activities contemplated by this Agreement or the Stock Purchase Agreement that (a) have been approved by Roche, or (b) are required to be issued by Sarepta to comply with Applicable Law. In all circumstances, to the extent practicable, Sarepta shall provide Roche with a draft of such press release or announcement at least two days prior to its first intended publication for Roche's review. During such two-day period, Roche may approve the draft press release or announcement and permit Sarepta to issue the press release or announcement or contact Sarepta to discuss modification to the draft press release or announcement. If Roche asks for modification of any press release following the initial press release, then Sarepta will consider implementing such modification in good faith. To ensure communication alignment between the Parties or Stock Purchase Agreement issuance of a permitted press release or announcement by Sarepta shall consist solely of the press release or other publicly announced language previously issued by either Party in accordance with this Agreement or shall follow the response guidelines that may be mutually developed by the Parties.

12.8.2 **Other Releases**. Other than such press release and the public disclosures permitted by this Section 12.8 (Publicity; Use of Names), and Section 12.4 (Authorized Disclosures), the Parties agree that the portions of any other news release or other public announcement relating to this Agreement, the Stock Purchase Agreement, or the performance hereunder or thereunder that would disclose information other than that already in the public domain will first be reviewed and approved by both Parties (with such approval not to be unreasonably withheld, conditioned, or delayed). However, the Parties agree that after (a) a disclosure pursuant to Section 12.8 (Publicity; Use of Names) or Section 12.4 (Authorized Disclosures) or (b) the issuance of a press release (including the initial press release) or other public announcement pursuant to this Section 12.8.1 (Press Release) that has been reviewed and approved by the other Party, the disclosing Party may make subsequent public disclosures reiterating such information without having to obtain the other Party's prior consent and approval so long as the information in such press release or other public announcement remains true, correct, and the most current information with respect to the subject matters set forth therein. Similarly, after a Publication has been made available to the public in accordance with Section 12.6 (Publications), (i) each Party may post such Publication or a link to it on its corporate web site (or any website managed by such Party in connection with a Clinical Trial for a Licensed Product, as appropriate) without the prior written consent of the other Party and (ii) the disclosing Party may make subsequent public disclosures reiterating the information in such prior Publications without having to obtain the other Party's prior consent and approval so long as the information in such Publication remains true, correct, and the most current information with respect to the subject matters set forth therein.

12.8.3 **Disclosures**. Notwithstanding any provision to the contrary set forth in this Agreement, each Party has the right to publicly disclose (in written, oral, or other form): (a) the achievement of any Regulatory Milestone Event or Sales Milestone Event under this Agreement (including the amount, payment, and timing of any such milestone event); (b) the commencement, completion, material data, or key results of any Clinical Trials for the Sarepta Products or Sarepta Diagnostic Product conducted by or on behalf of either Party; and (c) the achievement of Regulatory Approval for any Sarepta Product or Sarepta Diagnostic Product in its Territory; *provided* that, subject to Section 12.4.1(c) (Authorized Disclosures; Permitted Circumstances), Sarepta may disclose the achievement of Regulatory Approval for any Sarepta Product or Sarepta Diagnostic Product in the Roche Territory.

12.8.4 **Use of Names and Logos**. Each Party will have the right to use the other Party's name in presentations, its website, collateral materials, and other public communications to describe the collaboration relationship, as well as in press releases and other announcements issued pursuant to this Section 12.8 (Publicity; Use of Names); *provided* that each Party will use the other Party's stylized corporate trademarks and logos only in accordance with the other Party's standard written trademark usage guidelines communicated by either Party to the other in writing from time to time.

12.9 **Attorney-Client Privilege**. Neither Party is waiving, nor will be deemed to have waived or diminished, any of its attorney work product protections, attorney-client privileges or similar protections and privileges or the like as a result of disclosing information pursuant to this Agreement, or any of its Confidential Information (including Confidential Information related to pending or threatened litigation) to the Receiving Party, regardless of whether the Disclosing Party has asserted, such privileges and protections. The Parties: (a) share a common legal and commercial interest in such disclosure that is subject to such privileges and protections; (b) are or may become joint defendants in proceedings to which the information covered by such protections and privileges relates; (c) intend that such privileges and protections remain intact should either Party become subject to any actual or threatened proceeding to which the Disclosing Party's Confidential Information covered by such protections and privileges relates; and (d) intend that after the Effective Date both the Receiving Party and the Disclosing Party will have the right to assert such protections and privileges. Notwithstanding the foregoing, nothing in this Section 12.9 (Attorney-Client Privilege) will apply with respect to a dispute between the Parties (including their respective Affiliates) in connection with this Agreement or the activities of the Parties (including their respective Affiliates) hereunder.

ARTICLE 13
INDEMNIFICATION

13.1 **Indemnification by Sarepta**. Sarepta will indemnify, hold harmless, and defend Roche and its Affiliates and their respective, directors, officers, employees, and agents (the "**Roche Indemnitees**") from and against any and all Third Party suits, claims, actions, and demands ("**Third Party Claims**") and all liabilities, expenses, or losses (including reasonable attorneys' fees, court costs, witness fees, damages, judgments, fines, and amounts paid in settlement) arising therefrom ("**Losses**") to the extent that the applicable Third Party Claims and such Losses arise out of (a) a breach of this Agreement by Sarepta or any of its Affiliates, subcontractors or Sublicensees, (b) the Exploitation of a Sarepta Product by Sarepta or any of its Affiliates, subcontractors, or Sublicensees (c) Sarepta's failure to undertake any recall or product withdrawal of a Sarepta Product for which it is responsible pursuant to Section 5.10 (Recall, Withdrawal, or Field Alert of a Licensed Product), or (d) the fraud, gross negligence or willful misconduct of any Sarepta Indemnitee. Notwithstanding any provision to the contrary set forth in this Agreement, Sarepta will not have any obligation to indemnify Roche Indemnitees to the extent that any Third Party Claims or Losses arise out of the fraud, gross negligence, or willful misconduct of any Roche Indemnitee, any breach of this Agreement by Roche or any of its Affiliates, subcontractors, or Sublicensees, the Exploitation of a Licensed Product by Roche or any of its Affiliates, subcontractors, or Sublicensees, or Roche's failure to undertake any recall or product withdrawal of a Licensed Product in the Roche Territory in accordance with Section 5.10 (Recall, Withdrawal, or Field Alert of a Licensed Product).

13.2 **Indemnification by Roche**. Roche will indemnify, hold harmless, and defend Sarepta and its Affiliates, and their respective directors, officers, employees, and agents (the "**Sarepta Indemnitees**") from and against any and all Third Party Claims and Losses arising therefrom, to the extent that the applicable Third Party Claims and such Losses arise out of (a) a breach of this Agreement by Roche or its Affiliates, subcontractors, or Sublicensees, (b) the Exploitation of a Licensed Product by Roche or its Affiliates, subcontractors, or Sublicensees, (c) Roche's failure to undertake any recall or product withdrawal of a Licensed Product for which it is responsible pursuant to Section 5.10 (Recall, Withdrawal, or Field Alert of a Licensed Product), or (d) the fraud, gross negligence, or willful misconduct of any Roche Indemnitee. Notwithstanding any provision to the contrary set forth in this Agreement, Roche will not have any obligation to indemnify the Sarepta Indemnitees to the extent that any Third Party Claims or Losses arise out of the gross negligence or willful misconduct of any Sarepta Indemnitee, any breach of this Agreement by Sarepta or any of its Affiliates, subcontractors, or Sublicensees, the Exploitation of a Sarepta Product by Sarepta or any of its Affiliates, subcontractors, or Sublicensees, or Sarepta's failure to undertake any recall or product withdrawal of a Licensed Product in the Sarepta Territory in accordance with Section 5.10 (Recall, Withdrawal, or Field Alert of a Licensed Product).

13.3 **Indemnification Procedure**. Each Party, if seeking indemnification under this Article 13 (Indemnification) (the "**Indemnified Party**"), will give written notice of the Third Party Claim to the other Party (the "**Indemnifying Party**") no later than five Business Days after becoming aware of the Third Party Claim; *provided*, *however*, that any failure or delay in providing such notice will not relieve the Indemnifying Party of its indemnification obligation, except to the extent it is actually prejudiced by such failure or delay. Each Party will promptly furnish to the other Party, copies of all papers and official documents it receives in respect of any Third Party Claims or Losses arising therefrom. The Indemnifying Party will have the right to assume and control the defense of the indemnification Third Party Claim at its own expense with counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnified Party; *provided*, *however*, that an Indemnified Party will have the right to retain its own counsel, with the fees and expenses to be paid by the Indemnifying Party, if representation of such Indemnified Party by the counsel retained by the Indemnifying Party would be inappropriate due to actual or potential differing interests between the Indemnified Party and any other party represented by such counsel in such proceedings. If the Indemnifying Party does not assume the defense of the Third Party Claim as described in this Section 13.3 (Indemnification Procedure), then the Indemnified Party may defend the Third Party Claim but will have no obligation to do so. The Indemnified Party will not settle or compromise the Third Party Claim without the prior written consent of the Indemnifying Party, and the Indemnifying Party will not settle or compromise the Third Party Claim in any manner that would have an adverse effect on the Indemnified Party's interests (including any rights under this Agreement or the scope, validity, or enforceability of any Patent Rights, Confidential Information, or other rights licensed to Roche by Sarepta hereunder), in each case, without the prior written consent of the Indemnified Party, which consent (by the Indemnifying Party or Indemnified Party, as the case may be) will not be unreasonably withheld, conditioned, or delayed. The Indemnified Party will reasonably cooperate with the Indemnifying Party at the Indemnifying Party's expense and will make available to the Indemnifying Party all pertinent information under the control of the Indemnified Party, which information will be subject to Article 12 (Confidentiality). The Indemnifying Party will not be liable for any settlement or other disposition of Losses by the Indemnified Party if such settlement is reached without the written consent (not to be unreasonably withheld, conditioned or delayed) of the Indemnifying Party in accordance with this Section 13.3 (Indemnification Procedure).

13.4 **Insurance**. Each Party will procure and maintain comprehensive general liability operations insurance, adequate to cover its obligations hereunder and that is at all times sufficient to cover its obligations. During the period in which any Licensed Product is being clinically tested in human subjects or commercially distributed or sold by such Party pursuant to this Agreement, the Parties shall maintain clinical trial liability insurance coverage that in no event be less than $[**] per loss occurrence for any period during which the Parties or its Affiliates or any of their Sublicensees are conducting a clinical trial and $[**] for any period during which the Parties or its Affiliates or any of their Sublicensees are selling Licensed Product(s). The Parties shall maintain workers' compensation insurance in accordance with statutory requirements not less than $[**]. Each of the above insurance policies shall be primary insurance. It is understood that such insurance will not be construed to create a limit of either Party's liability with respect to its indemnification obligations under this Article 13 (Indemnification). Sarepta shall name Roche as an additional insured by endorsement on product liability insurance policies and shall carry insurance with insurance companies with an A.M. Best's rating of A-VII or better. Each Party will provide the other Party with written evidence of such insurance upon request. Each Party will provide the other Party with written notice at least 30 days prior to the cancellation, nonrenewal, or material change in such insurance that materially adversely affects the rights of the other Party hereunder. Notwithstanding any provision to the contrary set forth in this Agreement, Roche may self-insure in whole or in part the insurance requirements described in this Section 13.4 (Insurance) in accordance with its own internal policies for self-insurance.

ARTICLE 14
TERM AND TERMINATION

14.1 **Term**. The term of this Agreement will begin on the Effective Date and, unless earlier terminated in accordance with this Article 14 (Term and Termination), will continue (a) with respect to each of the Exon-Skipping Products and each other Option Product until any of the conditions described in Section 2.7.5 (Termination of Option) apply, if Roche does not exercise the applicable Option within the applicable Option Exercise Period, and (b) on a Licensed Product-by-Licensed Product and country-by-country basis, until the expiration of the Royalty Term for such Licensed Product in such country (the "**Term**").

14.2 **Termination for Breach**.

14.2.1 **Notice and Cure**. Subject to the terms of this Section 14.2 (Termination for Breach), a Party (the "**Non-Breaching Party**") will have the right, in addition to any other rights and remedies under this Agreement and under Applicable Law, to terminate this Agreement in its entirety in the event the other Party (the "**Breaching Party**") materially breaches a material term of this Agreement; *provided*, *however*, that (a) if such material breach relates only to one or more of Regions, and not all Regions, then the Non-Breaching Party shall only have the right to terminate this Agreement with respect to the Region to which such material breach relates, and (b) if one or more Options are exercised and accordingly there are more than one Licensed Product under this Agreement and such material breach relates to only one Licensed Product and not all Licensed Products, then the Non-Breaching Party shall only have the right to terminate this Agreement with respect to the Licensed Product to which such material breach relates. The Non-Breaching Party will first provide written notice to the Breaching Party, which notice will identify with particularity the alleged breach and state the Non-Breaching Party's intent to terminate this Agreement if such breach is not cured. With respect to material breaches of any payment provision hereunder, the Breaching Party will have a period of [**] after such written notice is provided to cure such breach. With respect to all other breaches, the Breaching Party will have a period of [**] after such written notice is provided to cure such breach. If the Breaching Party fails to cure the applicable breach within the relevant cure period set forth in this Section 14.2 (Termination for Breach), then the Non-Breaching Party may terminate this Agreement in the applicable Region or, if the breach affects the entire Roche Territory, in its entirety, immediately upon written notice thereof to the Breaching Party.

14.2.2 **Certain Breaches of Diligence in a Region**. Notwithstanding any provision to the contrary set forth in this Agreement and on a Licensed Product-by-Licensed Product basis,

(a) Roche's breach of its Development diligence obligation set forth in Section 4.2.2 (Of Roche) with respect to a Roche Major Country in the European Region but not all Roche Major Countries in the European Region, will neither give Sarepta the right to terminate this Agreement pursuant to Section 14.2.2 (Termination for Breach) with respect to such Roche Major Country in the European Region in which Roche failed to use Commercially Reasonable Efforts nor will it give Sarepta the right to terminate this Agreement with respect to the European Region, *provided* that Roche uses Commercially Reasonable Efforts to Develop in the European Region when considered as a whole;

(b) Roche's breach of its Commercialization diligence obligation set forth in Section 6.5 (Roche Commercialization Diligence Obligation) with respect to a country in a Region but not all countries in the Region, will neither give Sarepta the right to terminate this Agreement pursuant to this Section 14.2.2 (Termination for Breach) with respect to such country in which Roche failed to use Commercially Reasonable Efforts nor give Sarepta the right to terminate this Agreement with respect to the applicable Region, provided that Roche uses Commercially Reasonable Efforts to Commercialize in the applicable Region when considered as a whole.

14.3 **Supply Failure**. In the event of a Supply Failure, Roche shall have the right to terminate the Agreement in its entirety by providing written notice to Sarepta no later than [**] following such Supply Failure.

14.4 **Termination by Roche for Convenience**. Following the Effective Date, Roche will have the right to terminate the Agreement (a) in its entirety upon (i) [**] prior written notice as long as none of the Licensed Products has achieved first patient dosed for a Pivotal Clinical Trial, or (ii) [**] prior written notice if any of the Licensed Products has achieved first patient dosed for a Pivotal Clinical Trial or (b) on a Licensed Product-by-Licensed Product basis (including Exon-Skipping Product-by- Exon-Skipping Product basis) with respect to one or more Regions at any time during the Term for any reason upon (A) [**] prior written notice if the applicable Licensed Product has not achieved first patient dosed of a Pivotal Clinical Trial or (B) [**] prior written notice if the applicable Licensed Product has achieved first patient dosed for a Pivotal Clinical Trial.

14.5 **Termination for Bankruptcy**. Following the Effective Date, this Agreement may be terminated in its entirety at any time during the Term by either Party by providing written notice to the other Party in the event of any of the following: (a) the institution of any bankruptcy, receivership, insolvency, reorganization, or other similar proceedings by or against the other Party under any bankruptcy, insolvency, or other similar law now or hereinafter in effect, where in the case of involuntary proceedings such proceedings have not been dismissed or discharged within 90 days after they are instituted; (b) the making of an assignment for the benefit of creditors; (c) the appointment of a receiver for all or substantially all of the other Party's assets; or (e) any corporate action is taken by the board of directors of the other Party in furtherance of any of the foregoing actions.

14.6 **Cessation of Development and Commercialization**. On a Licensed Product-by-Licensed Product and Region-by-Region basis, if Roche and its Affiliates do not conduct any material Development or Commercialization activities with respect to a Licensed Product in one or more Regions for a continuous period of longer than [**] at any time following the first Regulatory Approval of such Licensed Product in the European Union, then Sarepta may, at its election, terminate this Agreement with respect to such Licensed Product and such Regions upon [**] prior written notice to Roche. Notwithstanding any provision to the contrary set forth in this Agreement, such [**] period set forth in this Section 14.6 (Cessation of Development and Commercialization) will automatically be tolled if such delays are due to [**].

14.7 **[**]**.

14.8 **Effects of Termination**. In the event of any termination (but not expiration) of this Agreement in its entirety or on a Licensed Product-by-Licensed Product basis, all rights in the Licensed Products that are the subject of such termination (each, a "**Terminated Product,**" *provided* that all Licensed Products will be Terminated Products if the Agreement is terminated in its entirety) in the Terminated Regions will revert to Sarepta, and the following will apply with respect to the Terminated Products in the Terminated Regions:

14.8.1 **Termination of Licenses**. As of the effective date of termination of this Agreement, all rights and licenses granted to each Party under Section 2.1 (Grant of Licenses to Roche) and Section 2.2 (Grant of Licenses to Sarepta) or otherwise under this Agreement, in each case, with respect to the Terminated Products in the Terminated Regions, will each terminate and all Sublicenses granted by Roche or its Affiliates pursuant to, and subject to, Section 2.3 (Rights to Grant Sublicenses) with respect to the Terminated Products in the Terminated Regions will also terminate, but each Party will retain its joint ownership interests in the Joint Collaboration Technology.

14.8.2 **Return of Confidential Information**. As soon as reasonably practicable after the effective date of termination of this Agreement, Roche will cease using the Sarepta Technology in connection with the Terminated Products in the Terminated Regions and will return to Sarepta or destroy all copies of any documents containing any Sarepta Know-How or Option Product Know-How to the extent relating to the Terminated Products in the Terminated Regions and then in existence and in the possession of Roche. If this Agreement is terminated in its entirety and upon request in writing by the Disclosing Party, the other Party will return or destroy (at the other Party's election) all Confidential Information of the other Party in its possession upon termination of this Agreement and, if applicable, the Receiving Party will provide a written confirmation of such destruction within 30 days of such request. Notwithstanding the foregoing or any provision to the contrary set forth in this Agreement: (a) the foregoing terms of this Section 14.8.2 (Return of Confidential Information) will not apply to any Confidential Information that is necessary to allow such Party to perform its obligations or exercise any of its rights that expressly survive the applicable termination of this Agreement, and the Receiving Party may retain one copy of such Confidential Information for its legal archives; and (b) the Receiving Party will not be required to destroy electronic files containing such Confidential Information that are made in the ordinary course of its business information back-up procedures pursuant to its electronic record retention and destruction practices that apply to its own general electronic files and information.

14.8.3 **Sarepta Designees**. To facilitate the reversion of the Terminated Products to Sarepta, upon any termination of this Agreement and within [**] after receipt or delivery of (as applicable) notice of termination, Sarepta shall provide Roche with a notice that describes Sarepta's *bona fide* intention to continue Developing and Commercializing a Terminated Product and (b) Sarepta's request for Roche's continuation of activities with respect to the Terminated Product in support of reversion of the Terminated Product back to Sarepta as set forth in Section 14.7 (Effects of Termination) until such activities are complete (a "**Continuation Election Notice**"). The Continuation Election Notice will include the countries in the Terminated Regions in which Sarepta intends to continue Development and Commercialization of the Terminated Products (the "**Continued Countries List**") and, if applicable and to the extent available, a list of designees in each country in the Continued Countries List to whom Sarepta would like certain Regulatory Submissions, Regulatory Approvals, and Reimbursement Approvals for the Terminated Products in the Terminated Regions then Controlled by Roche or any of its Affiliates or Sublicensees, to be assigned (the "**Country Designees List**"). After Sarepta's delivery of the Continuation Election Notice to Roche within [**] after receipt or delivery of (as applicable) notice of termination, the rights and obligations set forth in Section 14.8.4 through Section 14.8.13 shall apply. If Sarepta does not provide Roche with a Continuation Election Notice as set forth in this Section 14.8.3 (Sarepta Designees) and a Continued Countries List and a Country Designees List within [**] after notice in writing from Roche that Sarepta has not provided such lists within the [**] period set forth in this Section 14.8.3 (Sarepta Designees), then the terms set forth in Section 14.8.4 through Section 14.8.13 shall not be applicable.

14.8.4 **Intellectual Property License to Sarepta**. Upon any termination of this Agreement, Roche will, and hereby does, grant to Sarepta, effective upon the effective date of such termination and without any warranty and at Sarepta's sole risk, a [**], non-transferable (except as set forth in Section 17.1 (Assignment)) license (with the right to grant sublicenses including through multiple tiers) under the Roche Background Technology and the Roche Collaboration Technology Controlled by Roche or any of its Affiliates as of the effective date of such termination and Roche's interest in the Joint Collaboration Technology, in each case, solely to Exploit the Terminated Products in the Field in the Terminated Regions (or, in the case of termination of this Agreement in its entirety, worldwide), which license will be exclusive with respect to the Roche Collaboration Technology and Roche's interest in the Joint Collaboration Technology and non-exclusive and solely to the extent necessary with respect to the Roche Background Technology.

14.8.5 **[**]**.

14.8.6 **Assignment of Agreements**. Upon any termination of this Agreement, Roche will use reasonable efforts to assign to Sarepta any Third Party agreements pursuant to which Roche then Controls any Roche Collaboration Patent Rights that Cover, or Roche Collaboration Know-How that relates to, a Terminated Product in a Terminated Region, if permitted under such Third Party agreement (and will use reasonable efforts to seek any consent required from the applicable Third Party in connection with such an assignment) and solely to the extent such Third Party agreements relates to such Terminated Product in a Terminated Region (it being understood that the foregoing obligation shall not apply to any such Third Party agreement that also relates to any products or services other than applicable Terminated Products or any regions other than the applicable Terminated Regions). If such Third Party agreement cannot or will not be assigned to Sarepta as contemplated by the previous sentence, then upon Sarepta's reasonable request, Roche will use reasonable efforts to maintain such Third Party agreement and to grant Sarepta the

sublicenses or other rights under such Roche Collaboration Patent Rights or Roche Collaboration Know-How necessary for Sarepta to Exploit the Terminated Products in the Terminated Regions (to the extent permitted under such Third Party agreement). If such a sublicense or other right is granted to Sarepta, then Sarepta will pay to Roche [**] of all payments due to the applicable Third Party under any such Third Party agreement in consideration of such sublicense or other rights. If Roche is unable to sublicense any such Roche Collaboration Patent Rights or Roche Collaboration Know-How to Sarepta without the consent of the Third Party, then Roche undertakes, on request from Sarepta, to use reasonable efforts to procure such consent with respect to the Terminated Products in the Terminated Regions on behalf of Sarepta to the extent that it is able to do so, and Sarepta will pay such fees and agree to be bound by the terms agreed between Roche and the Third Party licensor.

14.8.7 **Assignment and Disclosure**. Upon any termination of this Agreement, to the extent requested by Sarepta following the date that a Party provides notice of termination of this Agreement (and in any event no later than the later of 30 days after the effective date of termination), Roche will use reasonable efforts promptly upon request of Sarepta to:

(a) assign and transfer to Sarepta or its designee all of Roche's rights, title, and interests in and to all (i) clinical trial agreements, manufacturing and supply agreements, distribution agreements, and other agreements to which Roche is a party that relates to the Terminated Product and (ii) data from any applicable Clinical Trials in Roche's Control, in each case, solely to the extent assignable without consent of, or the provision of consideration (whether monetary or otherwise) to, any Third Party and not cancelled and solely to the extent the foregoing relates exclusively to the Terminated Products in the Terminated Regions and are necessary for the Exploitation of the Terminated Products in the Terminated Regions;

(b) to the extent any agreement or data set forth in the foregoing clause (a) is not assignable to Sarepta or does not exclusively relate to the Terminated Products in the Terminated Regions, reasonably cooperate with Sarepta to arrange to continue to provide such services, at the costs of Sarepta, for a reasonable time but in no case longer than for 18 months after termination of this Agreement with respect to such Terminated Products in the Terminated Regions to facilitate the orderly transition of all Development, Commercialization, and other activities then being performed by or on behalf of Roche or its Affiliates or Sublicensees for the Terminated Products in the Terminated Regions to Sarepta or its designee;

(c) assign and transfer (and if unable to assign and transfer, exclusively license) to Sarepta or its designee, as of the effective date of termination, all of Roche's rights, title, and interests in and to the Product Marks and any domain names associated with the Product Marks (to the extent that Roche or its Affiliates has any), in each case, for the Terminated Products in the Terminated Regions, and promptly provide to Sarepta all login and password information necessary to maintain such domain names;

(d) assign and transfer to Sarepta or its designee all of Roche's rights, title, and interests in and to any necessary Product Materials for the Terminated Products in the Terminated Regions, training materials, medical education materials, packaging and labeling, related to the Terminated Products in the Terminated Regions, and copyrights and any registrations for the foregoing (and, with respect to copyrights, if unable to assign and transfer, exclusively license); and

(e) disclose to Sarepta or its designee all material and updated documents, records, and materials that are controlled by Roche or that Roche is able to obtain using reasonable efforts, and that embody the foregoing.

Subject to Section 14.8.14 (Termination by Roche for Breach), Roche will be responsible for the costs and expenses associated with the assignments set forth in this Section 14.8.7 (Assignment and Disclosure).

14.8.8 Regulatory Submissions and Regulatory Approvals. Upon any termination of this Agreement, Roche will and hereby does, and will cause its Affiliates and Sublicensees to, assign and transfer to Sarepta or its designee all of Roche's rights, title, and interests in and to all Regulatory Submissions, Regulatory Approvals, and Reimbursement Approvals for the Terminated Products in the Terminated Regions then Controlled by Roche or any of its Affiliates or Sublicensees, and (b) to the extent assignment pursuant to clause (a) is delayed or is not permitted by the applicable Regulatory Authority, permit Sarepta to cross-reference and rely upon any Regulatory Submissions, Regulatory Approvals, and Reimbursement Approvals filed by Roche with respect to such Terminated Products in the Terminated Regions. Upon Sarepta's reasonable written request, Roche will execute and deliver, or will cause to be executed and delivered, to Sarepta or its designee such endorsements, assignments, commitments, acknowledgements, and other documents as may be necessary to assign, convey, transfer, and deliver to Sarepta or its designee all of Roche's or its applicable Affiliate's or designee's rights, title, and interests in and to all such assigned Regulatory Submissions, Regulatory Approvals, and Reimbursement Approvals, including submitting to each applicable Regulatory Authority or other Governmental Authority in the Terminated Regions a letter or other necessary documentation (with copy to Sarepta) notifying such Regulatory Authority or other Governmental Authority of, or otherwise giving effect to, the transfer of ownership to Sarepta of all such assigned Regulatory Submissions, Regulatory Approvals, and Reimbursement Approvals. In addition, upon Sarepta's reasonable written request, Roche will, at its cost and expense, provide to Sarepta copies of all material related documentation, including material non-clinical, preclinical, and clinical data related to the Terminated Products in the Terminated Regions that are then held by or reasonably available to Roche or its Affiliates, *provided* that Roche shall have no obligation to provide copies of any such documentation to the extent previously received by Roche from Sarepta or provided from Roche to Sarepta or otherwise publicly available. The Parties will discuss and establish appropriate arrangements with respect to safety data exchange.

14.8.9 Appointment as Exclusive Distributor. Upon any termination of this Agreement, if Roche is Commercializing any Terminated Products in any country of the Continued Countries List as of the applicable effective date of termination, then, at Sarepta's election (in its sole discretion) on a country-by-country basis and at Sarepta's expense plus a reasonable mark-up, until such time as all Regulatory Approvals with respect to such Terminated Products in such country have been assigned and transferred to Sarepta, Roche will appoint Sarepta or its designee as its exclusive distributor of such Terminated Products in such country and grant Sarepta or its designee the right to appoint sub-distributors, to the extent not prohibited by any written agreement between Roche or any of its Affiliates and a Third Party, *provided* that, for the avoidance of doubt, Roche shall not be required to pay to Sarepta any of the payments set forth in Section 9.4 (Milestone Payments) or Section 9.5 (Royalties) with respect to any sales of Terminated Products.

14.8.10 **Know-How Transfer Support**. Upon any termination of this Agreement other than by Roche for Sarepta's material breach pursuant to Section 14.2 (Termination for Breach), in furtherance of the license of Roche Background Know-How and Roche Collaboration Know-How pursuant to Section 14.8.4 (Intellectual Property License to Sarepta), Roche will, for a period of one hundred and eighty (180) days from the effective date of such termination, provide such consultation or other assistance, as Sarepta may reasonably request to assist Sarepta in becoming familiar with such Roche Background Know-How and Roche Collaboration Know-How in order for Sarepta to undertake further Exploitation of the Terminated Products in countries of the Continued Countries List, at Sarepta's cost and expense.

14.8.11 **Inventory**. Upon any termination of this Agreement, at Sarepta's election and request, Roche will transfer to Sarepta or its designee some or all inventory of the Terminated Products for the Terminated Regions (including all final product, bulk drug substance, intermediates, works-in-process, formulation materials, reference standards, drug product clinical reserve samples, packaged retention samples, and the like) then in the possession or Control of Roche, its Affiliates or Sublicensees; *provided* that Sarepta will pay Roche a price equal to the Supply Price incurred by Roche for such Terminated Product.

14.8.12 **Wind Down and Transition**. Upon any termination of this Agreement, Roche will be responsible, at its own cost and expense, for the wind-down of Roche's and its Affiliates' and its Sublicensees' activities with respect to the Terminated Products in the Terminated Regions.

14.8.13 **Other Assistance; Further Assurances**. Without limiting the assistance to be provided under Section 14.8.10 (Know-How Transfer Support), Roche will provide any other assistance reasonably requested by Sarepta for the purpose of allowing Sarepta or its designee to proceed expeditiously with the Exploitation of the Terminated Products in the Terminated Regions for a period of [**] after the effective date of termination of this Agreement. Roche will execute all documents, including transitional services agreements, and take all such further actions as may be reasonably requested by Sarepta in order to give effect to the requirements in this Section 14.7 (Effects of Termination).

14.8.14 **Termination by Roche for Breach**. Notwithstanding any provision to the contrary in this Section 14.7 (Effects of Termination), in the event of any termination of this Agreement by Roche pursuant to Section 14.2 (Termination for Breach) or Section 14.3 (Supply Failure), Roche may, in its sole discretion, wind down or cease any and all Development and Commercialization of the Terminated Products in the Field in the Terminated Regions prior to the effective date of such termination, and Sarepta will be responsible for reimbursing Roche for the Internal Costs and External Costs incurred by Roche in the course of performing its obligations set forth in this Section 14.7 (Effects of Termination).

14.9 **Effects of Expiration**. Upon expiration (but not termination) of this Agreement with respect to a Licensed Product and a particular country in the Roche Territory pursuant to Section 14.1 (Term), the rights and licenses granted under Section 2.1 (Grant of Licenses to Roche), Section 2.2 (Grant of Licenses to Sarepta), and Section 10.16.4 (Trademark License) for such Licensed Product in such country will become worldwide, full-paid, non-exclusive, perpetual, and irrevocable.

14.10 **Survival; Accrued Rights**. The following Articles and Sections of this Agreement will survive expiration or early termination of this Agreement for any reason: Article 1 (Definitions); Section 9.5.2 (Royalty Reduction) (but only with respect to Net Sales made during the Term); Section 9.5.4(b) (Royalty Payments) (but only with respect to payment obligations accruing during the Term and only for a period of 3 years after expiration or termination); Section 9.12 (Late Payment; Disputed Payment) (but only with respect to payment obligations accruing during the Term); Section 10.2.1 (Sarepta Technology); Section 10.2.2 (Roche Collaboration Technology); Section 10.2.3 (Joint Collaboration Technology); Section 10.6 (Prosecution of Joint Collaboration Patent Rights); Section 11.1 (Mutual Representations and Warranties) until the date that is six years after the Effective Date; Section 11.2 (Additional Sarepta Warranties) until the date that is six years after the Effective Date; and Section 11.3 (Additional Roche Warranties) until the date that is six years after the Effective Date; Section 11.9 (Limitation of Liability); Section 12.1 (Duty of Confidence); Section 12.2 (Confidential Information); Section 12.3 (Exemptions); Section 12.4 (Authorized Disclosures); Section 12.5 (Tax Treatment); Article 13 (Indemnification) (excluding Section 13.3 (Insurance)); Section 14.8 (Effects of Termination); Section 14.9 (Effects of Expiration); Section 14.10 (Survival; Accrued Rights); Article 15 (Effectiveness); Article 16 (Dispute Resolution; Governing Law); Section 17.1 (Assignment); Section 17.2 (Entire Agreement; Amendment); Section 17.3 (No Strict Construction; Interpretation); Section 17.4 (Severability); Section 17.5 (Notices); Section 17.12 (No Waiver); and Section 17.13 (Cumulative Remedies). In any event, expiration or termination of this Agreement will not relieve the Parties of any liability that accrued hereunder prior to the effective date of such expiration or termination nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement, nor prejudice either Party's right to obtain performance of any obligation.

ARTICLE 15
EFFECTIVENESS

15.1 **Effective Date**. Except for the Parties' obligations under Article 12 (Confidentiality) and this Article 15 (Effectiveness), which will be effective as of the Execution Date, this Agreement will not become effective until the first Business Day after the Antitrust Clearance Date (the "**Effective Date**"); [**].

15.2 **Filings**. Each Party will, within 10 Business Days following the Execution Date, file those Antitrust Filings required under Antitrust Law [**] (the "**Required Filings**"). The Parties will reasonably cooperate with one another to the extent necessary in the preparation and execution of all such documents that are required to be filed pursuant to the Required Filings. Each Party will be responsible for its own costs and expenses associated with any such Required Filing, including premerger filing fees incurred by each Party associated with any such Required Filing. With respect to the Required Filings, the Parties will each use reasonable efforts to ensure that any applicable waiting period under the applicable Antitrust Law expires or is terminated as soon as practicable and to obtain any necessary approvals or consents under such applicable Antitrust Law, at the earliest possible date after the date of filing. Notwithstanding any provision to the contrary set forth in this Agreement and the Stock Purchase Agreement, nothing in this Agreement (including this Section 15.2 (Filings)) or the Stock Purchase Agreement will require either Party or any of its Affiliates to (a) disclose to the other Party or any of its Affiliates any information that is subject to obligations of confidentiality or non use owed to Third Parties (nor will either Party be required to conduct joint meetings with any Governmental Authority in which such information might be shared with the other Party) in connection with any Antitrust Filing, (b) commit to any consent decree or similar undertaking, or any divestiture, license (in whole or in part), or any arrangement to hold separate (or any similar arrangement) with respect to any of its products or assets, or (c) litigate. Sarepta will not do any of the foregoing without Roche's prior written consent.

15.3 **Outside Date**. This Agreement will terminate (a) at the election of either Party, immediately upon written notice to the other Party, if [**], seeks [**] injunction under applicable antitrust and non-competition laws against Sarepta and Roche to enjoin the transactions contemplated by this Agreement and the Stock Purchase Agreement; or (b) (i) at the election of Sarepta, immediately upon written notice to Roche, in the event that the Antitrust Clearance Date will not have occurred on or prior to [**] after the effective date of the Required Filing, and (ii) at the election of Roche, immediately upon written notice to Sarepta, in the event that the Antitrust Clearance Date will not have occurred on or prior to [**] after the effective date of the Required Filing and, in either case ((i) or (ii)), the Parties have not agreed in writing to extend the Antitrust Clearance Date. In the event of such termination, this Agreement will be of no further force and effect.

ARTICLE 16
DISPUTE RESOLUTION; GOVERNING LAW

16.1 **Executive Officers; Disputes**. Each Party will ensure that an Executive Officer is designated for such Party at all times during the Term for dispute resolution purposes, and will promptly notify the other Party of any change in its designated Executive Officer. Except as expressly set forth in this Agreement, in the event of a dispute arising under, relating to, or in connection with this Agreement (except for disputes arising at the JSC, which will be resolved in accordance with Section 3.7 (Decision-Making)), the Parties will refer such dispute to their respective Executive Officer, and such Executive Officers or designees will attempt in good faith to resolve such dispute. If the Parties are unable to resolve any such dispute within 30 days after referring such dispute to the designated Executive Officers pursuant to this Section 16.1 (Executive Officers; Disputes), then, other than a dispute to be resolved by a Regulatory Expert, either Party will have the right to pursue any and all remedies available at law or equity, as set forth in Section 16.2 (Jurisdiction; Venue) or Section 16.3 (Intellectual Property Disputes), as applicable.

16.2 **Jurisdiction; Venue**. Except as expressly provided in Section 16.3 (Intellectual Property Disputes) and Section 16.4 (Equitable Remedies), each Party irrevocably submits to the exclusive jurisdiction of (a) the state courts of the State of New York in Manhattan, New York, and (b) the United States District Court for the Southern District of New York, for the purposes of any suit, action, or other proceeding arising out of this Agreement or out of any transaction contemplated hereby. Each Party agrees to commence any such action, suit, or proceeding either in the United States District Court for the Southern District of New York or if such suit, action, or other proceeding may not be brought in such court for jurisdictional reasons, in a state court of the State of New York in Manhattan, New York. Each Party irrevocably and unconditionally waives any objection to the laying of venue of any action, suit, or proceeding arising out of this Agreement or the transactions contemplated hereby in (i) any state court of the State of New York in Manhattan, New York, or (ii) the United States District Court for the Southern District of New York, and hereby and thereby further irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such action, suit, or proceeding brought in any such court has been brought in an inconvenient forum. Each Party irrevocably consents to service of process in the manner provided under Section 17.5 (Notices) or by first class certified mail, return receipt requested, postage prepaid.

16.3 **Intellectual Property Disputes**. Notwithstanding any provision to the contrary set forth in this Agreement, if a dispute arises under this Agreement with respect to the validity, scope, enforceability, or ownership of any Patent Right or other intellectual property rights, and such dispute is not resolved in accordance with Section 16.1 (Executive Officers; Disputes), then such dispute will be submitted to a court of competent jurisdiction in the jurisdiction in which such Patent Right or other intellectual property right was granted or arose.

16.4 **Equitable Remedies**. Notwithstanding any provision to the contrary set forth in this Agreement, the Parties each stipulate and agree that (a) the other Party's Confidential Information includes highly sensitive trade secret information such that a breach of Article 12 (Confidentiality) by a Party will cause irrevocable harm for which monetary damages would not provide a sufficient remedy; and (b) in such case of such breach of Article 12 (Confidentiality), the non-breaching Party will be entitled to equitable relief, including specific performance, temporary or permanent restraining orders, preliminary injunction, permanent injunction, or other equitable relief without the posting of any bond or other security, from any court of competent jurisdiction. In addition, and notwithstanding any provision to the contrary set forth in this Agreement, in the event of any other actual or threatened breach hereunder, the aggrieved Party may seek equitable relief (including specific performance, temporary or permanent restraining orders, or other equitable relief) from any court of competent jurisdiction without first submitting to the dispute resolution procedures set forth in Article 16 (Dispute Resolution; Governing Law).

16.5 **Governing Law; English Language**. This Agreement and all amendments, modifications, alterations, or supplements hereto, and the rights of the Parties, will be construed under and governed by the laws of the State of New York, United States, exclusive of its conflicts of laws principles. This Agreement has been prepared in the English language and the English language will control its interpretation. All consents, notices, reports, and other written documents to be delivered or provided by a Party under this Agreement will be in the English language, and in the event of any conflict between the provisions of any document and the English language translation thereof, the terms of the English language translation will control.

16.6 **Waiver of Jury Trial**. TO THE EXTENT NOT PROHIBITED BY APPLICABLE LAW THAT CANNOT BE WAIVED, THE PARTIES HEREBY WAIVE, AND COVENANT THAT THEY WILL NOT ASSERT (WHETHER AS PLAINTIFF, DEFENDANT, OR OTHERWISE), ANY RIGHT TO TRIAL BY JURY IN ANY ACTION ARISING IN WHOLE OR IN PART UNDER OR IN CONNECTION WITH THIS AGREEMENT, WHETHER NOW EXISTING OR HEREAFTER ARISING, AND WHETHER SOUNDING IN CONTRACT, TORT, OR OTHERWISE. THE PARTIES AGREE THAT ANY OF THEM MAY FILE A COPY OF THIS PARAGRAPH WITH ANY COURT AS WRITTEN EVIDENCE OF THE KNOWING, VOLUNTARY, AND BARGAINED-FOR AGREEMENT AMONG THE PARTIES IRREVOCABLY TO WAIVE ITS RIGHT TO TRIAL BY JURY IN ANY PROCEEDING WHATSOEVER BETWEEN THEM RELATING TO THIS AGREEMENT, WHICH WILL INSTEAD BE TRIED IN A COURT OF COMPETENT JURISDICTION BY A JUDGE SITTING WITHOUT A JURY.

ARTICLE 17
MISCELLANEOUS

17.1 **Assignment**. Neither Party may assign this Agreement or the licenses granted hereunder without the other Party's prior written consent unless such assignment is to (a) a Third Party successor or purchaser of all or substantially all of the assets or businesses to which this Agreement relates whether pursuant to a sale of assets, merger, or other transaction or series of transactions, in which case the assigning Party will provide written notice to the other Party and need not obtain the other Party's consent, or (b) an Affiliate of such Party, in which case the assigning Party will provide prior written notice to the other Party and need not obtain the other Party's consent; *provided* that the assigning Party remains fully liable for the performance of its obligations hereunder by such assignee. In addition, and notwithstanding the foregoing, Sarepta may assign its right to receive payments under this Agreement as part of a royalty financing transaction undertaken for *bona fide* financing purposes. Any other assignment of this Agreement by a Party requires the prior written consent of the other Party. Any assignment of this Agreement in violation of this Section 17.1 (Assignment) will be null, void, and of no legal effect. This Agreement will be binding on and will inure to the benefit of the permitted successors and assigns of the Parties.

17.2 **Entire Agreement; Amendment**. This Agreement, together with all exhibits and schedules attached hereto, constitutes the entire agreement between the Parties with respect to the subject matter hereof, and supersedes and merges all prior and contemporaneous negotiations, representations, and understandings regarding the same, (including that certain Confidentiality Agreement, dated [**], by and between Sarepta Therapeutics, Inc. and Roche Holdings, Inc. ("**Confidential Disclosure Agreement**")). All information shared by the Parties pursuant to the Confidential Disclosure Agreement will be Confidential Information under this Agreement from and after the Effective Date, and the use and disclosure thereof will be governed by Article 12 (Confidentiality). This Agreement may not be modified or amended, except by another agreement in writing executed by duly authorized signatories of each Party.

17.3 **No Strict Construction; Interpretation**. This Agreement has been prepared jointly and will not be strictly construed against either Party. Ambiguities, if any, in this Agreement will not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision. Except where the context expressly requires otherwise, (a) whenever any provision of this Agreement uses the term "including" (or "includes"), such term will be deemed to mean "including without limitation" and "including but not limited to" (or "includes without limitations" and "includes but is not limited to") regardless of whether the words "without limitation" or "but not limited to" actually follow the term "including" (or "includes"); (b) "herein," "hereby," "hereunder," "hereof," and other equivalent words will refer to this Agreement in its entirety and not solely to the particular portion of this Agreement in which any such word is used; (c) all definitions set forth herein will be deemed applicable whether the words defined are used herein in the singular or the plural; (d) wherever used herein, any pronoun or pronouns will be deemed to include both the singular and plural and to cover all genders; (e) the recitals set forth at the start of this Agreement, along with the schedules and exhibits to this Agreement, and the terms and conditions incorporated in such recitals and schedules and exhibits will be deemed integral parts of this Agreement and all references in this Agreement to this Agreement will encompass such recitals and schedules and exhibits and the terms and conditions incorporated in such recitals and schedules and exhibits; *provided* that in the event of any conflict between the terms and conditions of this Agreement and any terms and conditions set forth in the recitals, schedules, or exhibits, the terms of this Agreement will control; (f) in the event of any conflict between the terms and conditions of this Agreement and any terms and conditions that may be set forth on any order, invoice, verbal agreement, or otherwise, the terms and conditions of this Agreement will govern; (g) unless otherwise provided, all references to Sections, Articles, and Schedules in this Agreement are to Sections, Articles, and Schedules of and to this Agreement; (h) any reference to any federal, national, state, local, or foreign statute or law will be deemed to also refer to all rules and regulations promulgated thereunder, and any reference to any law, rule, or regulation will be deemed to include the then current amendments thereto or any replacement or successor law, rule, or regulation thereof and any and all Applicable Law; (i) wherever used, the word "**shall**" and the word "**will**" are each understood to be imperative or mandatory in nature and are interchangeable with one another; (j) the word "**or**" will not be exclusive; (k) references to a particular Person include such Person's successors and assigns to the extent not prohibited by this Agreement; (l) the section headings and captions used herein are inserted for convenience of reference only and will not be construed to create obligations, benefits, or limitations; (m) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented, or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein); (n) the word "**notice**" means notice in writing (whether or not specifically stated) and will include notices, consents, approvals and other written communications contemplated under this Agreement; and (o) provisions that require that a Party, the Parties or any committee hereunder "**agree,**" "**consent,**" or "**approve**" or the like will require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes, or otherwise (but excluding e mail and instant messaging).

17.4 **Severability**. If any provision of this Agreement is declared invalid by a court of last resort or by any court or other governmental body the decision of which an appeal is not taken within the time provided by law, then and in such event, this Agreement will be deemed to have been terminated only as to the portion thereof that relates to the provision invalidated by that decision and only in the relevant jurisdiction, but this Agreement will remain in force, in all other respects and all other jurisdictions; *provided*, *however*, that if the provision so invalidated is essential to the Agreement as a whole, then the Parties will negotiate in good faith to amend the terms hereof as nearly as practical to carry out the original intent of the Parties, and, failing such amendment, either Party may submit the matter for resolution pursuant to Article 16 (Dispute Resolution; Governing Law).

17.5 **Notices**. All notices that are required or permitted hereunder will be in writing and sufficient if delivered by internationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, and in each case, addressed as follows (with a courtesy copy sent by email, which will not constitute notice):

If to Sarepta:

Sarepta Therapeutics Three, LLC
215 First Street
Cambridge, MA 02142
Attention: Matthew Gall
Email: [**]

With a copy (which will not constitute notice for purposes of this Agreement) to:

Ropes & Gray LLP
Prudential Tower, 800 Boylston Street
Boston, MA 02199-3600
Attention: David M. McIntosh
Email: [**]

If to Roche:

F. Hoffmann-La Roche Ltd
Grenzacherstrasse 124
4070 Basel
Switzerland
Attention: Legal Department
Facsimile: [**]

With a copy (which will not constitute notice for purposes of this Agreement) to:

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice will be deemed to have been given: (a) on the Business Day after dispatch if sent by internationally-recognized overnight courier; (b) on the fifth Business Day after dispatch if sent by registered or certified mail, postage prepaid, return receipt requested; and (c) when promptly confirmed by personal delivery, registered or certified mail or overnight courier if sent by facsimile.

17.6 **Further Assurances**. The Parties agree to reasonably cooperate with each other in connection with any actions required to be taken as part of their respective obligations under this Agreement, and will (a) furnish to each other such further information; (b) execute and deliver to each other such other documents; and (c) do such other acts and things (including working collaboratively to correct any clerical, typographical, or other similar errors in this Agreement), all as the other Party may reasonably request for the purpose of carrying out the intent of this Agreement.

17.7 **Performance by Affiliates**. Notwithstanding any provision to the contrary set forth herein, either Party will have the right to perform any or all of its obligations and exercise any or all of its rights under this Agreement through any Affiliate. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement and will cause its Affiliates to comply with the provisions of this Agreement in connection with such performance.

17.8 **Exit of the United Kingdom from EU**. Exit of the United Kingdom from E.U. At either Party's request, the Parties will discuss and agree upon such amendments to this Agreement as may be necessary to fairly and reasonably adjust the terms of this Agreement in light of the United Kingdom's exit from the E.U. Any such amendment should preserve the basic economic and legal terms of this Agreement insofar as possible in light of the change in circumstances caused by the United Kingdom's exit from the E.U.

17.9 **Agency**. Neither Party is, nor will be deemed to be an employee, agent, or representative of the other Party for any purpose. Each Party is an independent contractor, not an employee or Roche of the other Party. Neither Party will have the authority to speak for, represent, or obligate the other Party in any way without prior written authority from the other Party.

17.10 **Binding Effect; No Third Party Beneficiaries or Obligors**. As of the Execution Date, this Agreement will be binding upon and inure to the benefit of the Parties and their respective permitted successors and assigns. Except as set forth in Article 13 (Indemnification), no Person other than Sarepta, Roche, and their respective permitted successors and assigns hereunder will be deemed an intended beneficiary hereunder, nor have any right to enforce any obligation of any Party to this Agreement, nor will any Person other than Sarepta and Roche and their respective permitted successors and assigns have any obligations to any Party under this Agreement.

17.11 **Compliance with Export Regulations**. Neither Party will export any technology licensed to it by the other Party under this Agreement except in compliance with U.S. export laws and regulations.

17.12 **No Waiver**. Any provision of this Agreement may be waived if, but only if such waiver is in writing and is signed by the Party against whom the waiver is to be effective. Any omission or delay by either Party at any time to enforce any right or remedy reserved to it, or to require performance of any of the terms, covenants, or provisions hereof, by the other Party, will not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement. Any waiver by a Party of a particular breach or default by the other Party will not operate or be construed as a waiver of any subsequent breach or default by the other Party.

17.13 **Cumulative Remedies**. No remedy referred to in this Agreement, including termination of this Agreement, is intended to be exclusive, but each will be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

17.14 **Bankruptcy**. All licenses granted under this Agreement will be deemed licenses of rights to intellectual property for purposes of Section 365(n) of the U.S. Bankruptcy Code and a licensee under the Agreement will retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code. All Royalties and Milestone Payments will be deemed "**royalties**" for purposes of the U.S. Bankruptcy Code.

17.15 **Counterparts**. This Agreement may be executed in two or more counterparts, all of which taken together will be regarded as one and the same instrument. Each Party may execute this Agreement in Adobe™ Portable Document Format (PDF) sent by electronic mail. PDF signatures of authorized signatories of the Parties will be deemed to be original signatures, will be valid and binding upon the Parties, and, upon delivery, will constitute due execution of this Agreement.

[Remainder of page intentionally left blank; Signature page follows.]

IN WITNESS WHEREOF, the Parties have executed this Agreement through their duly authorized representatives to be effective as of the Execution Date.

Sarepta Therapeutics Three, LLC

By: /s/ Peter Walsh

Name: Peter Walsh

Title: Manager

F. HOFFMANN-LA ROCHE LTD

By: /s/ James Sabky

Name: James Sabky

Title: Global Head, Pharma Partnering

By: /s/ Stefan Arnold

Name: Stefan Arnold

Title: Head Legal Pharma

79445843_10

EXECUTION VERSION

EXHIBIT 10.52

STOCK PURCHASE AGREEMENT

BY AND BETWEEN

SAREPTA THERAPEUTICS, INC.

AND

ROCHE FINANCE LTD

DATED DECEMBER 21, 2019

Table of Contents

STOCK PURCHASE AGREEMENT

THIS STOCK PURCHASE AGREEMENT (this "**Agreement**"), is made as of December 21, 2019, by and between Sarepta Therapeutics, Inc., a Delaware corporation (the "**Company**"), and Roche Finance Ltd, a Swiss company (the "**Purchaser**"). The Company and the Purchaser may be referred to herein individually as a "**Party**" and collectively as the "**Parties**."

The Parties hereby agree as follows:

Section 1. Purchase and Sale of Common Stock.

1.1. Sale and Issuance of Common Stock. Subject to the terms and conditions of this Agreement, the Purchaser agrees to purchase at the Closing, and the Company agrees to sell and issue to the Purchaser at the Closing, 2,522,227 shares of the Company's Common Stock, $0.0001 par value per share (the "**Common Stock**"), at a price per share equal to $158.59 (for an aggregate purchase price of $399,999,979.93 (the "**Purchase Price**")). The shares of Common Stock issued to the Purchaser pursuant to this Agreement will be referred to in this Agreement as the "**Shares**." If, between the date hereof and the Closing, any change in the issued share capital of the Company shall occur by reason of any reclassification, recapitalization, stock split or combination, exchange or readjustment of shares (or any similar change in the share capital of the Company in connection with any merger, reorganization, amalgamation or spin-off), or any stock dividend thereon with a record date during such period, the number of Shares and price per Share shall be appropriately adjusted.

1.2. Payment. At the Closing, the Purchaser will pay the Purchase Price by wire transfer of immediately available funds in accordance with wire instructions provided by the Company to the Purchaser prior to the Closing.

1.3. Closing; Delivery.

(a) The closing of the transactions contemplated by this Section 1 (the "**Closing**") will be held on the date on which the Upfront Payment (as defined in the Collaboration Agreement) is required to be paid or at such other time or date as may be jointly designated by the Company and the Purchaser (the "**Closing Date**") at such place as may be jointly designated by the Company and the Purchaser.

(b) Closing Deliverables. At the Closing, the Purchaser will deliver or cause to be delivered to the Company, the Purchase Price, and the Company will deliver or cause to be delivered to the Purchaser, evidence reasonably satisfactory to the Purchaser of the issuance of the Shares to the Purchaser in book entry form.

1.4. No Registration. The Purchaser acknowledges and agrees that the Company undertakes no obligation to register the issuance of the Shares to the Purchaser or any resale of the Shares by the Purchaser.

1.5. Defined Terms Used in this Agreement. In addition to the terms defined elsewhere in this Agreement, the following terms used in this Agreement will be construed to have the meanings set forth or referenced below.

(a) "**Affiliate**" means, with respect to any Person, another Person that controls, is controlled by or is under common control with such Person; *provided* that with respect to the Purchaser, the term "Affiliate" will not include any employee benefit plan of Purchaser. A Person will be deemed to control another Person if such Person possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by contract or otherwise. For the purposes of this Agreement, in no event (i) will Purchaser or any of its Affiliates be deemed Affiliates of the Company or any of its Affiliates, nor will the Company or any of its Affiliates be deemed Affiliates of the Purchaser or any of its Affiliates or (ii) will Chugai Pharmaceutical Co., Ltd. (or any of its Subsidiaries) be deemed an Affiliate of the Purchaser unless and until Roche provides the Company with written notice of its desire to include any such Person as an Affiliate.

(b) "**Business Day**" means any day (other than a Saturday or Sunday) on which the banks in New York, New York and Basel, Switzerland are both open for business.

(c) "**Capital Stock**" means, with respect to any Person, any and all shares, interests, participations, rights in, or other equivalents (however designated and whether voting or non-voting) of such Person's capital stock, and any and all rights, warrants or options exercisable or exchangeable for or convertible into such capital stock.

(d) "**Collaboration Agreement**" means that certain License, Collaboration, and Option Agreement by and between Sarepta Therapeutics Three, LLC and F. Hoffmann-La Roche Ltd, dated as of December 21, 2019.

(e) "**Encumbrance**" means any security interest, lien, pledge, claim, charge, escrow, encumbrance, option, right of first offer, right of first refusal, preemptive right, mortgage, indenture, security agreement or other similar agreement, arrangement, contract, commitment, understanding, or obligation, whether written or oral, and whether or not relating in any way to credit or the borrowing of money.

(f) "**Exchange Act**" means the Securities Exchange Act of 1934, as amended, as in effect from time to time.

(g) "**GAAP**" means generally accepted accounting principles in the United States applied on a consistent basis.

(h) "**Governmental Entity**" means any court, agency, authority, department, regulatory body or other instrumentality of any government or country or of any national, federal, state, provincial, regional, county, city or other political subdivision of any such government or country or any supranational organization of which any such country is a member.

(i) "**Laws**" mean all United States and foreign national, federal, state, and local laws, statutes, ordinances, rules, regulations, orders, treaties and decrees.

(j) "**Material Adverse Effect**" means, with respect to a Person, any fact, circumstance, change, event, occurrence or effect that, individually, or in the aggregate with any such other facts, circumstances, changes, events, occurrences or effects, would have, or would reasonably be expected to have, a material adverse effect on (i) the financial condition, business, properties, assets, liabilities, or results of operations of such Person and its Affiliates, taken as a whole, or (ii) the ability of such Person and its Affiliates to perform and comply with their respective obligations under this Agreement or the Collaboration Agreement.

(k) "**Nasdaq**" means the Nasdaq Global Select Market.

(l) "**Order**" means any order, judgment, injunction, edict, decree, ruling, pronouncement, determination, decision, opinion, sentence, subpoena, writ or award issued, made, entered into or rendered by any court, administrative agency or other Governmental Entity or by any arbitrator.

(m) "**Person**" means any corporation, sole proprietorship, limited or general partnership, limited liability partnership, limited liability company, business trust, joint stock company, joint venture, trust, incorporated or unincorporated association, governmental or political body, subdivision, authority, bureau, or agency, or any other entity or body similar to any of the foregoing, or an individual, and will include any successor (by merger or otherwise) of such entity.

(n) "**Rule 144**" means Rule 144 (or any successor provisions) under the Securities Act, as amended, as in effect from time to time.

(o) "**Securities Act**" means the Securities Act of 1933.

(p) "**Subsidiary**" means, with respect to any Person, any corporation, partnership, joint venture, limited liability company or other entity (x) that is a controlled Affiliate of such Person, (y) of which such Person or a Subsidiary of such person is a general partner or (y) of which such Person or a Subsidiary of such person has the power to elect a majority of the board of directors or persons performing similar functions with respect to such entity (whether by ownership of securities or otherwise).

(q) "**Third Party**" means any Person other than a Party and its Affiliates.

1.6. No Strict Construction; Interpretation. This Agreement has been prepared jointly and will not be strictly construed against either Party. Ambiguities, if any, in this Agreement will not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision. Except where the context expressly requires otherwise, (a) whenever any provision of this Agreement uses the term "including" (or "includes"), such term will be deemed to mean "including without limitation" and "including but not limited to" (or "includes without limitations" and "includes but is not limited to") regardless of whether the words "without limitation" or "but not limited to" actually follow the term "including" (or "includes"); (b) "herein," "hereby," "hereunder," "hereof," and other equivalent words will refer to this Agreement in its entirety and not solely to the particular portion of this Agreement in which any such word is used; (c) all definitions set forth herein will be deemed applicable whether the words

defined are used herein in the singular or the plural; (d) wherever used herein, any pronoun or pronouns will be deemed to include both the singular and plural and to cover all genders; (e) the schedules and exhibits to this Agreement, and the terms and conditions incorporated in such schedules and exhibits will be deemed integral parts of this Agreement and all references in this Agreement to this Agreement will encompass such schedules and exhibits and the terms and conditions incorporated in such schedules and exhibits; *provided* that in the event of any conflict between the terms and conditions of this Agreement and any terms and conditions set forth in the schedules or exhibits, the terms of this Agreement will control; (f) unless otherwise provided, all references to Sections, Articles, and Schedules in this Agreement are to Sections, Articles, and Schedules of and to this Agreement; (g) any reference to any federal, national, state, local, or foreign statute or law will be deemed to also refer to all rules and regulations promulgated thereunder, and any reference to any law, rule, or regulation will be deemed to include the then-current amendments thereto or any replacement or successor law, rule, or regulation thereof and any and all applicable Law; (h) wherever used, the word "shall" and the word "will" are each understood to be imperative or mandatory in nature and are interchangeable with one another; (i) references to a particular Person include such Person's successors and assigns to the extent not prohibited by this Agreement; (j) the section headings and captions used herein are inserted for convenience of reference only and will not be construed to create obligations, benefits, or limitations; (k) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented, or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein); (l) the word "notice" means notice in writing (whether or not specifically stated) and will include notices, consents, approvals and other written communications contemplated under this Agreement; and (m) provisions that require that a Party, the Parties or any committee hereunder "agree," "consent," or "approve" or the like will require that such agreement, consent or approval be specific and in an executed writing.

Section 2. Representations and Warranties of the Company. The Company hereby represents and warrants to the Purchaser that the following representations and warranties are true and complete as of the date hereof and as of the Closing:

2.1. Organization and Power. The Company and each of its Subsidiaries is duly organized, validly existing and in good standing under the Laws of its jurisdiction of incorporation and has the requisite corporate power and authority to carry on its business as it is now being conducted. The Company and each of its Subsidiaries is duly qualified and licensed as a foreign corporation to do business, and is in good standing in each jurisdiction in which the character of its assets owned or held under lease or the nature of its business makes such qualification necessary, except where the failure so to qualify or be licensed would not, individually or in the aggregate, be material to the Company or any of its Subsidiaries. None of the Company or any of its Subsidiaries is in material breach of its organizational documents.

2.2. Authorization. The Company has the requisite corporate power and authority to enter into this Agreement and to consummate the transactions contemplated hereby. The execution and delivery by the Company of this Agreement, the issuance, sale and delivery of the Shares by the Company, the compliance by the Company with each of the provisions of this Agreement, and the consummation by the Company of the transactions contemplated hereby (a) are within the corporate power and authority of the Company (including such approval and authorization by the Company's board of directors required under the Laws of the State of Delaware and Company's certificate of incorporation and bylaws) and (b) have been duly authorized by all necessary corporate action of the Company. This Agreement has been duly and validly executed and delivered by the Company. Assuming due authorization, execution and delivery by the Purchaser of this Agreement, this Agreement constitutes a valid and binding agreement of the Company enforceable against the Company in accordance with its terms, except to the extent such enforcement is limited by (i) any applicable bankruptcy, insolvency and other similar Laws affecting the enforcement of creditors' rights generally and (ii) general principles of equity, including the possible unavailability of specific performance or injunctive relief or other equitable remedies. No other corporate proceedings (including any vote of the holders of the Company's capital stock) are necessary for the execution and delivery by the Company of this Agreement, the performance by it of its obligations under this Agreement or the consummation by it of the transactions contemplated hereby.

2.3. No Conflicts; Consents and Approvals; No Violation. Neither the execution, delivery or performance by the Company of this Agreement nor the consummation by the Company of the transactions contemplated hereby will (a) result in a breach or a violation of, any provision of the certificate of incorporation, bylaws or other organizational documents (including shareholders' and similar agreements) of the Company or of the certificate of incorporation, bylaws or other organizational documents (including shareholders' and similar agreements) of any of its Subsidiaries; (b) constitute, with or without notice or the passage of time or both, a breach, violation or default, create an Encumbrance, or give rise to any right of termination, modification, cancellation, payment or prepayment, suspension, limitation, revocation or acceleration, under (i) any Law applicable to the Company or (ii) any provision of any agreement or other instrument to which the Company or any of its Subsidiaries is a Party or pursuant to which any of them or any of their assets or properties is subject, except for, in the case of each clause (i) and (ii), breaches, violations, defaults, Encumbrances, or rights of termination, modification, cancellation, prepayment, suspension, limitation, revocation or acceleration, which, individually or in the aggregate, would not be material to the Company and its Subsidiaries taken as a whole; or (c) require any consent, Order, approval or authorization of, notification or submission to, filing with, license or permit from, or exemption or waiver by, any Governmental Entity or any other Person (collectively, the "**Consents, Approvals and Filings**") on the part of the Company or any of its Subsidiaries, except for (w) the consents, approvals and filings required under the Securities Act, the Exchange Act and applicable state securities Laws, (x) the consents, approvals and filings required under rules of Nasdaq, (y) competition filings, notices and clearances and (z) such other consents, approvals and filings which the failure of the Company or any of its Subsidiaries to make or obtain would not, individually or in the aggregate, be material to the Company and its Subsidiaries taken as a whole. The Company is not in violation of any term or provision of its certificate of incorporation or by-laws, and, other than any violation that would not, individually or in the aggregate, be material to the Company and its Subsidiaries taken as a whole, the Company is not in violation of any material term or provision of any agreement, indebtedness, mortgage, indenture, contract, Law or Order applicable to the Company.

2.4. Broker's Fee. Other than Goldman Sachs (all of the fees and expenses of which will be paid by the Company and not the Purchaser), no agent, broker, investment banker or other Person is or will be entitled to any broker's or finder's fee or any other commission or similar fee from the Company or any of its Subsidiaries in connection with any of the transactions contemplated by this Agreement or the Collaboration Agreement.

2.5. Listing. The Common Stock is, and the Shares will be, listed on Nasdaq. The Company has not taken any action designed to, or which is likely to have the effect of, delisting the Common Stock from Nasdaq. As of the date hereof, the Company has not received any notification that, and has no knowledge that, the SEC (as defined below) or Nasdaq is contemplating terminating such listing.

2.6. Valid Issuance. The Shares, when issued, sold and delivered in accordance with the terms and for the consideration set forth in this Agreement, will be validly issued, fully paid and non-assessable and free of Encumbrances and restrictions on transfer (other than the restrictions on transfer expressly set forth in this Agreement, the restrictions on transfer generally applicable under applicable state and federal securities laws, and liens or encumbrances created by or imposed by the Purchaser). Assuming the accuracy of the representations and warranties of the Purchaser contained in Section 3, subject to the consents, approvals and filings described in Section 2.3, the Shares will be issued in compliance with all applicable federal and state securities laws and the issuance and sale thereof is exempt from the registration and prospectus delivery requirements of the Securities Act. Without limiting the foregoing, neither the Company nor, to the knowledge of the Company, any other person that the Company authorizes to act on its behalf, has engaged in a general solicitation or general advertising (within the meaning of Regulation D of the Securities Act) of investors with respect to offers or sales of the Common Stock and neither the Company nor, to the knowledge of the Company, any person acting on the Company's behalf has made any offers or sales of any security or solicited any offers to buy any security, under circumstances that would cause the offering or issuance of Common Stock under this Agreement to be integrated with prior offerings by the Company for purposes of the Securities Act that would result in no exemption from registration under the Securities Act being available, nor shall the Company take any action or steps that would cause the offering or issuance of the Common Stock under this Agreement to be integrated with other offerings such that no such exemption is available. No "bad actor" disqualifying event described in Rule 506(d)(1)(i)-(viii) of the Securities Act (a "Disqualification Event") is applicable to the Company or, to the Company's knowledge, any Company Covered Person (as defined below), except for a Disqualification Event as to which Rule 506(d)(2)(ii–iv) or (d)(3) is applicable. "Company Covered Person" means, with respect to the Company as an "issuer" for purposes of Rule 506 promulgated under the Securities Act, any Person listed in the first paragraph of Rule 506(d)(1).

2.7. SEC Documents; Financial Statements; Internal Controls and Procedures.

(a) The Company has filed or furnished all forms, documents and reports required to be filed or furnished by it with the Securities and Exchange Commission (the "**SEC**") on a timely basis since January 1, 2018 (together with any documents so filed or furnished during such period on a voluntary basis, in each case as may have been amended, the "**SEC Documents**"). Each of the SEC Documents complied as to form in all material respects with the applicable requirements of applicable Law, including the Securities Act, the Exchange Act and the Sarbanes-Oxley Act. As of the date filed or furnished with the SEC, or as of the date amended, in the case of such filings which have been amended, none of the SEC Documents contained any untrue statement of a material fact or omitted to state any material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading. There are no material outstanding or unresolved comments received from the SEC with respect to any of the SEC Documents.

(b) The consolidated financial statements (including all related notes and schedules) of the Company included in the SEC Documents, fairly presented in accordance with GAAP the consolidated financial position of the Company and its consolidated Subsidiaries, as at the respective dates thereof, and the consolidated results of their operations, their consolidated cash flows and changes in stockholders' equity for the respective periods then ended and were prepared in all material respects in conformity with GAAP (except, in the case of the unaudited financial statements, for the absence of footnotes) applied on a consistent basis during the periods referred to therein (except as may be expressly indicated therein or in the notes thereto). Since January 1, 2018, subject to any applicable grace periods, the Company has been and is in compliance in all material respects with the applicable provisions of the Sarbanes-Oxley Act and the applicable rules and regulations of Nasdaq.

(c) The Company has designed and maintains disclosure controls and procedures and internal control over financial reporting (as such terms are defined in paragraphs (e) and (f), respectively, of Rule 13a-15 under the Exchange Act) as required by Rule 13a-15 under the Exchange Act and as necessary to permit preparation of financial statements in conformity with GAAP. The Company's disclosure controls and procedures are reasonably designed to ensure that all information required to be disclosed by the Company in the reports that it files or furnishes under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC, and that all such information is accumulated and communicated to the Company's principal executive officer and its principal financial officer by others in the Company or its Subsidiaries to allow timely decisions regarding required disclosure and to make the certifications required pursuant to Sections 302 and 906 of the Sarbanes-Oxley Act. The Company has disclosed, based on its most recent evaluation prior to the date hereof, to the Company's auditors and the audit committee of the Company's board of directors (i) any material weaknesses in its internal control over financial reporting and (ii) any allegation of fraud that involves management of the Company or any other employees of the Company and its Subsidiaries who have a significant role in the Company's internal control over financial reporting or disclosure controls and procedures. Since January 1, 2018, neither the Company nor any of its Subsidiaries has received any written complaint, allegation, assertion or claim regarding the accounting or auditing practices, procedures, methodologies or methods of the Company or its Subsidiaries or their respective internal accounting controls. As of the date of this

Agreement, to the knowledge of the Company, there is no reason that its outside auditors and its chief executive officer and chief financial officer will not be able to give the certifications and attestations required pursuant to the rules and regulations adopted pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, without qualification, when next due.

2.8. Regulation M Compliance. Since January 1, 2018, the Company has not, and to its knowledge no one acting on its behalf has, (a) taken, directly or indirectly, any action designed to cause or to result in the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of any of the Shares, (b) sold, bid for, purchased, or paid any compensation for soliciting purchases of, any of the Shares, or (c) paid or agreed to pay to any Person any compensation for soliciting another to purchase any other securities of the Company.

2.9. Full Disclosure. Other than the transactions that are the subject of this Agreement and the Collaboration Agreement (which may or may not be material), as of the date hereof, no fact or circumstance exists that would be required to be disclosed publicly pursuant to applicable Law, including in a current report on Form 8-K or in a registration statement filed under the Securities Act (were such a registration statement filed on the date hereof), that has not been disclosed in an SEC Document filed on or after January 1, 2019.

2.10. Capitalization.

(a) As of December 19, 2019 (the "**Measurement Time**"), the authorized capital stock of the Company consists of 99,000,000 shares of Common Stock and 3,333,333 shares of Preferred Stock. As of the Measurement Time, there were 75,211,796 shares of Common Stock outstanding and outstanding awards to purchase 8,970,251 shares of Common Stock under various incentive stock plans. Since the Measurement Time, the Company has not issued any shares of Common Stock (or securities convertible into, or exchangeable or exercisable therefor) other than shares duly issued pursuant to outstanding awards in accordance with the terms of the Company's incentive stock plans. As of the date hereof, there are no shares of Preferred Stock outstanding.

(i) Additionally, as of the Measurement Time, there were 3,416,917 shares of Common Stock available for future issuance under the Company's 2018 Equity Incentive Plan, 571,180 shares of Common Stock available for issuance under the Company's Amended and Restated 2013 Employee Stock Purchase Plan, and 567,935 shares of Common Stock available for issuance under the Company's 2014 Employment Commencement Incentive Plan.

(ii) Sarepta does not have any shares in its treasury.

(b) All of the issued and outstanding shares of Common Stock have been duly authorized and validly issued and are fully paid, nonassessable and free of preemptive rights. The Company does not have outstanding shareholder purchase rights or "poison pill" or any similar arrangement in effect, and no antitakeover, control share acquisition, fair price, moratorium or other antitakeover Law applies or purports to apply to this Agreement or the transactions contemplated hereby.

(c) The Company directly or indirectly owns 100% of the equity securities of Sarepta Therapeutics Three, LLC ("**Sarepta III**").

(d) Other than as described in the following sentence, no bonds, debentures, notes or other indebtedness having the right to vote (or convertible into or exchangeable for securities having the right to vote) on any matters on which the stockholders of the Company or any of its Subsidiaries may vote ("**Voting Debt**") are issued and outstanding. On November 14, 2017, the Company issued $570.0 million senior notes due on November 15, 2024 (the "**2024 Notes**"). The 2024 Notes were issued at face value and bear interest at the rate of 1.50% per annum, payable semi-annually in cash on each May 15 and November 15, commencing on May 15, 2018. Upon conversion, the Company may pay cash, shares of its Common Stock or a combination of cash and stock, as determined by the Company in its discretion. The 2024 Notes may be convertible into 7,763,552 shares of the Company's Common Stock under certain circumstances prior to maturity at a conversion rate of 13.621 shares per $1,000 principal amount of the 2024 Notes, which represents a conversion price of $73.42 per share, subject to adjustment under certain conditions. Except as set forth above, neither the Company nor any of its Subsidiaries (including Sarepta III) have or are bound by any outstanding equity securities or any options, preemptive rights, rights of first offer, warrants, calls (except for the Company's capped call transactions with J.P. Morgan and Goldman Sachs (as publicly disclosed as of the date hereof in the SEC Documents), commitments or other rights or agreements calling for the purchase or issuance of, or securities or rights convertible into, or exchangeable for, any shares of Common Stock or any other equity securities of the Company or Sarepta III or Voting Debt or any securities representing the right to purchase or otherwise receive any shares of capital stock or equity securities, as applicable, of the Company or Sarepta III (including any rights plan or agreement).

2.11. Litigation. As of the date hereof, there is no action, suit, proceeding, audit, investigation or Order pending, threatened in writing or, to the knowledge of the Company, threatened orally that seeks to or has the effect of enjoining, prohibiting, materially impairing or materially delaying the consummation of the transactions contemplated hereby against the Company or any of its Subsidiaries or any of their respective assets before or by any Governmental Entity.

2.12. Taxes. The Company is not a "U.S. real property holding corporation" within the meaning of Section 897 of the Internal Revenue Code of 1986, as amended.

2.13. Collaboration Agreement Representations. The Company hereby makes the representations and warranties of Sarepta III in Section 11.2 of the Collaboration Agreement (for the avoidance of doubt, solely as of the date hereof).

2.14. CFIUS. The collaboration between the Parties (and/or their Affiliates) contemplated by the Collaboration Agreement does not involve the production, design, testing, manufacture, fabrication or development of any "critical technologies" as that term is defined in 31 C.F.R. §801.204.

Section 3. Representations and Warranties of the Purchaser. The Purchaser hereby represents and warrants to the Company that the following representations and warranties are true and complete as of the date hereof and as of the Closing:

3.1. Organization. The Purchaser is an entity duly organized, validly existing and in good standing under the Laws of its jurisdiction of formation, and has the requisite power and authority to carry on its business as it is now being conducted. The Purchaser is duly qualified and licensed as a foreign corporation to do business, and is in good standing in each jurisdiction in which the character of its assets owned or held under lease or the nature of its business makes such qualification necessary, except where the failure so to qualify or be licensed would not, individually or in the aggregate, have a Material Adverse Effect on Purchaser.

3.2. Authorization. The Purchaser has the requisite power and authority to enter into this Agreement and to consummate the transactions contemplated hereby. The execution and delivery by the Purchaser of this Agreement and the compliance by the Purchaser with each of the provisions of this Agreement (including the consummation by the Purchaser of the transactions contemplated hereby) (a) are within the requisite power and authority of the Purchaser and (b) have been duly authorized by all necessary action on the part of the Purchaser. This Agreement has been duly and validly executed and delivered by the Purchaser. Assuming due authorization, execution and delivery by the Company of this Agreement, this Agreement will constitute a valid and binding agreement of the Purchaser enforceable against the Purchaser in accordance with its terms, except to the extent such enforcement is limited by (i) any applicable bankruptcy, insolvency and other similar Laws affecting the enforcement of creditors' rights generally and (ii) general principles of equity, including the possible unavailability of specific performance or injunctive relief or other equitable remedies.

3.3. No Conflicts; Consents and Approvals; No Violation. Neither the execution, delivery or performance by the Purchaser of this Agreement nor the consummation of the transactions contemplated hereby will (a) result in a breach or a violation of, any provision of the articles of incorporation, bylaws or other organizational documents of the Purchaser or of the articles of incorporation, bylaws or other organizational documents of any of its Subsidiaries; (b) constitute, with or without notice or the passage of time or both, a breach, violation or default, create an Encumbrance, or give rise to any right of termination, modification, cancellation, prepayment, suspension, limitation, revocation or acceleration, under (i) any Law applicable to the Purchaser, or (ii) any provision of any agreement or other instrument to which the Purchaser is a Party or pursuant to which the Purchaser or its assets or properties is subject, except for, in the case of each clause (i) and (ii), breaches, violations, defaults, Encumbrances, or rights of termination, modification, cancellation, prepayment, suspension, limitation, revocation or acceleration, which, individually or in the aggregate, would not materially adversely affect the ability of the Purchaser to perform its obligations under this Agreement or to consummate the transactions contemplated hereby; or (c) require any Consents, Approvals and Filings on the part of the Purchaser, except for (A) the Consents, Approvals and Filings required under the Exchange Act and applicable state securities Laws, (B) competition filings, notices and clearances and (C) such other Consents, Approvals and Filings which the failure of the Purchaser to make or obtain would not materially adversely affect the ability of the Purchaser to perform its obligations under this Agreement or to consummate the transactions contemplated hereby.

3.4. Broker's Fee. No agent, broker, investment banker or other Person is or will be entitled to any broker's or finder's fee or any other commission or similar fee from the Purchaser in connection with the transactions contemplated by this Agreement to occur at the Closing for which the Purchaser or any Affiliate might be liable.

3.5. Litigation. As of the date hereof, there is no action, suit, proceeding, audit, investigation or Order pending, threatened in writing or, to the knowledge of the Purchaser, threatened orally that seeks to or has the effect of enjoining, prohibiting, materially impairing or materially delaying the consummation of the transactions contemplated hereby against the Purchaser or any of its Subsidiaries or any of their respective assets before or by any Governmental Entity.

3.6. Securities Law Matters.

(a) The Purchaser is acquiring the Shares for its own account, for investment and not with a view to, or for sale in connection with, the distribution thereof within the meaning of the Securities Act.

(b) The Purchaser is an "accredited investor," as that term is as defined in Rule 501(a) of Regulation D under the Securities Act. The Purchaser has sufficient knowledge and experience in financial and business matters to be capable of evaluating the merits and risks of its investment in the Shares and is capable of bearing the economic risks of such investment.

(c) The Purchaser and its advisers have been furnished with all materials relating to the business, finances and operations of the Company, its Subsidiaries and materials relating to the offer and sale of the Shares that have been requested by the Purchaser or its advisers. The Purchaser and its advisers have been afforded the opportunity to ask questions of the Company's management concerning the Company and the Shares.

(d) The Purchaser understands that the sale or re-sale of the Shares has not been and is not being registered under the Securities Act or any applicable state securities laws, and the Shares may not be offered, sold or otherwise transferred unless (i) the Shares are offered, sold or transferred pursuant to an effective registration statement under the Securities Act, or (ii) the Shares are offered, sold or transferred pursuant to an exemption from registration under the Securities Act and any applicable state securities laws.

(e) Neither the Purchaser, nor any of its officers, directors, employees, agents, stockholders or partners has either directly or indirectly, including, through a broker or finder engaged in any general solicitation or published any advertisement in connection with the offer and sale of the Shares.

(f) The principal office of the Purchaser is located at the address set forth on the Purchaser's signature page hereto.

Section 4. Transfer or Resale Restrictions; Legends; Covenants.

4.1. Agreement to Hold Shares. The Purchaser will not, from the date hereof until the 181st day following the Closing Date (a) lend; offer; pledge; sell; contract to sell; sell any option or contract to purchase; purchase any option or contract to sell; grant any option, right, or warrant to purchase; or otherwise transfer or dispose of, directly or indirectly, any Shares or (b) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the Shares, whether any such transaction described in clause (a) or (b) above is to be settled by delivery of Shares, in cash, or otherwise. Notwithstanding the foregoing or anything else in this Agreement, the Purchaser and its Affiliates may sell or otherwise transfer any or all of the Shares to any Affiliate of the Purchaser.

4.2. Legends. The Purchaser understands that the Shares may be notated with one or all of the following legends:

(a) "THE SHARES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AND HAVE BEEN ACQUIRED FOR INVESTMENT AND NOT WITH A VIEW TO, OR IN CONNECTION WITH, THE SALE OR DISTRIBUTION THEREOF. NO SUCH TRANSFER MAY BE EFFECTED WITHOUT AN EFFECTIVE REGISTRATION STATEMENT RELATED THERETO OR AN OPINION OF COUNSEL IN A FORM SATISFACTORY TO THE COMPANY THAT SUCH REGISTRATION IS NOT REQUIRED UNDER THE SECURITIES ACT OF 1933."; or

(b) "THE SALE, PLEDGE, HYPOTHECATION OR TRANSFER OF THESE SECURITIES IS SUBJECT TO THE TERMS AND CONDITIONS OF A STOCK PURCHASE AGREEMENT DATED DECEMBER 21, 2019 BETWEEN SAREPTA THERAPEUTICS, INC. AND ROCHE FINANCE LTD"; or

(c) Any legend required by the securities Laws of any state to the extent such Laws are applicable to the Shares represented by the certificate, instrument, or book entry so legended.

4.3. Cooperation. The Company (and any successor issuer) agrees to use commercially reasonable efforts to cooperate in connection with any attempt by the Purchaser or any of its Affiliates to sell or otherwise dispose of the Shares or other securities of the Company (or any successor issuer) pursuant to Rule 144 and any other rule or regulation of the SEC that may at any time permit a holder of such securities to sell such securities to the public without registration (collectively, an "Available Exemption"). Such commercially reasonable efforts shall include:

(a) making and keeping available adequate current public information, as those terms are understood and defined in such Available Exemption, at all times;

(b) filing with the SEC in a timely manner all reports and other documents required under the Securities Act and the Exchange Act; and

(c) furnishing to the Purchaser and its Affiliates, promptly upon request: (i) a written statement by the Company (or any successor issuer) that it has complied with the reporting requirements of the Securities Act and the Exchange Act, or that it qualifies as a registrant whose securities may be resold pursuant to Form S-3; and (ii) such other information as may be reasonably requested in connection with an Available Exemption, including, if reasonably necessary for the Purchaser or any of its Affiliates to consummate a sale pursuant to an Available Exemption, legal opinions to remove any restrictive legends or stop transfer orders on the Shares as may be reasonably requested by the Purchaser and its Affiliates (as if such transfer were being consummated pursuant to an underwritten offering).

4.4. Covenants. Until the Closing, the Company shall not (without the prior written consent of the Purchaser, not to be unreasonably withheld):

(a) (x) split, combine or reclassify any shares, or propose to split, combine or reclassify any of its share capital, or issue or authorize or propose the issuance or authorization of any other securities in respect of, or in lieu of or in substitution for, shares of its share capital, or (y) declare, or make payment in respect of, any dividend or other distribution upon any shares of capital stock of the Company;

(b) redeem, repurchase or acquire any capital stock of the Company or any of its Subsidiaries, other than repurchases of capital stock from employees, officers or directors of the Company or any of its Subsidiaries in the ordinary course of business pursuant to any of the Company's agreements or plans in effect as of the date of this Agreement; or

(c) amend its governing documents in a manner that would be adverse to the Purchaser.

Section 5. Conditions to Closing.

5.1. Conditions to Obligations of the Parties. The Parties' respective obligations to complete the purchase and sale of the Shares and deliver the Shares to the Purchaser is subject to the fulfillment or waiver of the following conditions at or prior to the Closing:

(a) Effective Date. The Effective Date (as defined in the Collaboration Agreement) shall have occurred.

(b) Collaboration Agreement. The Collaboration Agreement shall remain in full force and effect, binding on the parties thereto.

Section 6. Termination.

6.1. Automatic Termination of Agreement. If the Collaboration Agreement is terminated at any time prior to the Closing, then this Agreement will automatically terminate as of the effective date of termination of the Collaboration Agreement.

6.2. Effect of Termination. In the event of the termination of this Agreement pursuant to Section 6.1 hereof, this Agreement (except for this Section 6.2 and Section 7 (other than Section 7.1), and any definitions set forth in this Agreement and used in such sections) will forthwith become void and have no effect, without any liability on the part of any Party hereto or its Affiliates; *provided*, *however*, that nothing contained in this Section 6.2 will relieve any Party from liability for fraud or any intentional or willful breach of this Agreement.

Section 7. Miscellaneous.

7.1. Survival of Warranties. The representations and warranties of the Parties contained in this Agreement shall survive the Closing for six years. The covenants, agreements and obligations of the Parties contained in this Agreement shall survive the Closing until the applicable statute of limitations, recognizing any tolling period. Notwithstanding the preceding two sentences, any breach of a representation, warranty, covenant or agreement shall survive the time at which it would otherwise terminate if notice of such breach shall have been given to the breaching Party prior to such time.

7.2. Successors and Assigns. The terms and conditions of this Agreement will inure to the benefit of and be binding upon the respective successors and assigns of the Parties. No Party may assign, delegate or otherwise transfer any of its rights or obligations under this Agreement without the consent of the other Party, except that the Purchaser may transfer or assign its rights and obligations under this Agreement, in whole in part or from time to time in part, to one or more of its Affiliates at any time; *provided* that such transfer or assignment shall not relieve the Purchaser of its obligations hereunder. Nothing in this Agreement, express or implied, is intended to confer upon any Party other than the Parties hereto or their respective successors and assigns any rights, remedies, obligations or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement.

7.3. Governing Law. This Agreement and all claims or causes of action (whether in tort, contract or otherwise) that may be based upon, arise out of or relate to this Agreement or the negotiation, execution or performance of this Agreement (including any claim or cause of action based upon, arising out of or related to any representation or warranty made in or in connection with this Agreement) will be governed by and construed in accordance with the Laws of the State of New York, without giving effect to any choice or conflict of law provision or rule (whether of the State of New York or any other jurisdiction) that would cause the application of the Laws of any jurisdiction other than the State of New York.

7.4. Titles and Subtitles. The titles and subtitles used in this Agreement are used for convenience only and are not to be considered in construing or interpreting this Agreement.

7.5. Notices. Section 17.5 of the Collaboration Agreement is hereby incorporated by reference, *mutatis mutandis*; *provided* that, any notice to the Purchaser shall also be sent to:

	Roche Finance Ltd Grenzacherstrasse 122 4070 Basel, Switzerland Attn: Roche Venture Fund, Carole Nuechterlein Fax: [**]
With a simultaneous copy (which shall not constitute notice) to:	F. Hoffmann-La Roche Ltd Group Legal Department Grenzacherstrasse 124 CH-4070 Basel, Switzerland Attention: Dr. Beat Kraehenmann Fax: [**]

7.6. Expenses. Each Party will pay its own expenses incurred in connection with the preparation, negotiation, execution, delivery, and performance of this Agreement and the consummation of the transactions contemplated hereby.

7.7. Waiver. Waiver by the Company or the Purchaser of a breach hereunder by the Purchaser or the Company, respectively, will not be construed as a waiver of any subsequent breach of the same or any other provision. No delay or omission by a Party in exercising or availing itself of any right, power or privilege hereunder will preclude the later exercise of any such right, power or privilege by such Party. No waiver will be effective unless made in writing with specific reference to the relevant provision(s) of this Agreement and signed by a duly authorized representative of the Party granting the waiver. All remedies, either under this Agreement or by law or otherwise afforded to any Party, will be cumulative and not alternative.

7.8. Amendments. Any term of this Agreement may be amended or terminated only with the written consent of the Company and the Purchaser.

7.9. Severability. The invalidity or unenforceability of any provision hereof will in no way affect the validity or enforceability of any other provision.

7.10. Entire Agreement. This Agreement and the Collaboration Agreement constitute the full and entire understanding and agreement between the Parties with respect to the subject matter hereof and thereof, and any other written or oral agreement relating to the subject matter hereof or thereof existing among the Parties are expressly canceled.

7.11. Exclusive Jurisdiction; Venue. Each of the Parties hereto irrevocably agrees that any legal action or proceeding with respect to this Agreement and the rights and obligations arising hereunder, or for recognition and enforcement of any judgment in respect of this Agreement and the rights and obligations arising hereunder brought by another Party hereto or its successors or assigns, will be brought and determined exclusively in (a) the state courts of the State of New York in Manhattan, New York, or (b) the United States District Court for the Southern District of New York. Each of the Parties hereto hereby irrevocably submits with regard to any such action or proceeding for itself and in respect of its property, generally and unconditionally, to the personal jurisdiction of the aforesaid courts and agrees that it will not bring any action relating to

this Agreement or any of the transactions contemplated by this Agreement in any court other than the aforesaid courts. Each of the Parties hereto hereby irrevocably waives, and agrees not to assert as a defense, counterclaim or otherwise, in any action or proceeding with respect to this Agreement, (a) any claim that it is not personally subject to the jurisdiction of the above named courts for any reason other than the failure to serve in accordance with this Section 7.11, (b) any claim that it or its property is exempt or immune from the jurisdiction of any such court or from any legal process commenced in such courts (whether through service of notice, attachment prior to judgment, attachment in aid of execution of judgment, execution of judgment or otherwise) and (c) to the fullest extent permitted by the applicable Law, any claim that (i) the suit, action or proceeding in such court is brought in an inconvenient forum, (ii) the venue of such suit, action or proceeding is improper or (iii) this Agreement, or the subject matter hereof, may not be enforced in or by such courts. Each of the Parties hereto agrees that service of process upon such Party in any such action or proceeding will be effective if such process is given as a notice in accordance with Section 7.5.

7.12. Waiver of Jury Trial. EACH OF THE PARTIES TO THIS AGREEMENT HEREBY IRREVOCABLY WAIVES TO THE EXTENT PERMITTED BY APPLICABLE LAW ANY AND ALL RIGHT TO A TRIAL BY JURY IN ANY DIRECT OR INDIRECT ACTION, PROCEEDING OR COUNTERCLAIM ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY. EACH PARTY (A) CERTIFIES THAT NO REPRESENTATIVE, AGENT OR ATTORNEY OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER, (B) MAKES THIS WAIVER VOLUNTARILY, AND (C) ACKNOWLEDGES THAT EACH PARTY HAS BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS CONTAINED IN THIS SECTION 7.12.

7.13. Counterparts. This Agreement may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail or other transmission method and any counterpart so delivered will be deemed to have been duly and validly delivered and be valid and effective for all purposes. This Agreement shall become effective when each Party shall have received a counterpart hereof signed by the other Party. Until and unless each Party has received a counterpart signed by the other Party, this Agreement shall have no effect and no Party shall have any right or obligation hereunder (whether by virtue of any other oral or written agreement or communication or otherwise).

7.14. Specific Performance. The Parties agree that irreparable damage would occur if any provision of this Agreement were not performed in accordance with the terms hereof and that, prior to the valid termination of this Agreement in accordance with the terms hereof, the Parties shall be entitled (without posting of any bond) to an injunction or injunctions to prevent breaches of this Agreement or to enforce specifically the performance of the terms and provisions hereof in the courts referred to in Section 7.11, in addition to any other remedy to which they are entitled at law or in equity.

[*Remainder of page intentionally left blank*]

IN WITNESS WHEREOF, the Parties have executed this Stock Purchase Agreement as of the date first written above.

COMPANY:

SAREPTA THERAPEUTICS, INC.

By: /s/ Douglas S. Ingram

Name: Douglas S. Ingram

Title: President and CEO

IN WITNESS WHEREOF, the Parties have executed this Stock Purchase Agreement as of the date first written above.

PURCHASER:

ROCHE FINANCE LTD

By: /s/ Carole Neuchterlein

Name: Carole Neuchterlein

Title: Authorized Signatory

By: /s/ Felix Kobel

Name: Dr. Felix Kobel

Title: Attorney at Law

EXHIBIT 10.53

EXECUTION VERSION

LOAN AGREEMENT

Dated as of December 13, 2019

among

SAREPTA THERAPEUTICS, INC.

(as ***Borrower***),

THE GUARANTORS PARTY HERETO,

BIOPHARMA CREDIT PLC

(as ***Collateral Agent*** and a ***Lender***),

and

BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP

(as a ***Lender***)

LOAN AGREEMENT

THIS LOAN AGREEMENT (this "**Agreement**"), dated as of December 13, 2019 (the "**Effective Date**") by and among SAREPTA THERAPEUTICS, INC., a Delaware corporation (as "**Borrower**"), the Guarantors from time to time party hereto, BIOPHARMA CREDIT PLC, a public limited company incorporated under the laws of England and Wales (as the "**Collateral Agent**" and a "**Lender**") and BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP, a Cayman Islands exempted limited partnership (as a "**Lender**"), provides the terms on which each Lender shall make, and Borrower shall repay, the Credit Extensions (as hereinafter defined). The parties hereto agree as follows:

1. ACCOUNTING AND OTHER TERMS

Except as otherwise expressly provided herein, all accounting terms not otherwise defined in this Agreement shall have the meanings assigned to them in conformity with Applicable Accounting Standards. Calculations and determinations must be made following Applicable Accounting Standards. If at any time any change in Applicable Accounting Standards would affect the computation of any financial requirement set forth in any Loan Document, and either Borrower or the Collateral Agent shall so request, the Collateral Agent and Borrower shall negotiate in good faith to amend such requirement to preserve the original intent thereof in light of such change in Applicable Accounting Standards; provided, that, until so amended, such requirement shall continue to be computed in accordance with Applicable Accounting Standards prior to such change therein. Without limiting the foregoing, leases shall continue to be classified and accounted for on a basis consistent with that reflected in the audited consolidated financial statements of Borrower for the fiscal year ended December 31, 2018 for all purposes of this Agreement, notwithstanding any change in Applicable Accounting Standards relating thereto or the application thereof, unless Borrower and the Collateral Agent shall enter into a mutually acceptable amendment addressing such changes, as provided for above. Capitalized terms not otherwise defined in this Agreement shall have the meanings set forth in Section 13. All other terms contained in this Agreement, unless otherwise indicated, shall have the meaning provided by the Code to the extent such terms are defined therein. All references to "Dollars" or "$" are United States Dollars, unless otherwise noted.

For purposes of determining compliance with Section 6 with respect to the amount of any Indebtedness in a currency other than Dollars, no Default or Event of Default shall be deemed to have occurred solely as a result of changes in rates of currency exchange occurring after the time such Indebtedness is incurred, made or acquired (so long as such Indebtedness, at the time incurred, made or acquired, was permitted hereunder).

2. LOANS AND TERMS OF PAYMENT

2.1. **Promise to Pay.** Borrower hereby unconditionally promises to pay Lenders the outstanding principal amount of the Term Loans advanced to Borrower by Lenders and accrued and unpaid interest thereon and any other amounts due hereunder as and when due in accordance with this Agreement.

2.2. Term Loans.

(a) Availability. Subject to the terms and conditions of this Agreement (including Sections 3.1 (in the case of the Tranche A Loan), 3.2 (in the case of the Tranche B Loan), 3.3 and 3.5):

(i) Each Lender severally agrees to make a term loan to Borrower on the Tranche A Closing Date in an original principal amount equal to such Lender's Tranche A Loan Commitment (collectively, the "**Tranche A Loan**"); and

(ii) At Borrower's election pursuant to Section 3.5, each Lender severally agrees to make a term loan to Borrower on the Tranche B Closing Date in an original principal amount equal to such Lender's Applicable Percentage of the Tranche B Loan Amount requested by the Borrower (collectively, the "**Tranche B Loan**").

After repayment or prepayment (in whole or in part), no Term Loan (or any portion thereof) may be re-borrowed.

(b) Repayment. All unpaid principal (including accrued and capitalized PIK Interest) with respect to the Term Loans (and, for the avoidance of doubt, all accrued, unpaid and uncapitalized interest, all due and unpaid Lender Expenses and any and all other amounts payable under the Loan Documents) is due and payable in full on the Term Loan Maturity Date. The Term Loans may be prepaid only in accordance with Section 2.2(c), except as provided in Section 8.1.

(c) Prepayment of Term Loans.

(i) Borrower shall have the option, at any time after the Tranche A Closing Date, to prepay, in whole or in part (in multiples of not less than $5,000,000 or such lesser amount as may then be outstanding), the Tranche A Loan or the Tranche B Loan advanced by Lenders under this Agreement; provided that (A) Borrower provides written notice to the Collateral Agent of its election (which shall be irrevocable unless the Collateral Agent otherwise consents in writing; provided that such notice of proposed prepayment may be revoked or modified in connection with a prepayment of Term Loans at any time on or prior to the date of prepayment if such prepayment is contingent, and notice of such contingency has been provided pursuant to this sentence, on the consummation of a refinancing or other specified transaction that does not close on the originally anticipated closing date) to prepay all or the applicable portion of the Term Loans, which such notice shall include the amount of the Tranche A Loan or the amount of the Tranche B Loan to be prepaid, at least five (5) Business Days prior to such prepayment, and (B) such prepayment shall be accompanied by any and all accrued, unpaid and uncapitalized interest on the aggregate principal amount (including accrued and capitalized PIK Interest) to be prepaid to the date of prepayment and any applicable amounts payable solely with respect to the prepayment of such principal amount under this Section 2.2(c)(i) pursuant to Section 2.2(e), Section 2.2(f) or Section 2.7(b) and, in the case of a prepayment in whole of the Term Loans, all other amounts payable or accrued and not yet paid (or capitalized) under this Agreement and the other Loan Documents; provided, further, that any prepayment pursuant to this Section 2.2(c)(i) shall be applied first to the Tranche A Loan and then to the Tranche B Loan as described in Section 2.2(d) below. The Collateral Agent will promptly notify each Lender of its receipt of such notice, and the amount of such Lender's Applicable Percentage of such prepayment.

(ii) Upon a Change in Control, Borrower shall promptly, and in any event no later than ten (10) days after the consummation of such Change in Control, notify the Collateral Agent in writing of the occurrence of a Change in Control, which notice shall include reasonable detail as to the nature, timing and other circumstances of such Change in Control (such notice, a "**Change in Control Notice**"). Borrower shall prepay in full all of the Term Loans advanced by Lenders under this Agreement, no later than ten (10) Business Days after delivery to the Collateral Agent of the Change in Control Notice, in an amount equal to the sum of (A) all unpaid principal (including accrued and capitalized PIK Interest) and any and all accrued, unpaid and uncapitalized interest with respect to the Term Loans (or such remaining outstanding portion thereof), and (B) any applicable amounts payable solely with respect to the prepayment of such principal under this Section 2.2(c)(ii) pursuant to Section 2.2(e), Section 2.2(f) and Section 2.7(b) and all other amounts payable or accrued and not yet paid (or capitalized) under this Agreement and the other Loan Documents. The Collateral Agent will promptly notify each Lender of its receipt of the Change in Control Notice, and the amount of such Lender's Applicable Percentage of such prepayment.

(d) Prepayment Application. Any prepayment of the Term Loans pursuant to Section 2.2(c) (together with the accompanying Makewhole Amount, Prepayment Premium or Additional Loan Consideration that is payable pursuant to Section 2.2(e), Section 2.2(f) or Section 2.7(b), as applicable) shall be paid to Lenders in accordance with their respective Applicable Percentages for application to the Obligations in the following order: (i) first, to due and unpaid Lender Expenses; (ii) second, to accrued, unpaid and uncapitalized interest at the Default Rate incurred pursuant to Section 2.3(b), if any; (iii) third, without duplication of amounts paid pursuant to clause (ii) above, to accrued, unpaid and uncapitalized interest at the Term Loan Rate; (iv) fourth, to the Additional Loan Consideration; (v) fifth, to the Prepayment Premium; (vi) sixth, to the Makewhole Amount, if applicable; (vii) seventh, to the outstanding principal amount (including accrued and capitalized PIK Interest) of the Tranche A Loan or Tranche B Loan being prepaid (which, in the case of any partial prepayment pursuant to Section 2.2(c)(i), shall be applied first to reduce the principal amount of the Tranche A Loan and then to reduce the principal of the Tranche B Loan); and (viii) eighth, in the case of a prepayment of the Term Loans in whole, to any remaining amounts then due and payable under this Agreement and the other Loan Documents.

(e) Makewhole Amount.

(i) Any prepayment of the Tranche A Loan by Borrower (A) pursuant to Section 2.2(c)(i) or Section 2.2(c)(ii), or (B) as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a), in each case occurring prior to the 2nd-year anniversary of the Tranche A Closing Date shall, in any such case, be accompanied by payment of an amount equal to the Tranche A Makewhole Amount.

(ii) Any prepayment of the Tranche B Loan by Borrower (A) pursuant to Section 2.2(c)(i) or Section 2.2(c)(ii), or (B) as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a), in each case occurring prior to the 2nd-year anniversary of the Tranche B Closing Date shall, in any such case, be accompanied by payment of an amount equal to the Tranche B Makewhole Amount.

(f) Prepayment Premium.

(i) Any prepayment of the Tranche A Loan by Borrower (A) pursuant to Section 2.2(c)(i) or Section 2.2(c)(ii), or (B) as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a), shall, in any such case, be accompanied by payment of an amount equal to the Tranche A Prepayment Premium.

(ii) Any prepayment of the Tranche B Loan by Borrower (A) pursuant to Section 2.2(c)(i) or Section 2.2(c)(ii), or (B) as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a), shall, in any such case, be accompanied by payment of an amount equal to the Tranche B Prepayment Premium.

2.3. Payment of Interest on the Credit Extensions.

(a) Interest Rate.

(i) Subject to Section 2.3(b), the principal amount outstanding under each Term Loan shall accrue interest at a per annum rate equal to eight and one-half percent (8.50%) per annum (the "**Term Loan Rate**"), which interest shall be payable quarterly in arrears in accordance with this Section 2.3.

(ii) Interest shall accrue on each Term Loan commencing on, and including, the day on which such Term Loan is made, and shall accrue on such Term Loan, or any portion thereof, for the day on which such Term Loan or such portion is paid.

(iii) Notwithstanding the foregoing, fifty percent (50.0%) of the interest on the Tranche A Loan payable during the first twelve (12) months following the Tranche A Closing hereunder may be paid-in-kind (the "**PIK Interest**") at the election of Borrower in its discretion on any applicable Interest Date (which PIK Interest shall be capitalized on each such applicable Interest Date and such capitalized amount shall be added to the then outstanding principal amount of the Tranche A Loan and constitute outstanding principal for all purposes hereof); provided that, Borrower shall deliver to the Collateral Agent notice (which notice shall be irrevocable) of such election no later than two (2) Business Days prior to any such applicable Interest Date.

(b) Default Rate. In the event Borrower fails to pay any of the Obligations when due, immediately (and without notice to any Credit Party or demand by the Collateral Agent or any Lender for payment therefor), such past due Obligations shall bear interest at a rate per annum which is two percentage points (2.00%) above the rate that is otherwise applicable thereto (the "**Default Rate**"), and such interest shall be payable entirely in cash on demand of the Collateral Agent. Payment or acceptance of the increased interest rate provided in this Section 2.3(b) is not a permitted alternative to timely payment and shall not constitute a waiver of any Event of Default or otherwise prejudice or limit any rights or remedies of the Collateral Agent or any Lender.

(c) 360-Day Year. Interest shall be computed on the basis of a year of 360 days and the actual number of days elapsed.

(d) Payments. Except as otherwise expressly provided herein, all loan payments and any other payments hereunder by (or on behalf of) Borrower hereunder shall be made on the date specified herein to the bank account of each Lender as such Lender (or the Collateral Agent on its behalf) shall have designated in a written notice to Borrower delivered on or before the Tranche A Closing Date (which such notice may be updated by such Lender (or the Collateral Agent) from time to time after the Tranche A Closing Date). Except as otherwise expressly provided herein, interest is payable quarterly on the Interest Date of each calendar quarter. Payments of principal or interest received after 2:00 p.m. on such date are considered received at the opening of business on the next Business Day. When any payment is due on a day that is not a Business Day, such payment is due the immediately next Business Day and additional fees or interest, as applicable, shall continue to accrue until paid. All payments to be made by Borrower hereunder or under any other Loan Document, including payments of principal and interest made hereunder and pursuant to any other Loan Document, and all fees, expenses, indemnities and reimbursements, shall be made without set-off, recoupment or counterclaim, in lawful money of the United States and in immediately available funds.

2.4. Expenses. Borrower shall pay to or reimburse (or pay directly on behalf of) each Lender and the Collateral Agent, as applicable, all of such Person's Lender Expenses incurred through and after the Effective Date, within thirty (30) days (or such shorter period as expressly provided below) after receipt of a written demand therefor by such Lender or the Collateral Agent (with, in the case of any Lender, a copy of such demand to the Collateral Agent), setting forth in reasonable detail such Person's Lender Expenses; provided, however, that for purposes of this Section 2.4 and solely in the case of satisfying the conditions precedent in Sections 3.1(k) and 3.2(d), as applicable, the parties hereto agree that the funds flow memo prepared and delivered by the Collateral Agent on or before the Tranche A Closing Date or Tranche B Closing Date, as the case may be, for attachment to the Payment/Advance Request for each Term Loan shall constitute such written demand so long as reasonable detail of the Lender Expenses set forth therein are delivered to Borrower within two (2) Business Days following such Closing Date.

2.5. Requirements of Law; Increased Costs. In the event that any applicable Change in Law:

(a) Does or shall subject any Lender to any tax of any kind whatsoever with respect to this Agreement or the Term Loans made hereunder (except, in each case, Indemnified Taxes, Taxes described in clause (b) through (d) of the definition of Excluded Taxes, and Connection Income Taxes);

(b) Does or shall impose, modify or hold applicable any reserve, capital requirement, special deposit, compulsory loan or similar requirements against assets held by, or deposits or other liabilities in or for the account of, advances or loans by, or other credit extended by, or any other acquisition of funds by, any Lender; or

(c) Does or shall impose on any Lender any other condition (other than Taxes); and the result of any of the foregoing is to increase the cost to such Lender (as determined by such Lender in good faith using calculation methods customary in the industry) of making, renewing or maintaining the Term Loans or to reduce any amount receivable in respect thereof or to reduce the rate of return on the capital of such Lender or any Person controlling such Lender,

then, in any such case, Borrower shall promptly pay to the applicable Lender, within thirty (30) days of its receipt of the certificate described below, any additional amounts necessary to compensate such Lender for such additional cost or reduced amounts receivable or rate of return as reasonably determined by such Lender with respect to this Agreement or the Term Loans made hereunder; provided. that amounts shall only be payable by Borrower to such Lender under this Section 2.5 so long as it is such Lender's general policy and practice to demand compensation of its other borrowers in similar circumstances under comparable provisions of other financing agreements and, upon the request of Borrower, such Lender provides a certificate to such effect (with a copy of such certificate to the Collateral Agent). If any Lender becomes entitled to claim any additional amounts pursuant to this Section 2.5, it shall promptly notify Borrower in writing of the event by reason of which it has become so entitled (with a copy of such notice to the Collateral Agent), and a certificate as to any additional amounts payable pursuant to the foregoing sentence containing the calculation thereof in reasonable detail submitted by such Lender to Borrower (with a copy of such certificate to the Collateral Agent) shall be conclusive in the absence of manifest error. The provisions hereof shall survive the termination of this Agreement and the payment of the outstanding Term Loans and all other

Obligations. Failure or delay on the part of any Lender to demand compensation for any increased costs or reduction in amounts received or receivable or reduction in return on capital under this Section 2.5 shall not constitute a waiver of such Lender's right to demand such compensation; provided that Borrower shall not be under any obligation to compensate such Lender under this Section 2.5 with respect to increased costs or reductions with respect to any period prior to the date that is 180 days prior to the date of the delivery of the notice required pursuant to the foregoing provisions of this paragraph; provided, further, that if the Change in Law giving rise to such increased costs or reductions is retroactive, then the 180-day period referred to above shall be extended to include the period of retroactive effect thereof.

2.6. Taxes; Withholding, Etc.

(a) All sums payable by any Credit Party hereunder and under the other Loan Documents shall (except to the extent required by Requirements of Law) be paid free and clear of, and without any deduction or withholding on account of, any Tax imposed, levied, collected, withheld or assessed by any Governmental Authority. In addition, Borrower agrees to pay, and shall indemnify and hold each Lender harmless from, Other Taxes, and as soon as practicable after the date of paying such sum, Borrower shall furnish to each Lender (as applicable, with a copy to the Collateral Agent) the original or a certified copy of a receipt evidencing payment thereof or other evidence reasonably satisfactory to the Collateral Agent of such payment and of the remittance thereof to the relevant taxing or other Governmental Authority.

(b) If any Credit Party or any other Person ("**Withholding Agent**") is required by Requirements of Law to make any deduction or withholding on account of any Tax (as determined in the good faith discretion of such Withholding Agent) from any sum paid or payable by any Credit Party to any Lender under any of the Loan Documents: (i) such Withholding Agent shall notify such Lender in writing (with a copy to the Collateral Agent) of any such requirement or any change in any such requirement promptly after such Withholding Agent becomes aware of it; (ii) such Withholding Agent shall make any such withholding or deduction; (iii) such Withholding Agent shall pay any such Tax before the date on which penalties attach thereto in accordance with Requirements of Law; (iv) if the Tax is an Indemnified Tax, the sum payable by such Withholding Agent in respect of which the relevant deduction, withholding or payment of Indemnified Tax is required shall be increased to the extent necessary to ensure that, after the making of that deduction, withholding or payment (including any deductions for Indemnified Taxes applicable to additional sums payable under this Section 2.6(b)), such Lender receives on the due date a net sum equal to what it would have received had no such deduction, withholding or payment of Indemnified Tax been required or made; and (v) as soon as practicable after paying any sum from which it is required by Requirements of Law to make any deduction or withholding, Borrower shall (or shall cause such Withholding Agent, if not Borrower, to) deliver to such Lender (with a copy to the Collateral Agent) the original or a certified copy of a receipt evidencing payment thereof or other evidence reasonably satisfactory to such Lender of such deduction, withholding or payment and of the remittance thereof to the relevant taxing or other Governmental Authority.

(c) Borrower shall indemnify each Lender for the full amount of any Indemnified Taxes (including Indemnified Taxes imposed or asserted on or attributable to amounts payable under this Section 2.6(c)) paid by such Lender and any liability (including any reasonable expenses) arising therefrom or with respect thereto whether or not such Indemnified Taxes were correctly or legally imposed or asserted by the relevant Governmental Authority. Any indemnification payment pursuant to this Section 2.6(c) shall be made to the applicable Lender within thirty (30) days from written demand therefor.

(d) Any Lender that is entitled to an exemption from or reduction of withholding Tax with respect to payments made under any Loan Document shall deliver to Borrower, at the time or times reasonably requested in writing by Borrower, such properly completed and executed documentation as will permit such payments to be made without withholding or at a reduced rate of withholding. In addition, such Lender, if reasonably requested in writing by Borrower, shall deliver such other documentation prescribed by Requirements of Law or otherwise required by Borrower to enable Borrower to determine whether or not such Lender is subject to backup withholding or information reporting requirements. Notwithstanding anything to the contrary in the preceding two sentences, the completion, execution and submission of such documentation (other than such documentation set forth in Section 2.6(d)(i), (ii) or (iv) below) shall not be required if in such Lender's reasonable judgment such completion, execution or submission would subject such Lender to any material unreimbursed cost or expense or would materially prejudice the legal or commercial position of such Lender (it being understood that providing any information currently required by any U.S. federal income tax withholding form is not considered at the time this Agreement is executed and delivered prejudicial to the position of a Lender). For the avoidance of doubt, for the purposes of this Section 2.6(d), the term "Lender" shall include each applicable assignee thereof. Without limiting the generality of the foregoing:

(i) If any Lender is organized under the laws of the United States of America or any state thereof, such Lender shall deliver to Borrower two (2) executed copies of Internal Revenue Service ("**IRS**") Form W-9 certifying that such Lender is exempt from U.S. federal backup withholding tax.

(ii) If any Lender is a Foreign Lender, such Lender shall deliver, and shall cause each applicable assignee thereof to deliver, to Borrower, on or prior to, the Tranche A Closing Date and, the date on which a Lender Transfer involving such Lender occurs, as applicable, and at such other times as may be necessary in the determination of Borrower (in the reasonable exercise of its discretion):

(1) in the case of a Foreign Lender claiming the benefits of an income tax treaty to which the United States is a party (x) with respect to payments of interest under any Loan Document, a properly completed and duly executed copy of IRS Form W-8BEN or IRS Form W-8BEN-E establishing an exemption from, or reduction of, U.S. federal withholding Tax pursuant to the "interest" article of such tax treaty and (y) with respect to any other applicable payments under any Loan Document, a properly completed and duly executed copy of IRS Form W-8BEN or IRS Form W-8BEN-E establishing an exemption from, or reduction of, U.S. federal withholding Tax pursuant to the "business profits" or "other income" article of such tax treaty;

(2) a completed and duly executed copy of IRS Form W-8ECI;

(3) to the extent that such Foreign Lender is not the beneficial owner, a properly completed and duly executed copy of IRS W-8IMY and a withholding statement, along with IRS Form W-9, W-8BEN-E, W-8BEN, W-8ECI and/or other certification documents from each beneficial owner, as applicable; provided that if the Foreign Lender is a partnership and one or more direct or indirect partners of such Foreign Lender are claiming the portfolio interest exemption, such Foreign Lender may provide a certificate referenced in Section 2.6(d)(ii)(4) below on behalf of each such direct and indirect partner; or

(4) in the case of a Foreign Lender claiming the benefits of the exemption for "portfolio interest" under Section 881(c) of the IRC, it shall provide Borrower with a properly completed and duly executed copy of IRS Form W-8BEN-E or IRS Form W-8BEN, as applicable, and a certificate reasonably satisfactory to Borrower to the effect that any interest received by such Foreign Lender is not received by a "bank" on "extension of credit made pursuant to a loan agreement entered into in the ordinary course of its trade or business" within the meaning of 881(c)(3)(A) of the IRC, a "10 percent shareholder" of Borrower within the meaning of Section 871(h)(3)(B) of the IRC, or a "controlled foreign corporation" related to Borrower as described in Section 881(c)(3)(C) of the IRC.

(iii) If any Lender is a Foreign Lender it shall, to the extent it is legally entitled to do so, deliver to Borrower (in such number of copies as shall be requested by the recipient) on or prior to the date on which such its becomes a party to this Agreement (and from time to time thereafter upon the reasonable request of Borrower), executed copies of any other form prescribed by applicable law as a basis for claiming exemption from or a reduction in U.S. federal withholding Tax, duly completed, together with such supplementary documentation as may be prescribed by applicable law to permit Borrower to determine the withholding or deduction required to be made.

(iv) If a payment made to any Lender under any Loan Document would be subject to U.S. federal withholding Tax imposed by FATCA if such Lender were to fail to comply with the applicable reporting requirements of FATCA (including those contained in Section 1471(b) or 1472(b) of the IRC, as applicable), such Lender shall deliver to Borrower at the time or times prescribed by law and at such time or times reasonably requested by Borrower such documentation prescribed by applicable law (including as prescribed by Section 1471(b)(3)(C)(i) of the IRC) and such additional documentation reasonably requested by Borrower as may be necessary for Borrower to comply with their obligations under FATCA and to determine that Lender has complied with its obligations under FATCA or to determine the amount to deduct and withhold from such payment. Solely for purposes of this clause (iv), "FATCA" shall include any amendments made to FATCA after the date of this Agreement.

(v) If any Lender is required to deliver any forms, statements, certificates or other evidence with respect to United States federal Tax or backup withholding matters pursuant to this Section 2.6(d), such Lender hereby agrees, from time to time after the initial delivery by such Lender of such forms, certificates or other evidence, whenever a lapse in time, change in circumstances or law, or additional guidance by a Governmental Authority renders such forms, certificates or other evidence obsolete or inaccurate in any material respect, to promptly deliver to Borrower two (2) new original copies, provide such successor form, and/or update any certifications.

(vi) Borrower shall not be required to pay any additional amount to any Lender under Section 2.6(b)(iii) if such Lender shall have failed (1) to timely deliver to Borrower the forms, certificates or other evidence referred to in this Section 2.6(d) (each of which shall be complete, accurate and duly executed), or (2) to notify Borrower of its inability to deliver any such forms, certificates or other evidence, as the case may be; provided that, if such Lender shall have satisfied the requirements of this Section 2.6(d) on the Tranche A Closing Date (or on the date such Lender initially acquires an interest in a Term Loan), nothing in this last sentence of this Section 2.6(d) shall relieve Borrower of its obligations to pay any additional amounts pursuant to this Section 2.6 in the event that, solely as a result of any change in any Requirements of Law or any change in the interpretation, administration or application thereof by any applicable Governmental Authority, such Lender is no longer legally entitled to deliver forms, certificates or other evidence at a subsequent date establishing the fact that such Lender is not subject to withholding as described herein and in the forms, certificates or other evidence initially provided by such Lender.

(e) If any party hereto determines, in its discretion exercised in good faith, that it has received a refund of any Taxes or a credit or offset for any Taxes as to which it has been indemnified pursuant to this Section 2.6 (including by the payment of additional amounts pursuant to this Section 2.6), it shall pay to the indemnifying party an amount equal to such refund, credit or offset (but only to the extent of indemnity payments made, or additional amounts paid, under this Section 2.6 with respect to the Taxes giving rise to such refund), net of all out-of-pocket expenses (including Taxes) of such indemnified party and without interest (other than any interest paid by the relevant Governmental Authority with respect to such refund). Such indemnifying party, upon the request of such indemnified party, shall repay to such indemnified party the amount paid over pursuant to this clause (e) in the event that such indemnified party is required to repay, credit or offset such refund to such Governmental Authority and the requirement to repay such refund to such Governmental Authority is not due to the indemnified party's failure to timely provide complete and accurate IRS forms and other documentation required pursuant to Section 2.6(d) or Section 2.8. Notwithstanding anything to the contrary in this clause (e), in no event will the indemnified party be required to pay any amount to an indemnifying party pursuant to this clause (e) if the payment of such amount would place the indemnified party in a less favorable net after-Tax position than the indemnified party would have been in if the indemnification payments or additional amounts giving rise to such refund had not been deducted, withheld or otherwise imposed and the indemnification payments or additional amounts with respect to such tax had never been paid. This clause (e) shall not be construed to require any indemnified party to make available its Tax returns (or any other information relating to its Taxes that it deems confidential) to the indemnifying party or any other Person.

2.7. Additional Consideration.

(a) As additional consideration for each Lender funding its Term Loans pursuant to Section 2.2 and Section 3.5, (i) on the Tranche A Closing Date, Borrower shall pay to each Lender an amount equal to the product of (A) the amount of the Tranche A Loan advanced by such Lender on the Tranche A Closing Date, multiplied by (B) one and three-quarters (1.75%) (each such product, the "**Additional Tranche A Commitment Consideration**") and (ii) on the Tranche B Closing Date (to the extent it occurs), Borrower shall pay to each Lender an amount equal to the product of (A) the amount of the Tranche B Loan advanced by such Lender on the Tranche B Closing Date, multiplied by (B) one and three-quarters (1.75%) (each such product, the "**Additional Tranche B Commitment Consideration**" and, together with the Additional Tranche A Commitment Consideration, the "**Additional Commitment Consideration**"). The Additional Tranche A Commitment Consideration and the Additional Tranche B Commitment Consideration, as applicable, shall be fully earned when paid and shall not be refundable for any reason whatsoever and such Additional Commitment Consideration shall be treated as original issue discount for U.S. federal income tax purposes.

(b) As additional consideration for each Lender's having made the Term Loans pursuant to Section 3.5, on the Term Loan Maturity Date or the date of any prepayment of any Term Loan by Borrower (i) pursuant to Section 2.2(c)(i) or Section 2.2(c)(ii) or (ii) as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a), Borrower shall pay to each Lender an amount equal to such Lender's Applicable Percentage of the product of (A) the principal amount (including accrued and capitalized PIK Interest) of the Term Loan(s) being paid or prepaid, multiplied by (B) 0.02 (each such product, the "**Additional Loan Consideration**" and, together with the Additional Commitment Consideration, the "**Additional Consideration**"). The Additional Loan Consideration shall be fully earned when paid and shall not be refundable for any reason whatsoever.

2.8. Evidence of Debt; Register; Collateral Agent's Books and Records; Term Loan Notes.

(a) Evidence of Debt; Register. Notwithstanding anything herein to the contrary, Borrower hereby designates the Collateral Agent to serve as Borrower's agent solely for purposes of maintaining at all times at the Collateral Agent's principal office a "book entry system" as described in Treasury Regulations Section 5f.103-1(c)(1)(ii) that identifies each beneficial owner that is entitled to a payment of principal and stated interest on each Term Loan (the "**Register**") so that each Term Loan is at all times in "registered form" as described in IRC Treasury Regulations Section 5f.103-1(c) or Proposed Section 1.163-5(b) (or, in each case, any amended or successor version). The Collateral Agent is hereby authorized by Borrower to record in the manual or data processing records of the Collateral Agent, the date and amount of each advance and the amount of the outstanding Obligations and the date and amount of each repayment of principal and each payment of interest or otherwise on account of the Obligations. Absent manifest error, such records of the Collateral Agent shall be conclusive as to the outstanding principal amount of the total outstanding Obligations, and the payment of interest, principal and other sums due hereunder; provided, however, that the failure of the Collateral Agent to make any such record entry with respect to any payment shall not limit or otherwise affect the obligations of Borrower under the Loan Documents. Each Term Loan: (i) shall, pursuant to this clause (a), be also registered as to both principal and any stated interest with Borrower or its agent, and (ii) may be transferred by any Lender only by (1) surrender of the old instrument and either (x) the reissuance by Borrower of the old instrument to the new Lender or (y) the issuance by Borrower of a new instrument to the new Lender, or (2) confirmation with Borrower that the right to the principal and stated interest on such Term Loan is maintained through the book entry system kept by the Collateral Agent. Each Lender, severally and not jointly with any other Lender, represents that any interest that may become due and owing under this Agreement qualifies for the portfolio interest exception from withholding on interest payments pursuant to IRC Sections 871(h) and 881(c)

(b) Term Loan Notes. Borrower shall execute and deliver to each Lender to evidence such Lender's Term Loans, (i) on the Tranche A Closing Date, the Tranche A Note and (ii) on the Tranche B Closing Date, the Tranche B Note (each, a "**Term Loan Note**").

3. CONDITIONS OF TERM LOANS

3.1. Conditions Precedent to Tranche A Loan. Each Lender's obligation to advance its Applicable Percentage of the Tranche A Loan Amount is subject to the satisfaction (or waiver in accordance with Section 11.5 hereof) of the following conditions:

(a) the Collateral Agent's and each Lender's receipt of copies of the Loan Documents (including the Tranche A Note, executed by Borrower, and the Collateral Documents but excluding any Control Agreements and any other Loan Document described in Schedule 5.14 of the Disclosure Letter to be delivered after the Tranche A Closing Date) executed and delivered by each applicable Credit Party, including, with respect to the Disclosure Letter and the Perfection Certificate dated as of the Effective Date and delivered in connection with the delivery of the Loan Agreement, updated copies thereof dated as of the Tranche A Closing Date if and to the extent any update thereto is necessary between the Effective Date and the Tranche A Closing Date (provided, that in no event may the Disclosure Letter or the Perfection Certificate be updated in a manner that would reflect or evidence a Default or Event of Default (with or without such update)) (the Disclosure Letter, the Perfection Certificate and such other schedules to the Loan Documents (including the Security Disclosure Letter) to be in form and substance reasonably satisfactory to the Collateral Agent);

(b) the Collateral Agent's receipt of (i) true, correct and complete copies of the Operating Documents of each of the Credit Parties, and (ii) a Secretary's Certificate, dated the Tranche A Closing Date, certifying that the foregoing copies are true, correct and complete (such Secretary's Certificate to be in form and substance reasonably satisfactory to the Collateral Agent);

(c) [reserved];

(d) the Collateral Agent's receipt of a good standing certificate for each Credit Party (where applicable), certified by the Secretary of State (or the equivalent thereof) of the jurisdiction of incorporation or formation of such Credit Party as of a date no earlier than thirty (30) days prior to the Tranche A Closing Date;

(e) the Collateral Agent's receipt of a Secretary's Certificate with completed Borrowing Resolutions with respect to the Loan Documents and the Tranche A Loan for each Credit Party, in form and substance reasonably satisfactory to the Collateral Agent;

(f) each Credit Party shall have obtained all Governmental Approvals and all consents of other Persons, if any, in each case that are necessary in connection with the transactions contemplated by the Loan Documents and each of the foregoing shall be in full force and effect and in form and substance reasonably satisfactory to the Collateral Agent;

(g) the Collateral Agent's receipt on the Tranche A Closing Date of an opinion of Ropes & Gray LLP, counsel to all of the Credit Parties, addressed to the Collateral Agent and each Lender, in form and substance reasonably satisfactory to the Collateral Agent;

(h) the Collateral Agent's receipt of (i) evidence that any products liability and general liability insurance policies maintained in the United States regarding any Collateral are in full force and effect and (ii) appropriate evidence showing the Collateral Agent, for the benefit of Lenders and the other Secured Parties, having been named as additional insured or loss payee, as applicable (such evidence to be in form and substance reasonably satisfactory to the Collateral Agent);

(i) the Collateral Agent's receipt of all documentation and other information required by bank regulatory authorities under applicable "know-your-customer" and anti-money laundering rules and regulations, including the U.S.A. Patriot Act (Title III of Pub. L. 107-56 (signed into law October 26, 2001)) (the "**Patriot Act**");

(j) payment of the Additional Tranche A Commitment Consideration concurrent with the funding of the Tranche A Loan;

(k) payment of any and all Lender Expenses then due as specified in Section 2.4 hereof concurrent with the funding of the Tranche A Loan;

(l) the Collateral Agent's receipt of a certificate, dated the Tranche A Closing Date and signed by a Responsible Officer of Borrower, confirming there is no Adverse Proceeding pending or, to the Knowledge of Borrower, threatened, that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change, except as set forth on Schedule 4.7 of the Disclosure Letter (such certificate to be in form and substance reasonably satisfactory to the Collateral Agent); and

(m) the Collateral Agent's receipt of a certificate, dated the Tranche A Closing Date and signed by a Responsible Officer of Borrower, confirming satisfaction of the conditions precedent set forth in this Section 3.1 and in Section 3.3 (such certificate to be in form and substance reasonably satisfactory to the Collateral Agent).

3.2. Conditions Precedent to Tranche B Loan. Each Lender's obligation to advance its Applicable Percentage of the Tranche B Loan Amount is subject to the satisfaction (or waiver in accordance with Section 11.5 hereof) of the following conditions:

(a) each Lender's receipt of the Tranche B Note, executed by Borrower, and the Collateral Agent's and such Lender's receipt of an updated Disclosure Letter, if and to the extent any update thereto is necessary between the Tranche A Closing Date and the Tranche B Closing Date (provided, that in no event may the Disclosure Letter be updated in a manner that would reflect or evidence a Default or Event of Default (with or without such update)) (to be in form and substance reasonably satisfactory to the Collateral Agent);

(b) the Collateral Agent's receipt of an updated Perfection Certificate for Borrower and its Subsidiaries, if and to the extent any update thereto is necessary between the Tranche A Closing Date and the Tranche B Closing Date (provided, that in no event may the Perfection Certificate be updated in a manner that would reflect or evidence a Default or an Event of Default (with or without such update)) (to be in form and substance reasonably satisfactory to the Collateral Agent);

(c) the Collateral Agent's receipt of a Secretary's Certificate with completed Borrowing Resolutions with respect to the Tranche B Loan for each Credit Party, in form and substance reasonably satisfactory to the Collateral Agent;

(d) payment of any and all accrued and unpaid Lender Expenses then due as specified in Section 2.4 hereof concurrent with the funding of the Tranche B Loan;

(e) no prepayment of the principal amount of the Tranche A Loan has been made, in whole or in part pursuant to Section 2.2(c) or as a result of the acceleration of the maturity of the Tranche A Loan pursuant to Section 8.1(a);

(f) Borrower's market capitalization as of the Trading Day on which the Borrower delivered to the Collateral Agent a completed Payment/Advance Request with respect to the Tranche B Loan, was at least $4.0 billion;

(g) the Collateral Agent's receipt of a certificate, dated the Tranche B Closing Date and signed by a Responsible Officer of Borrower, confirming there is no Adverse Proceeding pending or, to the Knowledge of Borrower, threatened, that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change, except as set forth on Schedule 4.7 of the Disclosure Letter delivered in accordance with Section 3.1(a) or, to the extent updated, clause (a) above (such certificate to be in form and substance reasonably satisfactory to the Collateral Agent);

(h) the Collateral Agent's receipt of a certificate, dated the Tranche B Closing Date and signed by a Responsible Officer of Borrower, confirming satisfaction of the conditions precedent set forth in this Section 3.2 and in Section 3.3 (such certificate to be in form and substance reasonably satisfactory to the Collateral Agent); and

(i) payment of the Additional Tranche B Commitment Consideration concurrent with the funding of the Tranche B Loan.

3.3. Additional Conditions Precedent to Term Loans. The obligation of each Lender to advance its Applicable Percentage of each Term Loan is subject to the following additional conditions precedent:

(a) the representations and warranties made by the Credit Parties in Section 4 of this Agreement and in the other Loan Documents are true and correct in all material respects, unless any such representation or warranty is stated to relate to a specific earlier date, in which case such representation or warranty shall be true and correct in all material respects as of such earlier date (it being understood that any representation or warranty that is qualified as to "materiality," "Material Adverse Change," or similar language shall be true and correct in all respects, in each case, on the applicable Closing Date (both with and without giving effect to the Term Loans) or as of such earlier date, as applicable);

(b) there shall not have occurred any Material Adverse Change since December 31, 2018; and

(c) no Default or Event of Default shall have occurred and be continuing as of the applicable Closing Date.

3.4. Covenant to Deliver. The Credit Parties agree to deliver to the Collateral Agent and each Lender each item required to be delivered to Collateral Agent under this Agreement as a condition precedent to any Credit Extension; provided, however, that any such items set forth on Schedule 5.14 of the Disclosure Letter shall be delivered to the Collateral Agent within the time period prescribed therefor on such schedule. The Credit Parties expressly agree that a Credit Extension made prior to the receipt by the Collateral Agent of any such item shall not constitute a waiver by the Collateral Agent or any Lender of the Credit Parties' obligation to deliver such item, and the making of any Credit Extension in the absence of any such item required to have been delivered by the date of such Credit Extension shall be in the applicable Lender's sole discretion.

3.5. Procedures for Borrowing. Subject to the prior satisfaction of all other applicable conditions to the making of each Term Loan set forth in this Agreement, to obtain any Term Loan, Borrower shall deliver to the Collateral Agent by electronic mail or facsimile a completed Payment/Advance Request for such Term Loan executed by a Responsible Officer of Borrower (which notice shall be irrevocable on and after the date on which such notice is given and Borrower shall be bound to make a borrowing in accordance therewith), in which case each Lender agrees to advance its Applicable Percentage of such Term Loan to Borrower on the Tranche A Closing Date or Tranche B Closing Date, as applicable, by wire transfer of same day funds in Dollars, to such account(s) in the United States as may be designated in writing to the Collateral Agent by Borrower prior to the Tranche A Closing Date or Tranche B Closing Date, as applicable; provided, however, that with respect to the Tranche B Loan, Borrower shall deliver to the Collateral Agent by electronic mail or facsimile, at its option should it wish to obtain the Tranche B Loan, such completed Payment/Advance Request on such date that is at least seventy-five (75) days (or such shorter period as may be agreed to by Lenders) prior to the Tranche B Closing Date set forth in such notice, which borrowing shall be subject to the satisfaction and or waiver of the applicable conditions precedent set forth in Section 3.2.

4. REPRESENTATIONS AND WARRANTIES

In order to induce each Lender and the Collateral Agent to enter into this Agreement and for each Lender to make the Credit Extensions to be made on the applicable Closing Date, each Credit Party, jointly and severally with each other Credit Party, represents and warrants to each Lender and the Collateral Agent that the following statements are true and correct as of the Effective Date and on the applicable Closing Date on which each Term Loan is made (both with and without giving effect to such Term Loan):

4.1. Due Organization, Power and Authority. Each of Borrower and each of its Subsidiaries: (a) is duly incorporated, organized or formed, and validly existing and, where applicable, in good standing under the laws of its jurisdiction of incorporation, organization or formation identified on Schedule 4.15 of the Disclosure Letter; (b) has all requisite power and authority to (i) own, lease, license and operate its assets and properties and to carry on its business as currently conducted in the ordinary course of business and (ii) execute and deliver the Loan Documents to which it is a party and to perform its obligations thereunder and otherwise carry out the transactions contemplated thereby; (c) is duly qualified and, where applicable, in good standing under the laws of each jurisdiction where its ownership, lease, license or operation of assets or properties or the conduct of its business requires such qualification; and (d) has all requisite Governmental Approvals to operate its business as currently conducted; except in each case referred to clauses (a) (other than with respect to Borrower and any other Credit Party), (b)(i), (c) or (d) above, to the extent that failure to do so could not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change.

4.2. Equity Interests. All of the outstanding Equity Interests in each Subsidiary of the Borrower, the Equity Interests in which are required to be pledged pursuant to the Collateral Documents, have been duly authorized and validly issued, are fully paid and, in the case of Equity Interests representing corporate interests, are non-assessable and, on the applicable Closing Date, all such Equity Interests owned directly by Borrower or any other Credit Party are owned free and clear of all Liens except for Permitted Liens. Schedule 4.2 of the Disclosure Letter identifies each Person, the Equity Interests in which are required to be pledged on the applicable Closing Date pursuant to the Collateral Documents.

4.3. Authorization; No Conflict. Except as set forth on Schedule 4.3 of the Disclosure Letter, the execution, delivery and performance by each Credit Party of the Loan Documents to which it is a party, and the consummation of the transactions contemplated thereby, (a) have been duly authorized by all necessary corporate or other organizational action and (b) do not and will not (i) contravene the terms of any of such Credit Party's Operating Documents, (ii) conflict with or result in any breach or contravention of, or require any payment to be made under (A) any provision of any security issued by such Credit Party or of any agreement, instrument or other undertaking to which such Credit Party is a party or affecting such Credit Party or the assets or properties of such Credit Party or any of its Subsidiaries or (B) any order, writ, judgment, injunction, decree, determination or award of any Governmental Authority by which such Credit Party or any of its properties or assets are subject, (iii) result in the creation of any Lien (other than under the Loan Document) or (iv) violate any Requirements of Law, except, in the cases of clauses (b)(ii) and (b)(iv) above, to the extent that such conflict, breach, contravention, payment or violation could not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change.

4.4. Government Consents; Third Party Consents. Except as set forth on Schedule 4.4 of the Disclosure Letter, no Governmental Approval or other approval, consent, exemption or authorization, or other action by, or notice to, or filing with, any Governmental Authority or any other Person (including any counterparty to any Material Contract) is necessary or required in connection with (a) the execution, delivery or performance by, or enforcement against, any Credit Party of this Agreement or any other Loan Document, or for the consummation of the transactions contemplated hereby or thereby, (b) the grant by any Credit Party of the Liens granted by it pursuant to the Collateral Documents, (c) the perfection or maintenance of the Liens created under the Collateral Documents (including the priority thereof) or (d) the exercise by the Collateral Agent or any Lender of its rights under the Loan Documents or the remedies in respect of the Collateral pursuant to the Collateral Documents, except for (i) filings necessary to perfect the Liens on the Collateral granted by the Credit Parties to the Collateral Agent for the benefit of Lenders and the other Secured Parties, (ii) the approvals, consents, exemptions, authorizations, actions, notices and filings which have been duly obtained, taken, given or made and are in full force and effect, (iii) filings under state or federal securities laws and (iv) those approvals, consents, exemptions, authorizations or other actions, notices or filings, the failure of which to obtain or make could not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change.

4.5. Binding Obligation. Each Loan Document has been duly executed and delivered by each Credit Party that is a party thereto and constitutes a legal, valid and binding obligation of such Credit Party, enforceable against such Credit Party in accordance with its respective terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws relating to or limiting creditors' rights generally or by general principles of equity.

4.6. **Collateral**. In connection with this Agreement, the Credit Parties have delivered to the Collateral Agent a completed, omnibus certificate signed by each Credit Party (the "**Perfection Certificate**"). Each Credit Party, jointly and severally, represents and warrants to the Collateral Agent and each Lender that:

(a) (i) its exact legal name is that indicated on the Perfection Certificate and on the signature page hereof; (ii) it is an organization of the type and is organized in the jurisdiction set forth in the Perfection Certificate; (iii) the Perfection Certificate accurately sets forth its organizational identification number or accurately states that it has none; (iv) the Perfection Certificate accurately sets forth its place of business, or, if more than one, its chief executive office as well as its mailing address (if different than its chief executive office); (v) except as disclosed on the Perfection Certificate, it (and each of its predecessors) has not, in the five (5) years prior to the Tranche A Closing Date, changed its jurisdiction of formation, organizational structure or type, or any organizational number assigned by its jurisdiction; and (vi) all other information set forth on the Perfection Certificate pertaining to it and each of its Subsidiaries is accurate and complete in all material respects as of the Closing Date. If any Credit Party is not now a Registered Organization but later becomes one, it shall promptly notify the Collateral Agent of such occurrence and provide the Collateral Agent with such Credit Party's organizational identification number.

(b) (i) it has good title to, has rights in, and subject to Permitted Subsidiary Distribution Restrictions, the power to transfer each item of the Collateral upon which it purports to grant a Lien under any Collateral Document, free and clear of any and all Liens except Permitted Liens, except for such minor irregularities or defects in title as could not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change and (ii) as of the applicable Closing Date, it has no deposit accounts maintained at a bank or other depository or financial institution located in the United States other than the deposit accounts described in the Perfection Certificate delivered to the Collateral Agent in connection herewith.

(c) A true, correct and complete list of each U.S. pending, registered or issued Patent, Copyright and Trademark material to the business of Borrower and its Subsidiaries, taken as a whole, relating to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of any Product in the Territory, which as of the applicable Closing Date is owned or co-owned by or exclusively or non-exclusively licensed to any Credit Party or any of its Subsidiaries (collectively, the "**Current Company IP**"), including its name/title, current owner or co-owners (including ownership interest), registration, patent or application number and registration or application date, issued or filed in the Territory, is set forth on Schedule 4.6(c) of the Disclosure Letter. Except as set forth on Schedule 4.6(c) of the Disclosure Letter, (i) to the Knowledge of Borrower, (A) each item of Current Company IP owned or co-owned by a Credit Party or any of its Subsidiaries is valid, subsisting and enforceable and no such item of Current Company IP has lapsed, expired, been cancelled or invalidated or become abandoned or unenforceable, except, as of the Tranche B Closing Date (as applicable), in each case, with respect to any such Current Company IP that Borrower and the co-owner thereof (if applicable) determine in its (or their, if applicable) reasonable business judgment is immaterial to the exploitation of any Product in the Territory after the Tranche A Closing Date, and (B) as of the applicable Closing Date, no written notice has been received challenging the inventorship or ownership, or relating to any lapse, expiration, invalidation, abandonment or unenforceability, of any such item of Current Company IP owned or co-owned by a Credit Party or any of its Subsidiaries, except, as of the Tranche B Closing Date (as applicable), in each case, as could not, individually or in the aggregate, reasonably be expected to result in a material adverse effect on any Product in the Territory, and (ii) to the Knowledge of Borrower, (A) each such item of Current Company IP which is licensed by a Credit Party or any of its Subsidiaries from another Person is valid, subsisting and enforceable and no such item of Current Company IP has lapsed, expired, been cancelled or invalidated, or become abandoned or unenforceable, except, as of the Tranche B Closing Date (as applicable), in each case, with respect to any Current Company IP that Borrower and the licensor thereof (if applicable) determines in its (or their, if applicable) reasonable business judgment is immaterial to the exploitation of any Product in the Territory after the Tranche A Closing Date, and (B) as of the applicable Closing Date, no written notice has been received challenging the inventorship or ownership, or relating to any lapse, expiration, invalidation, abandonment or unenforceability, of any such item of Current Company IP, except, as of the Tranche B Closing Date (as applicable), in each case, as could not, individually or in the aggregate, reasonably be expected to result in a material adverse effect on any Product in the Territory. To the Knowledge of Borrower, there are no published patents, patent applications, articles or prior art references that could reasonably be expected to materially adversely affect the exploitation of any Product in the Territory. Except as set forth on Schedule 4.6(c) of the Disclosure Letter, (x) each Person who has or has had any rights in or to Current Company IP or any trade secrets owned, co-owned or licensed by any Credit Party or any of its Subsidiaries, including each inventor named on the Patents within such Current Company IP filed by any Credit Party or any of its Subsidiaries, has executed an agreement assigning his, her or its entire right, title and interest in and to such Current Company IP or trade secrets (as applicable), and the inventions, improvements, ideas, discoveries, writings, works of authorship, information and other intellectual property embodied, described or claimed therein, to the stated owner(s) or licensor thereof, and (y) to the Knowledge of Borrower, no such Person has any contractual or other obligation that would preclude or conflict with such assignment or the exploitation of any Product in the Territory or entitle such Person to ongoing payments.

(d) (i) as of the applicable Closing Date, each Credit Party or any of its Subsidiaries possesses valid title to the Current Company IP for which it is listed as the owner on Schedule 4.6(c) of the Disclosure Letter, except, as of the Tranche B Closing Date (as applicable), in each case, with respect to any Current Company IP that Borrower and the licensor thereof (if applicable) determines in its (or their, if applicable) reasonable business judgment is immaterial to the exploitation of any Product in the Territory after the Tranche A Closing Date; and (ii) there are no Liens on any Current Company IP, other than Permitted Liens.

(e) There are no maintenance, annuity or renewal fees that are currently overdue beyond their allotted grace period for any of the Current Company IP which is owned or co-owned by or exclusively licensed to any Credit Party or any of its Subsidiaries, except, in each case, that could not reasonably be expected to have a materially adverse impact on such Credit Party's or Subsidiary's rights to such Current Company IP, nor have any applications or registrations therefor irrevocably lapsed or become abandoned, been cancelled or expired, except, as of the Tranche B Closing Date (as applicable), with respect to any such Current Company IP that Borrower and the co-owner thereof or the licensor thereof (if applicable) determine in its (or their, as applicable) reasonable business judgment is immaterial to the exploitation of any Product in the Territory after the Tranche A Closing Date. There are no maintenance, annuity or renewal fees that are currently overdue beyond their allotted grace period for any of the Current Company IP which is non-exclusively licensed to any Credit Party or any of its

Subsidiaries, except, in each case, that could not reasonably be expected to have a materially adverse impact on such Credit Party's or Subsidiary's rights to such Current Company IP, nor to the Knowledge of Borrower, have any applications or registrations therefor irrevocably lapsed or become abandoned, been cancelled or expired, except, as of the Tranche B Closing Date (as applicable), with respect to any such Current Company IP that the licensor thereof determines is immaterial after the Tranche A Closing Date.

(f) There are no unpaid fees or royalties owing by the Borrower or any of its Subsidiaries under any Current Company IP Agreement constituting a Material Contract that have become due, or are expected to become overdue, and that could reasonably be excepted to materially adversely affect the Borrower's or any of its Subsidiary's rights thereunder. Each Current Company IP Agreement constituting a Material Contract is in full force and effect and, to the Knowledge of Borrower, is legal, valid, binding, and enforceable in accordance with its respective terms, except as may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws relating to or limiting creditors' rights generally or by equitable principles relating to enforceability. Except as set forth on Schedule 4.6(f) of the Disclosure Letter, neither Borrower nor any of its Subsidiaries, as applicable, is in material breach of or default under any Current Company IP Agreement constituting a Material Contract to which it is a party or may otherwise be bound, and to the Knowledge of Borrower, no circumstances or grounds exist that would give rise to a claim of breach or right of rescission, termination, non-renewal, revision or amendment of any Current Company IP Agreement that constitutes a Material Contract, including the execution, delivery and performance of this Agreement and the other Loan Documents.

(g) To the Knowledge of Borrower, no payments by any Credit Party or any of its Subsidiaries are overdue to any other Person in respect of the Current Company IP, in each case that could reasonably be expected to materially adversely affect the Borrower's or any of its Subsidiary's rights thereunder.

(h) No Credit Party or any of its Subsidiaries has undertaken or omitted to undertake any acts, and, to the Knowledge of Borrower, no circumstance or grounds exist that would invalidate or render unenforceable, in whole or in part, (i) the Current Company IP in any manner that could reasonably be expected to materially adversely affect any Product, or (ii) in the case of Current Company IP owned or co-owned by, or exclusively or non-exclusively licensed to, any Credit Party or any of its Subsidiaries, other than with respect to Permitted Licenses and except as set forth on Schedule 4.6(h) of the Disclosure Letter, a Credit Party's or Subsidiary's entitlement to own or license and exploit such Current Company IP, except, as of the Tranche B Closing Date (as applicable), in each case, with respect to any such Current Company IP that Borrower and the co-owner or licensor thereof (if applicable) determine in its (or their, if applicable) reasonable business judgment is immaterial to the exploitation of any Product in the Territory after the Tranche A Closing Date.

(i) Except as set forth on Schedule 4.7 of the Disclosure Letter or advised pursuant to Section 5.2(b), there is no pending, decided or settled opposition, interference proceeding, reissue proceeding, reexamination proceeding, inter-partes review proceeding, post-grant review proceeding, cancellation proceeding, injunction, litigation, paragraph IV patent certification or lawsuit under the Hatch-Waxman Act, hearing, investigation, complaint, arbitration, mediation, demand, International Trade Commission investigation, decree, or any other dispute, disagreement, or claim, in each case and alleged in writing to Borrower or any of its Subsidiaries (collectively referred to hereinafter as "**Specified Disputes**"), nor to the Knowledge of Borrower, has any such Specified Dispute been threatened in writing, in each case challenging the legality, validity, enforceability or ownership of any Current Company IP, in each case that would have a material adverse effect on any Product in the Territory. Except as set forth on Schedule 4.6(i) of the Disclosure Letter, to the Knowledge of Borrower, there is no product or other technology of any third party that could reasonably be expected to infringe a Patent within the Current Company IP in a manner that would result in a material adverse effect on any Product in the Territory.

(j) As of the Tranche A Closing Date, no Credit Party is a party to, nor is it bound by, any Excluded License.

(k) In each case where an issued Patent within the Current Company IP is owned or co-owned by any Credit Party or any of its Subsidiaries by assignment, the assignment has been duly recorded with the U.S. Patent and Trademark Office.

(l) Except as set forth on Schedule 4.6(l) of the Disclosure Letter, there are no pending (in a court of law, court of equity or patent or intellectual property office, including the U.S. Patent and Trademark Office) or, to the Knowledge of Borrower, threatened (in writing) claims against Borrower or any of its Subsidiaries alleging that any research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of any Product in the Territory infringes or violates (or in the past infringed or violated) the rights of any third parties in or to any Intellectual Property ("**Third Party IP**") or constitutes a misappropriation of (or in the past constituted a misappropriation of) any Third Party IP, except, as of the Tranche B Closing Date (as applicable), in each case, as could not, individually or in the aggregate, reasonably be expected to result in a material adverse effect on any Product in the Territory.

(m) Except as set forth on Schedule 4.6(m) of the Disclosure Letter, the manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of any Product in the Territory does not, to the Knowledge of Borrower, form an alleged basis for a claim of infringement or violation (or an alleged basis for a claim of past infringement or violation) any issued or registered Third Party IP (including any issued Patent within the Third Party IP) or, to the Knowledge of Borrower, constitutes a misappropriation of (or in the past constituted a misappropriation of) any Third Party IP, except, as of the Tranche B Closing Date (as applicable), in each case, as could not, individually or in the aggregate, reasonably be expected to result in a material adverse effect on any Product in the Territory.

(n) Except as set forth on Schedule 4.6(n) of the Disclosure Letter, to the Knowledge of Borrower, there are no settlements, covenants not to sue, consents, judgments, orders or similar obligations imposed by a court of law, court of equity or patent or intellectual property office, including the U.S. Patent and Trademark Office which: (i) restrict the rights of any Credit Party or any of its Subsidiaries to use any U.S. Intellectual Property relating to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of any Product in the Territory (in order to accommodate any Third Party IP or otherwise), except, as of the Tranche B Closing Date (as applicable), in each case, as could not, individually or in the aggregate, reasonably be expected to result in a material adverse effect on any Product in the Territory or (ii) permit any third parties to use any Company IP, except, as of the Tranche B Closing Date (as applicable), in each case, as could not, individually or in the aggregate, reasonably be expected to result in a material adverse effect on any Product in the Territory.

(o) Except as set forth on Schedule 4.6(o) of the Disclosure Letter, to the Knowledge of Borrower, (i) there is no, nor has there been any, infringement or violation by any Person of any of the Company IP or the rights therein, except, as of the Tranche B Closing Date (as applicable), in each case, as could not, individually or in the aggregate, reasonably be expected to result in a material adverse effect on any Product in the Territory and (ii) there is no, nor has there been any, misappropriation by any Person of any of the Company IP or the subject matter thereof, except, as of the Tranche B Closing Date (as applicable), in each case, as could not, individually or in the aggregate, reasonably be expected to result in a material adverse effect on any Product in the Territory.

(p) Each Credit Party and each of its Subsidiaries (if applicable) has taken commercially reasonable measures customary in the pharmaceutical industry to protect the confidentiality and value of all U.S. trade secrets owned by such Credit Party or Subsidiary or used or held for use by such Credit Party or Subsidiary, in each case relating to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of any Product in the Territory.

(q) To the Knowledge of Borrower, any Product made, used or sold under the Patents within the Current Company IP has been marked with the proper patent notice, except, in each case, as could not, individually or in the aggregate, reasonably be expected to result in a material adverse effect on any Product in the Territory.

(r) Except as set forth on Schedule 4.6(r) of the Disclosure Letter, to the Knowledge of Borrower, at the time of any shipment of Product in the Territory occurring in the past three (3) years and prior to the applicable Closing Date, the units thereof so shipped complied in all material respects with their relevant specifications and were developed and manufactured in all material respects in accordance with current FDA Good Manufacturing Practices, FDA Good Clinical Practices and FDA Good Laboratory Practices (as applicable), except, as of the Tranche B Closing Date (as applicable), in each case, as could not, individually or in the aggregate, reasonably be expected to result in a material adverse effect on any Product in the Territory.

4.7. Adverse Proceedings, Compliance with Laws. Except as set forth on Schedule 4.7 of the Disclosure Letter or advised pursuant to Section 5.2(b), there are no Adverse Proceedings pending or, to the Knowledge of Borrower, threatened in writing, at law, in equity, in arbitration or before any Governmental Authority, by or against Borrower or any of its Subsidiaries or against any of their respective assets or properties or revenues (including involving allegations of sexual harassment or misconduct by any officer of Borrower or any of its Subsidiaries) that, either individually or in the aggregate, could reasonably be expected to materially adversely affect the Collateral (taken as a whole) or result in a Material Adverse Change. Neither Borrower nor any of its Subsidiaries (a) is in violation of any Requirements of Law (including Environmental Laws), except for such violations that, individually or in the aggregate, could not reasonably be expected to result in a Material Adverse Change, or (b) is subject to or in default with respect to any final judgments, orders, writs, injunctions, decrees, rules or regulations of any court or any federal, state, municipal or other governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, that, individually or in the aggregate, could reasonably be expected to materially adversely affect the Collateral (taken as a whole) or result in a Material Adverse Change.

4.8. Exchange Act Documents; Financial Statements; Financial Condition; No Material Adverse Change; Books and Records.

(a) The documents filed by Borrower with the SEC pursuant to the Exchange Act since January 1, 2019 (the "**Exchange Act Documents**"), when they were filed with the SEC, conformed in all material respects to the requirements of the Exchange Act, and as of the time they were filed with the SEC, none of such documents contained any untrue statement of a material fact or omitted to state a material fact necessary to make the statements therein (excluding any projections and forward-looking statements, estimates, budgets and general economic or industry data of a general nature), in the light of the circumstances under which they were made, not misleading; provided, that, with respect to projected financial information, Borrower represents only that such information was prepared in good faith based upon assumptions believed to be reasonable at the time (it being understood that such projections are not a guarantee of financial performance and are subject to uncertainties and contingencies, many of which are beyond the control of Borrower or any Subsidiary, and neither Borrower nor any Subsidiary can give any assurance that such projections will be attained, that actual results may differ in a material manner from such projections and any failure to meet such projections shall not be deemed to be a breach of any representation or covenant herein);

(b) The financial statements (including the related notes thereto) of Borrower and its Subsidiaries included in the Exchange Act Documents present fairly in all material respects the consolidated financial condition of Borrower and such Subsidiaries and their consolidated results of operations as of the dates indicated and the results of their operations and the changes in their cash flows for the periods specified. Such financial statements have been prepared in conformity with Applicable Accounting Standards applied on a consistent basis throughout the periods covered thereby, except as otherwise disclosed therein and, in the case of unaudited, interim financial statements, subject to normal year-end audit adjustments and the exclusion of certain footnotes, and any supporting schedules included in the Exchange Act Documents present fairly in all material respects the information required to be stated therein (subject to the proviso in Section 4.8(a) above with respect to projections);

(c) Since December 31, 2018, there has not occurred or failed to occur any change or event that has had or could reasonably be expected to have, either alone or in conjunction with any other change(s), event(s) or failure(s), a Material Adverse Change, except as has been disclosed in the Exchange Act Documents; and

(d) The Books of Borrower and each of its Subsidiaries in existence immediately prior to the applicable Closing Date contain full, true and correct entries of all dealings and transactions in relation to its business and activities in conformity in all material respects with Applicable Accounting Standards and all Requirements of Law.

4.9. Solvency. Borrower and its Subsidiaries, on a consolidated basis, are Solvent. Without limiting the generality of the foregoing, there has been no proposal made or resolution adopted by any competent corporate body for the dissolution or liquidation of Borrower, nor do any circumstances exist which may result in the dissolution or liquidation of Borrower.

4.10. Payment of Taxes. All U.S. federal income and other material Tax returns and reports (or extensions thereof) of each Credit Party and each of its Subsidiaries required to be filed by any of them have been timely filed and are correct in all material respects, and all material Taxes which are due and payable by any Credit Party or any of its Subsidiaries and all material assessments, fees and other governmental charges upon any Credit Party or any of its Subsidiaries and upon their respective properties, assets, income, businesses and franchises which are due and payable have been paid when due and payable except where the validity or amount thereof is being contested in good faith by appropriate proceedings; provided that (a) the applicable Credit Party has set aside on its books adequate reserves therefor in conformity with Applicable Accounting Standards and (b) the failure to pay such Taxes, individually or in the aggregate, could not reasonably be expected to result in a Material Adverse Change.

4.11. Environmental Matters. Neither Borrower nor any of its Subsidiaries nor any of their respective Facilities or operations is subject to any outstanding written order, consent decree or settlement agreement with any Person relating to any Environmental Law, any Environmental Claim, or any Hazardous Materials Activity that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change. There are and, to the Knowledge of Borrower, have been, no conditions, occurrences, or Hazardous Materials Activities that would reasonably be expected to form the basis of an Environmental Claim against Borrower or any of its Subsidiaries that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change. To the Knowledge of Borrower, no predecessor of Borrower or any of its Subsidiaries has filed any notice under any Environmental Law indicating past or present treatment of Hazardous Materials at any Facility, which would reasonably be expected to form the basis of an Environmental Claim against Borrower or any of its Subsidiaries that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change (but, for the avoidance of doubt, Borrower has not undertaken any investigation of or made any inquiries to, or relating to, any of its or its Subsidiaries' predecessors), and neither Borrower's nor any of its Subsidiaries' operations involves the generation, transportation, treatment, storage or disposal of hazardous waste, as defined under 40 C.F.R. Parts 260 270 or any state equivalent, which would reasonably be expected to form the basis of an Environmental Claim against Borrower or any of its Subsidiaries that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change. No event or condition has occurred or is occurring with respect to any Credit Party relating to any Environmental Law, any Release of Hazardous Materials, or any Hazardous Materials Activity that, individually or in the aggregate, has resulted in, or could reasonably be expected to result in, a Material Adverse Change.

4.12. Material Contracts. As of the applicable Closing Date, after giving effect to the consummation of the transactions contemplated by this Agreement, except as described on Schedule 4.12 of the Disclosure Letter, each Material Contract is a valid and binding obligation of the applicable Credit Party and, to the Knowledge of Borrower, each other party thereto, and is in full force and effect, and neither the applicable Credit Party nor, to the Knowledge of Borrower, any other party thereto is in material breach thereof or default thereunder, except where such breach or default (which default has not been cured or waived) could not reasonably be expected to give rise to any cancellation, termination or acceleration of such Credit Party's or Subsidiary's obligations thereunder by the applicable counterparty thereto or result in the invalidation thereof. As of the applicable Closing Date, except as described on Schedule 4.12 of the Disclosure Letter, no Credit Party or any of its Subsidiaries has received any written notice from any party thereto asserting or, to the Knowledge of Borrower threatening to assert, circumstances that could reasonably be expected to result in the cancellation, termination or invalidation of any Material Contract or the acceleration of such Credit Party's or Subsidiary's obligations thereunder.

4.13. Regulatory Compliance. No Credit Party is or is required to be an "investment company" under the Investment Company Act of 1940. Each Credit Party has complied in all material respects with the Federal Fair Labor Standards Act. Except as could not, either individually or in the aggregate, reasonably be expected to result in a Material Adverse Change, each Plan is in compliance with the applicable provisions of ERISA, the IRC and other U.S. federal or state Requirements of Law, respectively. (a) No ERISA Event has occurred or is reasonably expected to occur; (b) neither any Credit Party nor any ERISA Affiliate has incurred, or reasonably expects to incur, any liability (and no event has occurred which, with the giving of notice under Section 4219 of ERISA, would result in such liability) under Section 4201 *et seq*. or 4243 of ERISA with respect to a Multiemployer Plan; and (c) neither any Credit Party nor any ERISA Affiliate has engaged in a transaction that would be subject to Section 4069 or 4212(c) of ERISA, except, with respect to each of clauses (a), (b) and (c) above, as could not reasonably be expected, individually or in the aggregate, to result in a Material Adverse Change.

4.14. Margin Stock. Neither Borrower nor any of its Subsidiaries is engaged or will engage, principally or as one of its important activities, in the business of purchasing or carrying Margin Stock (within the meaning of Regulation U of the Federal Reserve Board), or extending credit for the purpose of purchasing or carrying Margin Stock. Neither Borrower nor any of its Subsidiaries has taken or permitted to be taken any action that might cause any Loan Document to violate Regulation T, U or X of the Federal Reserve Board.

4.15. Subsidiaries. As of the applicable Closing Date, Schedule 4.15 of the Disclosure Letter (a) sets forth the name and jurisdiction of incorporation, organization or formation of Borrower and each of its Subsidiaries and (b) sets forth the ownership interest of Borrower and any other Credit Party in each of their respective Subsidiaries, including the percentage of such ownership.

4.16. **Employee Matters.** Neither Borrower nor any of its Subsidiaries is engaged in any unfair labor practice that could reasonably be expected to result in a Material Adverse Change. There is (a) no unfair labor practice complaint pending against Borrower or any of its Subsidiaries or, to the Knowledge of Borrower, threatened in writing against any of them before the National Labor Relations Board, and no grievance or arbitration proceeding arising out of or under any collective bargaining agreement that is pending against Borrower or any of its Subsidiaries or, to the Knowledge of Borrower, threatened in writing against any of them, (b) no strike or work stoppage in existence or, to the Knowledge of Borrower, threatened in writing involving Borrower or any of its Subsidiaries, and (c) to the Knowledge of Borrower, no union representation question existing with respect to the employees of Borrower or any of its Subsidiaries and, to the Knowledge of Borrower, no union organization activity that is taking place that in each case specified in any of clauses (a), (b) and (c), individually or taken together with any other matter specified in clause (a), (b) or (c), could reasonably be expected to result in a Material Adverse Change.

4.17. Full Disclosure. None of the documents, certificates or written statements (excluding any projections and forward-looking statements, estimates, budgets and general economic or industry data of a general nature) furnished or otherwise made available to the Collateral Agent or any Lender by or on behalf of any Credit Party for use in connection with the transactions contemplated hereby (in each case, taken as a whole and as modified or supplemented by other information so furnished promptly after the same becomes available) contains any untrue statement of a material fact or omits to state a material fact necessary in order to make the statements contained herein or therein, as of the time when made or delivered, not misleading in light of the circumstances in which the same were made; provided, that, with respect to projected financial information, Borrower represents only that such information was prepared in good faith based upon assumptions believed to be reasonable at the time (it being understood that such projections are not a guarantee of financial performance and are subject to uncertainties and contingencies, many of which are beyond the control of Borrower or any Subsidiary, and neither Borrower nor any Subsidiary can give any assurance that such projections will be attained, that actual results may differ in a material manner from such projections and any failure to meet such projections shall not be deemed to be a breach of any representation or covenant herein). To the Knowledge of Borrower, there are no facts (other than matters of a general economic or industry nature) that, individually or in the aggregate, could reasonably be expected to result in a Material Adverse Change and that have not been disclosed herein or in such other documents, certificates and written statements furnished or made available to the Collateral Agent or any Lender for use in connection with the transactions contemplated hereby.

4.18. FCPA; Patriot Act; OFAC.

(a) None of Borrower, its Subsidiaries or, to the Knowledge of Borrower, any director, officer, agent or employee of Borrower or any Subsidiary of Borrower has (i) used any corporate funds of Borrower or any of its Subsidiaries for any unlawful contribution, gift, entertainment or other unlawful expense relating to political activity, (ii) made any direct or indirect unlawful payment to any foreign or domestic government official or employee from corporate funds of Borrower or any of its Subsidiaries, (iii) violated or is in violation of any provision of the U.S. Foreign Corrupt Practices Act of 1977 (the "**FCPA**") or the U.K. Bribery Act ("**UKBA**") or (iv) made any bribe, rebate, payoff, influence payment, kickback or other unlawful payment, and no part of the proceeds of any Credit Extension will be used, directly or indirectly, for any payments to any governmental official or employee, political party, official of a political party, candidate for political office or anyone else acting in an official capacity, in order to obtain, retain or direct business, or to obtain any improper advantage, in violation of the FCPA, UKBA or any other anti-corruption laws applicable to the Borrower or its Subsidiaries;

(b) (i) The operations of Borrower and its Subsidiaries are and have been conducted at all times in compliance with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, the Bank Secrecy Act of 1970 (as amended by Title III of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT) Act of 2001) and the anti-money laundering laws, rules and regulations of each jurisdiction (foreign or domestic) in which Borrower or any of its Subsidiaries is subject to such jurisdiction's Requirements of Law (collectively, the "**Anti-Money Laundering Laws**") and (ii) as of the applicable Closing Date, except as described on Schedule 4.18(b) of the Disclosure Letter, no action, suit or proceeding by or before any Governmental Authority or any arbitrator involving Borrower or any of its Subsidiaries with respect to the Anti-Money Laundering Laws is pending or to the Knowledge of Borrower, threatened in writing;

(c) None of Borrower, its Subsidiaries or, to the Knowledge of Borrower, any director, officer, agent or employee of Borrower or any Subsidiary of Borrower is the target or the subject of any sanctions administered and enforced by the Office of Foreign Assets Control of the U.S. Department of the Treasury ("**OFAC**"), the U.S. Department of State, the European Union, or Her Majesty's Treasury (collectively "**Sanctions**"). Borrower will not, directly or, to the Knowledge of Borrower, indirectly through an agent, use the proceeds of the Credit Extension, or lend, contribute or otherwise make available such proceeds to any Subsidiary, joint venture partner or other Person, for the purpose of financing the activities of any Person that is the target or the subject of Sanctions or in any country or territory that at the time of such funding, is the subject of Sanctions; and

(d) Borrower, its Subsidiaries, and to the Knowledge of Borrower, their respective directors, officers, agents and employees, are in compliance with all applicable Sanctions. Borrower and its Subsidiaries have instituted and maintain procedures reasonably designed to ensure compliance with applicable Sanctions.

4.19. Health Care Matters

(a) *Compliance with Health Care Laws*. Except as set forth on Schedule 4.19(a) of the Disclosure Letter, each Credit Party and, to the Knowledge of Borrower, each of its Subsidiaries and each officer, Affiliate, and employee acting on behalf of such Credit Party or any of its Subsidiaries, is in compliance in all material respects with all Health Care Law, except, as of the Tranche B Closing Date (as applicable), as could not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change.

(b) *Compliance with FDA Laws*. Each Credit Party and, to the Knowledge of Borrower, each of its Subsidiaries, are in compliance in all material respects with all applicable FDA Laws, including the Food Drug and Cosmetic Act (21 U.S.C. § 301 et seq.) and the regulations promulgated thereunder (the "**FDCA**"), relating to any research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of any Product in the Territory except, as of the Tranche B Closing Date (as applicable), in each case, as could not, individually or in the aggregate, reasonably be expected to result in a material adverse effect on any Product in the Territory. Each Product distributed or sold in the Territory at any and all times during the past four (4) years has been (i) manufactured in all material respects in accordance with current FDA Good Manufacturing Practices, FDA Good Clinical Practices and FDA Good Laboratory Practices (as applicable), except, as of the Tranche B Closing Date (as applicable), in each case, as could not, individually or in the aggregate, reasonably be expected to result in a material adverse effect on any Product in the Territory and (ii) if and to the extent such Product is required to be approved or cleared by the FDA pursuant to the FDCA in order to be legally marketed in the United States for such Product's intended uses, such Product has been approved or cleared for such intended uses, except, as of the Tranche B Closing Date (as applicable), in each case, as could not, individually or in the aggregate, reasonably be expected to result in a material adverse effect on any Product in the Territory.

(c) *Material Statements*. Within the past four (4) years, neither any Credit Party, nor, to the Knowledge of Borrower, any Subsidiary or any officer, Affiliate or employee of any Credit Party or Subsidiary in its capacity as a Subsidiary or as an officer, Affiliate or employee of a Credit Party or Subsidiary (as applicable), nor, to the Knowledge of Borrower, any agent of any Credit Party or Subsidiary, (i) has made an untrue statement of a material fact or a fraudulent statement to any Governmental Authority, (ii) has failed to disclose a material fact to any Governmental Authority, or (iii) has otherwise committed an act, made a statement or failed to make a statement that, in the case of clauses (i) through (iii) above, at the time such statement or disclosure was made (or, in the case of such failure, should have been made) or such act was committed, could reasonably be expected to, as of the Tranche A Closing Date, constitute a material violation of any Health Care Laws and, as of the Tranche B Closing Date (as applicable), result in a Material Adverse Change.

(d) *Proceedings; Audits*. Except as has been disclosed in the Exchange Act Documents or as set forth on Schedule 4.19(e) of the Disclosure Letter (i) there is no Adverse Proceeding pending or, to the Knowledge of Borrower, threatened in writing, against any Credit Party or any of its Subsidiaries relating to any allegations of non-compliance with any Health Care Laws, Data Protection Laws or FDA Laws, and (ii) to the Knowledge of Borrower, there are no facts, circumstances or conditions that, individually or in the aggregate, would reasonably be expected to form the basis for any such Adverse Proceeding that, as of the Tranche A Closing Date, in the case of clause (ii) above, could reasonably be expected to result in a Material Adverse Change and, as of the Tranche B Closing Date (as applicable), in the case of clauses (i) and (ii) above, could reasonably be expected to result in a Material Adverse Change.

(e) *Safety Notices*. Within the past three (3) years, neither any Credit Party nor any of its Subsidiaries has initiated or otherwise engaged in any recalls, field notifications, safety warnings, "dear doctor" letters, investigator notices, safety alerts or other similar notices of action, including as a result of any Risk Evaluation and Mitigation Strategy proposed or enforced by the FDA, relating to an alleged lack of safety or regulatory compliance of any Product that could reasonably be expected to result in a Material Adverse Change.

(f) *Prohibited Transactions; No Whistleblowers*. Within the past six (6) years, to the Knowledge of Borrower, neither any Credit Party, any Subsidiary, any officer, Affiliate or employee of a Credit Party or Subsidiary, nor, to the Knowledge of Borrower, any other Person acting on behalf of any Credit Party or any Subsidiary, directly or indirectly: (i) has offered or paid any remuneration, in cash or in kind, to, or made any financial arrangements with, any past, present or potential patient, supplier, physician or contractor, in order to illegally obtain business or payments from such Person in material violation of any Health Care Law; (ii) has given or made, or is party to any illegal agreement to give or make, any illegal gift or gratuitous payment of any kind, nature or description (whether in money, property or services) to any past, present or potential patient, supplier, physician or contractor, or any other Person in material violation of any Health Care Law; (iii) has given or made, or is party to any agreement to give or make on behalf of any Credit Party or any of its Subsidiaries, any contribution, payment or gift of funds or property to, or for the private use of, any governmental official, employee or agent where the contribution, payment or gift was a material violation of the laws of any U.S. Governmental Authority having jurisdiction over such payment, contribution or gift; or (iv) has made, or is party to any agreement to make, any payment to any Person with the intention or understanding that any part of such payment would be in material violation of any Health Care Law. To the Knowledge of Borrower, there are no actions pending or threatened (in writing) against any Credit Party or any of its Subsidiaries or any of their respective Affiliates under any U.S. federal or state whistleblower statute, including under the False Claims Act of 1863 (31 U.S.C. § 3729 et seq.), except, as of the Tranche B Closing Date (as applicable), in each case, such actions that could not reasonably be expected to result in a Material Adverse Change .

(g) *Exclusion*. Neither any Credit Party nor, to the Knowledge of Borrower, any Subsidiary or any officer, Affiliate or employee having authority to act on behalf of any Credit Party or any Subsidiary, is or, to the Knowledge of Borrower, has been threatened in writing to be: (i) excluded from any Governmental Payor Program pursuant to 42 U.S.C. § 1320a-7b and related regulations; (ii) "suspended" or "debarred" from selling any products to the U.S. government or its agencies pursuant to the Federal Acquisition Regulation relating to debarment and suspension applicable to federal government agencies generally (42 C.F.R. Subpart 9.4), or other U.S. Requirements of Law; (iii) debarred, disqualified, suspended or excluded from participation in Medicare, Medicaid or any other Governmental Payor Program or is listed on the General Services Administration list of excluded parties; or (iv) a party to any other action or proceeding by any Governmental Authority that would prohibit the applicable Credit Party or Subsidiary from distributing or selling any Product in the Territory or providing any services to any governmental or other purchaser pursuant to any Health Care Laws.

(h) *HIPAA*. Each Credit Party and, to the Knowledge of Borrower, each of its Subsidiaries, to the extent applicable, is in material compliance with all applicable federal, state and local laws and regulations regarding the privacy, security, and notification of breaches of health information and regarding electronic transactions, including HIPAA, and each Credit Party and, to the Knowledge of Borrower, each of its Subsidiaries, to the extent applicable, has implemented policies, procedures and training customary in the pharmaceutical industry or otherwise adequate to assure continued compliance and to detect non-compliance. No Credit Party is a "covered entity" as defined in 45 C.F.R. § 160.103.

(i) *Corporate Integrity Agreement*. Neither any Credit Party or Subsidiary or, to the Knowledge of Borrower, Affiliate, nor any officer, director, managing employee or, to the Knowledge of Borrower, agent (as those terms are defined in 42 C.F.R. § 1001.1001) of any Credit Party or Subsidiary, is a party or is otherwise subject to any order, individual integrity agreement, or corporate integrity agreement with any U.S. Governmental Authority concerning compliance with any laws, rules or regulations, issued under or in connection with a Governmental Payor Program.

4.20. Regulatory Approvals.

(a) Except as set forth on Schedule 4.20(a) of the Disclosure Letter, each Credit Party and each Subsidiary involved in any research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of any Product in the Territory has all U.S. Regulatory Approvals material to the conduct of its business and operations.

(b) Each Credit Party, each Subsidiary (as applicable) and, to the Knowledge of Borrower, each licensee of a Credit Party or a Subsidiary of any U.S. Intellectual Property relating to any Product, is in compliance with, and at all times during the past three (3) years, has complied with, all applicable, federal, state and local laws, rules and regulations governing the research, development, manufacture, production, use, commercialization, marketing, importing, distribution or sale of any Product in the Territory, including all such regulations promulgated by each applicable Regulatory Agency, except where such noncompliance would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change. No Credit Party or its Subsidiaries has received any written notice from any Regulatory Agency citing action or inaction by any Credit Party or any of its Subsidiaries that would constitute a violation of any applicable foreign, federal, state or local laws, rules, or regulations, including a Warning Letter or Untitled Letter from FDA, which could reasonably be expected to result in a Material Adverse Change.

4.21. Supply and Manufacturing.

(a) Except as set forth on Schedule 4.21(a) of the Disclosure Letter, to the Knowledge of Borrower, each Product has at all times in the past four (4) years been manufactured in sufficient quantities and of a sufficient quality to satisfy demand of such Product in the Territory, without the occurrence of any event causing inventory of such Product to have become exhausted prior to satisfying such demand or any other event in which the manufacture and release to the market of such Product in the Territory does not satisfy the sales demand for such Product in the Territory.

(b) Except as disclosed in the Exchange Act Documents or set forth on Schedule 4.21(b) of the Disclosure Letter, to the Knowledge of Borrower, (i) no manufacturer of any Product has received in the past four (4) years a Form 483 or is currently subject to a Form 483 directly relating to any Product with respect to any facility in the Territory manufacturing any Product, except, as of the Tranche B Closing Date (as applicable), in each case, as could not, individually or in the aggregate, reasonably be expected to result in a material adverse effect on any Product in the Territory and (ii) with respect to each such Form 483 received (if any), all material scientific and technical violations or other issues relating to good manufacturing practice requirements documented therein, and any disputes regarding any such violations or issues, have been corrected or otherwise resolved, except, as of the Tranche B Closing Date (as applicable), in each case, as could not, individually or in the aggregate, reasonably be expected to result in a material adverse effect on any Product in the Territory.

(c) Except as disclosed in Schedule 4.21(c), no Credit Party or any of its Subsidiaries has received any written notice from any party to any Manufacturing Agreement containing any indication by or intent or threat of, such party to reduce or cease, in any material respect, the supply of Product or the active pharmaceutical ingredient incorporated therein in the Territory through calendar year 2023 (or such earlier date in accordance with the terms and conditions of such Manufacturing Agreement, as applicable) except, as of the Tranche B Closing Date (as applicable), in each case, as could not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change.

4.22. Cybersecurity; Data Protection.

(a) Except as set forth on Schedule 4.22(a) of the Disclosure Letter, the information technology systems used in the business of Borrower and its Subsidiaries operate and perform in all material respects as required to permit Borrower and its Subsidiaries to conduct their business as presently conducted. Except as set forth on Schedule 4.22(a) of the Disclosure Letter, Borrower and its Subsidiaries have implemented and maintain a commercially reasonable enterprise-wide privacy and information security program with plans, policies and procedures for privacy, physical and cyber security, disaster recovery, business continuity and incident response, including reasonable and appropriate administrative, technical and physical safeguards to protect information subject to applicable Data Protection Laws as well as information and other materials in which Borrower or any of its Subsidiaries have Intellectual Property rights (including Company IP) or nondisclosure obligations, and the information technology systems of Borrower and each of its Subsidiaries, from any unauthorized access, use, control, disclosure, destruction or modification. Except as set forth on Schedule 4.22(a) of the Disclosure Letter, neither Borrower nor any of its Subsidiaries, nor to the Knowledge of Borrower, any vendor of Borrower or any of its Subsidiaries, has, in the past four (4) years, suffered any data breaches or other incidents that (i) have resulted in any unauthorized access, acquisition, use, control, disclosure, destruction, or modification of any information subject to Data Protection Laws, any information or other materials subject to non-disclosure obligations or any material Company IP, or (ii) have resulted in unauthorized access to, control of, or disruption of the information technology systems of Borrower or any of its Subsidiaries. Borrower and each of its Subsidiaries is in material compliance with the requirements of (A) their respective enterprise-wide privacy and information security programs, (B) applicable Data Protection Laws, (C) all Material Contracts regarding the privacy and security of customer, consumer, patient, employee and other personal data, (D) all contractual non-disclosure obligations and (E) their respective published privacy policies. In the past four (4) years, there have not been any third party claims related to, any loss, theft, unauthorized access to, or unauthorized acquisition, modification, disclosure, corruption, destruction, or other misuse of any information subject to Data Protection Laws (including any ransomware incident) that Borrower or any of its Subsidiaries creates, receives, maintains, or transmits.

(b) Except as would not cause or could not be reasonably expected to result in, individually or in the aggregate, a Material Adverse Change, to the Knowledge of Borrower, in the past four (4) years, neither Borrower nor any of its Subsidiaries has received any written notice of any claims, investigations (including investigations by any Governmental Authority), or alleged violations relating to any information subject to Data Protection Laws created, received, maintained or transmitted by Borrower or any of its Subsidiaries.

4.23. Additional Representations and Warranties.

(a) As of the Tranche A Closing Date, after giving effect to the Tranche A Loan, there is no Indebtedness other than the Existing Convertible Indebtedness, Permitted Indebtedness described in clauses (a) and (b) of the definition of "Permitted Indebtedness" and other Permitted Indebtedness in an aggregate outstanding amount not exceeding $1,000,000.

(b) There are no Hedging Agreements that are not Permitted Hedging Agreements.

5. AFFIRMATIVE COVENANTS

Each Credit Party covenants and agrees that, until payment in full of all Obligations (other than inchoate indemnity obligations), each Credit Party shall, and shall cause each of its Subsidiaries to:

5.1. Maintenance of Existence. (a) Preserve, renew and maintain in full force and effect its and all its Subsidiaries' legal existence under the Requirements of Law in their respective jurisdictions of organization, incorporation or formation; (b) take all commercially reasonable action to maintain all rights, privileges (including its good standing), permits, licenses and franchises necessary or desirable for it and all of its Subsidiaries in the ordinary course of its business, except in the case of clause (a) (other than with respect to Borrower) and clause (b) above, (i) to the extent that failure to do so could not reasonably be expected to result in a Material Adverse Change or (ii) pursuant to a transaction permitted by this Agreement; and (c) comply with all Requirements of Law of any Governmental Authority to which it is subject, except where the failure to do so could not reasonably be expected to result, individually or in the aggregate, in a Material Adverse Change.

5.2. Financial Statements, Notices. Deliver to the Collateral Agent:

(a) Financial Statements.

(i) Annual Financial Statements. As soon as available, but in any event within one hundred and twenty (120) days after the end of each fiscal year of Borrower (or such earlier date on which Borrower is required to file a Form 10-K under the Exchange Act, as applicable), beginning with the fiscal year ending December 31, 2019, a consolidated balance sheet of Borrower and its Subsidiaries as of the end of such fiscal year, and the related consolidated statements of income, cash flows and stockholders' equity for such fiscal year, setting forth in each case in comparative form the figures for the previous fiscal year, all prepared in accordance with Applicable Accounting Standards, with such consolidated financial statements to be audited and accompanied by (x) a report and opinion of Borrower's independent certified public accounting firm of recognized national standing (which report and opinion shall be prepared in accordance with Applicable Accounting Standards and shall not be subject to any qualification as to "going concern" or scope of audit (other than any qualification resulting from the Term Loan Maturity Date occurring within 12 months of the relevant audit)), stating that such financial statements fairly present, in all material respects, the consolidated financial condition, results of operations and cash flows of Borrower and its Subsidiaries as of the dates and for the periods specified in accordance with Applicable Accounting Standards, and (y) if and only if Borrower is required to comply with the internal control provisions pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 requiring an attestation report of such independent certified public accounting firm, an attestation report of such independent certified public accounting firm as to Borrower's internal controls pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 attesting to management's assessment that such internal controls meet the requirements of the Sarbanes-Oxley Act of 2002; provided, however, that Borrower shall be deemed to have made such delivery of such consolidated financial statements if such consolidated financial statements shall have been made available within the time period specified above on the SEC's EDGAR system (or any successor system adopted by the SEC);

(ii) Quarterly Financial Statements. As soon as available, but in any event within sixty (60) days after the end of each of the first three (3) fiscal quarters of each fiscal year of Borrower (or such earlier date on which Borrower is required to file a Form 10-Q under the Exchange Act, as applicable), beginning with the fiscal quarter ending March 31, 2020, a consolidated balance sheet of Borrower and its Subsidiaries as of the end of such fiscal quarter, and the related consolidated statements of income and cash flows and for such fiscal quarter and (in respect of the second and third fiscal quarters of such fiscal year) for the then-elapsed portion of Borrower's fiscal year, setting forth in each case in comparative form the figures for the comparable period or periods in the previous fiscal year, all prepared in accordance with Applicable Accounting Standards, subject to normal year-end audit adjustments and the absence of disclosures normally made in footnotes; provided, however, that Borrower shall be deemed to have made such delivery of such consolidated financial statements if such consolidated financial statements shall have been made available within the time period specified above on the SEC's EDGAR system (or any successor system adopted by the SEC). Such consolidated financial statements shall be certified by a Responsible Officer of Borrower as, to his or her knowledge, fairly presenting, in all material respects, the consolidated financial condition, results of operations and cash flows of Borrower and its Subsidiaries as of the dates and for the periods specified in accordance with Applicable Accounting Standards consistently applied, and on a basis consistent with the audited consolidated financial statements referred to under Section 5.2(a)(i), subject to normal year-end audit adjustments and the absence of footnotes; provided, however, that such certification by a Responsible Officer of Borrower shall be deemed to have made if a similar certification is required under the Sarbanes-Oxley Act of 2002 and such certification shall have been made available within the time period specified above on the SEC's EDGAR system (or any successor system adopted by the SEC); and

(iii) Information During Event of Default. As promptly as practicable (and in any event within five (5) Business Days of the request therefor), such additional information regarding the business or financial affairs of Borrower or any of its Subsidiaries, or compliance with the terms of this Agreement or any other Loan Documents, as the Collateral Agent may from time to time reasonably request during the existence of any Event of Default (subject to reasonable requirements of confidentiality, including requirements imposed by Requirements of Law or contract; provided that Borrower shall not be obligated to disclose any information that is reasonably subject to the assertion of attorney-client privilege or attorney work-product).

(b) Notice of Defaults or Events of Default, ERISA Events and Material Adverse Changes. Written notice as promptly as practicable (and in any event within five (5) Business Days) after a Responsible Officer of Borrower shall have become aware thereof, of the occurrence of any (i) Default or Event of Default, (ii) ERISA Event that results or could reasonably be expected to result in a Material Adverse Change or the imposition of a Lien on any Collateral or (iii) Material Adverse Change.

(c) Legal Action Notice. Prompt written notice (which shall be deemed given to the extent reported in the Borrower's periodic reporting under the Exchange Act and available on the SEC's EDGAR system (or any successor system adopted by the SEC)) of any legal action, litigation, investigation or proceeding pending or threatened in writing against any Credit Party or any Subsidiary (i) that could reasonably be expected to result in uninsured damages or costs to such Credit Party or such Subsidiary in an amount in excess of the materiality thresholds applied by Borrower in accordance with the Exchange Act and related regulations and standards for purposes of its Exchange Act reporting or (ii) which alleges potential violations of the Health Care Laws, the FDA Laws or any applicable statutes, rules, regulations, standards, guidelines, policies and order administered or issued by any foreign Governmental Authority, which, in the case of clauses (i) and (ii) above, could, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change; and in each such case, provide such additional information (including any material development therein) as the Collateral Agent may reasonably request in relation thereto; provided that Borrower shall not be obligated to disclose any information that is reasonably subject to the assertion of attorney-client privilege or attorney work-product.

5.3. Taxes. Timely file all U.S. federal income and other material required Tax returns and reports or extensions therefor and timely pay all material foreign, federal, state and local Taxes, assessments, deposits and contributions imposed upon it or any of its properties or assets or in respect of any of its income, businesses or franchises before any penalty or fine accrue thereon; provided, however, that no such Tax or any claim for Taxes that have become due and payable and have or may become a Lien on any Collateral shall be required to be paid if (a) it is being contested in good faith by appropriate proceedings promptly instituted and diligently conducted, so long as adequate reserves therefor have been set aside on its books and maintained in conformity with Applicable Accounting Standards, and (b) solely in the case of a Tax or claim that has or may become a Lien against any Collateral, such contest proceedings conclusively operate to stay the sale or forfeiture of any portion of any Collateral to satisfy such Tax or claim. No Credit Party will, nor will it permit any of its Subsidiaries to, file or consent to the filing of any consolidated income Tax return with any Person (other than Borrower or any of its Subsidiaries) without the Collateral Agent's consent.

5.4. Insurance. Maintain with financially sound and reputable insurance companies, insurance with respect to its properties and business against loss or damage of the kinds customarily insured against by Persons of comparable size engaged in the same or similar business, of such types and in such amounts (after giving effect to any self-insurance reasonable and customary for similarly situated Persons of comparable size engaged in the same or similar businesses as Borrower and its Subsidiaries) as are customarily carried under similar circumstances by such other Persons. Subject to Section 5.14, any products liability or general liability insurance maintained in the United States regarding Collateral shall name the Collateral Agent, on behalf of the Lenders and the other Secured Parties, as additional insured or loss payee, as applicable (the additional insured clauses or endorsements for which, in form and substance reasonably satisfactory to the Collateral Agent). So long as no Event of Default shall have occurred and be continuing, the Borrower and its Subsidiaries may retain all or any portion of the proceeds of any insurance of the Borrower and its Subsidiaries (and the Collateral Agent and each Lender shall promptly remit to the Borrower any proceeds with respect to any insurance received by it).

5.5. Operating Accounts. In the case of any Credit Party, contemporaneously with the establishment of any new Collateral Account at or with any bank or other depository or financial institution located in the United States, subject such account to a Control Agreement that is reasonably acceptable to the Collateral Agent. For each Collateral Account that each Credit Party at any time maintains, such Credit Party shall cause the applicable bank or other depository or financial institution located in the United States at or with which any Collateral Account is maintained to execute and deliver a Control Agreement or other appropriate instrument with respect to such Collateral Account to perfect the Collateral Agent's Lien, for the benefit of Lenders and the other Secured Parties, in such Collateral Account in accordance with the terms hereunder, which Control Agreement may not be terminated without the prior written consent of the Collateral Agent. The provisions of the previous two (2) sentences shall not apply to (1) accounts exclusively used for payroll, payroll Taxes and other employee wage and benefit payments to or for the benefit of any Credit Party's employees, (2) zero balance accounts, (3) accounts (including trust accounts)

used exclusively for escrow, customs, insurance or fiduciary purposes, (4) merchant accounts, (5) accounts used exclusively for compliance with any Requirements of Law to the extent such Requirements of Law prohibit the granting of a Lien thereon, (6) accounts which constitute cash collateral in respect of a Permitted Lien and (7) any other accounts designated as an Excluded Account by a Responsible Officer of Borrower in writing delivered to the Collateral Agent, the cash balance of which such accounts does not exceed $10,000,000 in the aggregate at any time (all such accounts in sub-clauses (1) through (7) above, collectively, the "**Excluded Accounts**"). Notwithstanding the foregoing, the Credit Parties shall have until the date that is ninety (90) days (or such longer period as the Collateral Agent may agree in its sole discretion) following (i) the Tranche A Closing Date to comply with the provisions of this Section 5.5 with regards to Collateral Accounts (other than Excluded Accounts) of the Credit Parties in existence on the Tranche A Closing Date (or opened during such 90-day period (or such longer period as the Collateral Agent may agree in its sole discretion)) and (ii) the closing date of any Acquisition or other Investment to comply with the provisions of this Section 5.5 with regards to Collateral Accounts (other than Excluded Accounts) of the Credit Parties acquired in connection with such Acquisition or other Investment.

5.6. Compliance with Laws. Comply in all respects with the Requirements of Law and all orders, writs, injunctions, decrees and judgments applicable to it or to its business or its assets or properties (including Environmental Laws, ERISA, Anti-Money Laundering Laws, OFAC, FCPA, Health Care Laws, FDA Laws, Data Protection Laws and the Federal Fair Labor Standards Act, and any foreign equivalents thereof), except if the failure to comply therewith could not, individually or taken together with any other such failures, reasonably be expected to result in a Material Adverse Change.

5.7. Protection of Intellectual Property Rights.

(a) Except as could not reasonably be expected to result in a Material Adverse Change, (i) protect, defend and maintain the validity and enforceability of the Company IP material to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of any Product in the Territory, including defending any future or current oppositions, interference proceedings, reissue proceedings, reexamination proceedings, inter-partes review proceedings, post-grant review proceedings, cancellation proceedings, injunctions, lawsuits, paragraph IV patent certifications or lawsuits under the Hatch-Waxman Act, hearings, investigations, complaints, arbitrations, mediations, demands, International Trade Commission investigations, decrees, or any other disputes, disagreements, or claims, challenging the legality, validity, enforceability or ownership of any Company IP; (ii) maintain the confidential nature of any material U.S. trade secrets and trade secret rights used in any research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of any Product in the Territory; and (iii) not allow any Company IP material to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of any Product in the Territory to be irrevocably abandoned, forfeited or dedicated to the public or any Current Company IP Agreement constituting a Material Contract to be terminated by Borrower or any of its Subsidiaries, as applicable, without the Collateral Agent's prior written consent (such consent not to be unreasonably withheld, conditioned or delayed); provided, however, that with respect to any such Company IP that is not owned by Borrower or any of its Subsidiaries, the obligations in clauses (i) and (iii) above shall apply only to the extent Borrower or any of its Subsidiaries have the right to take such actions or to cause any licensee or other third party to take such actions pursuant to applicable agreements or contractual rights.

(b) Except as Borrower may otherwise determine in its reasonable business or legal judgment, (i) use commercially reasonable efforts, at its (or its Subsidiaries', as applicable) sole expense, either directly or indirectly, with respect to any licensee or licensor under the terms of any Credit Party's (or any of its Subsidiary's) agreement with the respective licensee or licensor, as applicable, to take any and all actions (including taking legal action to specifically enforce the applicable terms of any license agreement) and prepare, execute, deliver and file agreements, documents or instruments which are necessary or desirable to (A) prosecute and maintain the Company IP material to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of any Product in the Territory and (B) diligently defend or assert the Company IP material to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of any Product in the Territory against material infringement, misappropriation, violation or interference by any other Persons and, in the case of Copyrights, Trademarks and Patents within the Company IP, against any claims of invalidity or unenforceability (including by bringing any legal action for infringement, dilution, violation or defending any

counterclaim of invalidity or action of a non-Affiliate third party for declaratory judgment of non-infringement or non-interference); and (ii) use commercially reasonable efforts to cause any licensee or licensor of any Company IP not to, and such Credit Party shall not, disclaim or abandon, or fail to take any action necessary or desirable to prevent the disclaimer or abandonment of Company IP material to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of any Product in the Territory, in each case only if such disclaimer or abandonment could reasonably be expected to have a Material Adverse Change.

(c) Except as Borrower may otherwise determine in its reasonable business or legal judgment, (i) protect and defend market exclusivity for the manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of any Product in the Territory through the Term Loan Maturity Date, and (ii) use commercially reasonable efforts to not allow for the manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of a generic version of any Product in the Territory before the Term Loan Maturity Date, in each case without the Collateral Agent's prior written consent.

5.8. Books and Records. Maintain proper Books, in which entries that are full, true and correct in all material respects and are in conformity with Applicable Accounting Standards consistently applied shall be made of all material financial transactions and matters involving the assets, properties and business of such Credit Party (or such Subsidiary), as the case may be.

5.9. Access to Collateral; Audits. Allow the Collateral Agent, or its agents or representatives, at any time after the occurrence and during the continuance of an Event of Default, during normal business hours and upon reasonable advance notice, to visit and inspect the Collateral and inspect, copy and audit any Credit Party's Books. The foregoing inspections and audits shall be at the relevant Credit Party's expense.

5.10. Use of Proceeds. (a) Use the proceeds of the Term Loans to fund its general corporate requirements, and (b) not use the proceeds of the Term Loans or any other Credit Extensions, directly or indirectly, for the purpose of purchasing or carrying any Margin Stock, for the purpose of reducing or retiring any Indebtedness that was originally incurred to purchase or carry any Margin Stock, for the purpose of extending credit to any other Person for the purpose of purchasing or carrying any Margin Stock or for any other purpose, in each case, that might cause any Term Loan or other Credit Extension to be considered a "purpose credit" within the meaning of Regulation T, U or X of the Federal Reserve Board. If requested by the Collateral Agent, Borrower shall complete and sign Part I of a copy of Federal Reserve Form G-3 referred to in Regulation U and deliver such copy to the Collateral Agent.

5.11. Further Assurances. Promptly upon the reasonable written request of the Collateral Agent, execute, acknowledge and deliver such further documents and do such other acts and things in order to effectuate or carry out more effectively the purposes of this Agreement and the other Loan Documents at its expense, including after the Tranche A Closing Date taking such steps as are reasonably deemed necessary or desirable by the Collateral Agent to maintain, protect and enforce its Lien, for the benefit of Lenders and the other Secured Parties, on Collateral securing the Obligations created under the Security Agreement and the other Loan Documents in accordance with the terms of the Security Agreement and the other Loan Documents, subject to Permitted Liens; provided, however, that Credit Parties and their Subsidiaries shall not be required to take any action under laws outside the United States to attach, maintain, perfect, protect or enforce any Lien of the Collateral Agent in favor and for the benefit of Lenders and the other Secured Parties on Collateral.

5.12. Additional Collateral; Guarantors. From and after the Tranche A Closing Date, except as otherwise approved in writing by the Collateral Agent, each Credit Party shall cause each of its Subsidiaries (other than Excluded Subsidiaries) to guarantee the Obligations and to cause each such Subsidiary to grant to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, a first priority security interest in and Lien upon, and pledge to the Collateral Agent for the benefit of Lenders and the other Secured Parties, subject to Permitted Liens, all of such Subsidiary's properties and assets constituting Collateral, whether now existing or hereafter acquired or existing, to secure such guaranty; provided, that such Credit Party's obligations to cause any Subsidiaries formed or acquired after the Tranche A Closing Date to take the foregoing actions shall be subject to the timing requirements of Section 5.13. Furthermore, except as otherwise approved in writing by the Collateral Agent, each Credit Party, from and after the Tranche A Closing Date, shall, and shall cause each of its Subsidiaries to, grant the Collateral

Agent, for the benefit of Lenders and the other Secured Parties, a first priority security interest in and Lien upon, and pledge to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, subject to Permitted Liens, the limitations set forth herein and the limitations set forth in the other Loan Documents, all of the Equity Interests (other than Excluded Equity Interests) in each of its Subsidiaries (including, for the avoidance of doubt, Sarepta Securities Corp., a Massachusetts corporation). Subject to Section 5.14, in connection with each pledge of certificated Equity Interests required under the Loan Documents, the Credit Parties shall deliver, or cause to be delivered, to the Collateral Agent, such certificate(s) together with stock powers or assignments, as applicable, properly endorsed for transfer to the Collateral Agent or duly executed in blank, in each case reasonably satisfactory to the Collateral Agent. Subject to Section 5.14, in connection with each pledge of uncertificated Equity Interests required under the Loan Documents, the Credit Parties shall deliver, or cause to be delivered, to the Collateral Agent an executed uncertificated stock control agreement among the issuer, the registered owner and the Collateral Agent, substantially in the form attached as an annex to the Security Agreement.

5.13. Formation or Acquisition of Subsidiaries. If Borrower or any of its Subsidiaries at any time after the Tranche A Closing Date forms or acquires a Subsidiary (including by division), as promptly as practicable but in no event later than thirty (30) days (or such longer period as the Collateral Agent may agree in its sole discretion) after such formation or acquisition: (a) without limiting the generality of clause (d) below, Borrower will cause such Subsidiary (other than an Excluded Subsidiary) to execute and deliver to the Collateral Agent a joinder to the Security Agreement in the form attached thereto and any relevant IP Agreement or other Collateral Documents, as applicable; (b) Borrower will deliver to the Collateral Agent (i) true, correct and complete copies of the Operating Documents of such Subsidiary (other than an Excluded Subsidiary), (ii) a Secretary's Certificate, certifying that the copies of the Operating Documents of such Subsidiary (other than an Excluded Subsidiary) are true, correct and complete (such Secretary's Certificate to be in form and substance reasonably satisfactory to the Collateral Agent) and (iii) a good standing certificate for such Subsidiary (other than an Excluded Subsidiary) certified by the Secretary of State (or the equivalent thereof) of its jurisdiction of organization, incorporation or formation; (c) Borrower will deliver to the Collateral Agent a Perfection Certificate, updated to reflect the formation or acquisition of such Subsidiary (other than an Excluded Subsidiary); and (d) Borrower will cause such Subsidiary to satisfy all requirements contained in this Agreement (including Section 5.12) and each other Loan Document if and to the extent applicable to such Subsidiary. Borrower, Lenders and the Collateral Agent hereby agree that any such Subsidiary (other than an Excluded Subsidiary) shall constitute a Credit Party for all purposes hereunder as of the date of the execution and delivery of the joinder contemplated by clause (a) above. Any document, agreement or instrument executed or issued pursuant to this Section 5.13 shall be a Loan Document.

5.14. Post-Closing Requirements. Borrower will, and will cause each of its Subsidiaries to, take each of the actions set forth on Schedule 5.14 of the Disclosure Letter within the time period prescribed therefor on such schedule (or such longer period as the Collateral Agent may agree in its sole discretion), which shall include, among other things, that (a) notwithstanding anything to the contrary in Section 5.4, the Credit Parties shall have until the date that is thirty (30) days following the Tranche A Closing Date (or such longer period as the Collateral Agent may agree in its sole discretion) to comply with the provisions of Section 5.4 with regards to naming the Collateral agent, on behalf of the Lenders and the other Secured Parties, as additional insured or loss payee, on any products liability and general liability insurance maintained in the United States regarding Collateral on the Tranche A Closing Date and (b) notwithstanding anything to the contrary in Section 5.5, the Credit Parties shall have until the date that is ninety (90) days following the Tranche A Closing Date (or such longer period as the Collateral Agent may agree in its sole discretion) to comply with the provisions of Section 5.5 with regards to Collateral Accounts of the Credit Parties in existence on the Tranche A Closing Date or opened during such 90-day period (or such longer period as the Collateral Agent may agree in its sole discretion). All representations and warranties and covenants contained in this Agreement and the other Loan Documents shall be deemed modified to the extent necessary to take the actions set forth on Schedule 5.14 of the Disclosure Letter within the time periods set forth therein, rather than elsewhere provided in the Loan Documents, such that to the extent any such action set forth in Schedule 5.14 of the Disclosure Letter is not overdue, the applicable Credit Party shall not be in breach of any representation or warranty or covenant contained in this Agreement or any other Loan Document applicable to such action for the period from the Tranche A Closing Date until the date on which such action is required to be fulfilled as set forth on Schedule 5.14 of the Disclosure Letter.

5.15. Inventory; Returns; Maintenance of Properties. Keep all Inventory in material compliance with all applicable FDA Good Manufacturing Practices. Each Credit Party will, and will cause each of its Subsidiaries to, maintain or cause to be maintained in good repair, working order and condition, ordinary wear and tear, casualty and condemnation excepted, all material tangible properties used or useful in its respective business, and from time to time will make or cause to be made all appropriate repairs, renewals and replacements thereof, except, in each case, where failure to do so could not reasonably be expected to result in a Material Adverse Change.

6. NEGATIVE COVENANTS

Each Credit Party covenants and agrees that, until payment in full of all Obligations (other than inchoate indemnity obligations), such Credit Party shall not, and shall cause each of its Subsidiaries not to:

6.1. Dispositions. Convey, sell, lease, transfer, assign, covenant not to sue, enter into a coexistence agreement, exclusively or non-exclusively license out, or otherwise dispose of (including any sale-leaseback or any transfer of assets pursuant to a plan of division), directly or indirectly and whether in one or a series of transactions (collectively, "**Transfer**"), all or any part of any Company IP, any Current IP Agreement, any Manufacturing Agreement, any Material Contract, any Collateral Account or any Equity Interests in Sarepta Securities Corp., a Massachusetts corporation; except, in each case of this Section 6.1: (i) Transfers that are under Permitted Licenses or made in connection with Permitted Liens; (ii) intercompany licenses or grants of rights of distribution, co-promotion or similar commercial rights between or among the Credit Parties or their Subsidiaries; (iii) Transfers between or among Credit Parties, provided that any and all steps as may be required to be taken in order to maintain a first priority security interest in and Lien upon such Collateral (including any Company IP constituting Collateral, Collateral Accounts and Equity Interests in Sarepta Securities Corp., a Massachusetts corporation), are taken contemporaneously with the completion of any such Transfer; (iv) Transfers by any Subsidiary that is not a Credit Party (1) to the Borrower or any other Credit Party or (2) to any other Subsidiary that is not a Credit Party; and (v) Transfers of Company IP, in each case not relating in any way to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of any Product in the Territory.

6.2. Fundamental Changes. Without at least ten (10) days prior written notice to the Collateral Agent, solely in the case of a Credit Party: (i) change its jurisdiction of organization, incorporation or formation, (ii) change its organizational structure or type, (iii) change its legal name, or (iv) change any organizational number (if any) assigned by its jurisdiction of organization, incorporation or formation.

6.3. Mergers, Liquidations or Dissolutions. Merge, divide itself into two (2) or more entities, consolidate, liquidate or dissolve, or permit any of its Subsidiaries to merge, divide itself into two (2) or more entities, consolidate, liquidate or dissolve with or into any other Person, except that:

(a) any Subsidiary of Borrower may merge, consolidate, liquidate or dissolve with or into Borrower, provided that Borrower is the surviving entity,

(b) any Subsidiary of Borrower may merge, consolidate, liquidate or dissolve with or into any other Subsidiary of Borrower, provided that if any party to such merger, consolidation, liquidation or dissolution is a Credit Party then either (i) such Credit Party is the surviving entity or (ii) the surviving or resulting entity executes and delivers to the Collateral Agent a joinder to the Security Agreement in the form attached thereto and any relevant IP Agreement or other Collateral Documents, as applicable, and otherwise satisfies the requirements of Section 5.13 substantially contemporaneously with completion of such merger or consolidation;

(c) any Subsidiary of Borrower may divide itself into two (2) or more entities or be dissolved or liquidated, provided that, if such Subsidiary is a Credit Party, the properties and assets of such Subsidiary are allocated or distributed to an existing or newly-formed Credit Party;

(d) any Subsidiary of Borrower that is not a Credit Party, the Equity Interests of which are excluded from Collateral, may merge, divide itself into two (2) or more entities, consolidate, liquidate or dissolve with or into any other Person in a transaction not otherwise prohibited by this Agreement;

(e) Borrower may consummate a merger so long as no Change of Control would result therefrom; and

(f) any Investment or disposition by a Subsidiary of the Borrower not prohibited by this Agreement may be structured as a merger, consolidation, liquidation or dissolution.

6.4. Indebtedness. Directly or indirectly, create, incur, assume or guaranty, or otherwise become or remain directly or indirectly liable with respect to, any Indebtedness (including any Indebtedness consisting of obligations evidenced by a bond, debenture, note or other similar instrument) that is not Permitted Indebtedness; provided, however, that the accrual of interest, the accretion of accreted value and the payment of interest in the form of additional Indebtedness shall not be deemed to be an incurrence of Indebtedness for purposes of this Section 6.4.

6.5. Encumbrances. Except for Permitted Liens, (i) create, incur, allow, or suffer to exist any Lien on any Collateral (or any portion thereof) or all or any part of any Company IP that does not constitute Collateral, or (ii) permit (other than pursuant to the terms of the Loan Documents) any material portion of the Collateral (or, in the case of Collateral consisting of Company IP relating to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of any Product in the Territory, Collateral Accounts or Equity Interests in Sarepta Securities Corp., a Massachusetts corporation, any portion) not to be subject to the first priority security interest granted in the Loan Documents or otherwise pursuant to the Collateral Documents, in each case of this clause (ii), other than as a direct result of any action by the Collateral Agent or any Lender or failure of the Collateral Agent or any Lender to perform an obligation thereof under the Loan Documents.

6.6. No Further Negative Pledges; Negative Pledge.

(a) No Credit Party nor any of its Subsidiaries shall enter into any agreement, document or instrument directly or indirectly prohibiting (or having the effect of prohibiting) or limiting the ability of such Credit Party or Subsidiary to create, incur, assume or suffer to exist any Lien upon any Collateral, whether now owned or hereafter acquired, in favor of the Collateral Agent, for the benefit of Lenders and the other Secured Parties, with respect to the Obligations or under the Loan Documents, in each case of this Section 6.6, other than Permitted Negative Pledges.

(b) Notwithstanding anything to the contrary in Section 6.1 or Section 6.5, no Credit Party will sell, assign, transfer, exchange or otherwise dispose of, or create, incur, allow or suffer to exist any Lien on, any Equity Interests constituting Collateral issued by any Subsidiary which are owned or otherwise held by such Credit Party, except for: (i) Permitted Liens; (ii) transfers between or among Credit Parties, provided that any and all steps as may be required to be taken in order to create and maintain a first priority security interest in and Lien upon such Equity Interests in favor of the Collateral Agent, for the benefit of Lenders and the other Secured Parties, are taken contemporaneously with the completion of any such transfer; and (iii) sales, assignments, transfers, exchanges or other dispositions to qualify directors if required by Requirements of Law or otherwise permitted under this Agreement, provided that such sale, assignment, transfer, exchange or other disposition shall be for the minimum number of Equity Interests as are necessary for such qualification under Requirements of Law.

6.7. Maintenance of Collateral Accounts. No Credit Party shall maintain any Collateral Account in the United States, except pursuant to the terms of Section 5.5 hereof.

6.8. Distributions. Pay any dividends or make any distribution or payment on or redeem, retire or purchase any Equity Interests, except, in each case of this Section 6.8, for Permitted Distributions.

Notwithstanding the foregoing, and for the avoidance of doubt, this Section 6.8 shall not prohibit (i) the conversion by holders of (including any cash payment upon conversion), or required payment of any principal or premium on (including, for the avoidance of doubt, in respect of a required repurchase in connection with the redemption of Permitted Convertible Debt upon satisfaction of a condition related to the stock price of Borrower's common stock) or required payment of any interest with respect to, any Permitted Convertible Indebtedness, in each case in accordance with the terms of the indenture governing such Permitted Convertible Indebtedness, or (ii) the entry into (including the payment of premiums in connection therewith) or any required payment with respect to, or required early unwind or settlement of, any Permitted Bond Hedge Transaction or Permitted Warrant Transaction, in each case in accordance with the terms of the agreement governing such Permitted Bond Hedge Transaction or Permitted Warrant Transaction.

Notwithstanding the foregoing, Borrower may repurchase, exchange or induce the conversion of Permitted Convertible Indebtedness by delivery of shares of Borrower's common stock or a different series of Permitted Convertible Indebtedness or by payment of cash (in an amount that does not exceed the proceeds received by Borrower from the substantially concurrent issuance of shares of Borrower's common stock *plus* the net cash proceeds, if any, received by the Borrower pursuant to the related exercise or early unwind or termination of the related Permitted Bond Hedge Transactions and Permitted Warrant Transactions, if any, pursuant to the immediately following proviso); provided that, for the avoidance of doubt, substantially concurrently with, or a commercially reasonable period of time before or after, the related settlement date for the Permitted Convertible Debt that are so repurchased, exchanged or converted, Borrower may exercise or unwind or terminate early (whether in cash, shares or any combination thereof) the portion of the Permitted Bond Hedge Transactions and Permitted Warrant Transactions, if any, corresponding to such Permitted Convertible Indebtedness that is so repurchased, exchanged or converted.

6.9. No Restrictions on Domestic Subsidiary Distributions. No Credit Party nor any of its Subsidiaries shall enter into any agreement, document or instrument directly or indirectly prohibiting (or having the effect of prohibiting) or limiting the ability of any Domestic Subsidiary of Borrower to (a) pay dividends or make any other distributions on any of such Domestic Subsidiary's Equity Interests owned by Borrower or any other Domestic Subsidiary of Borrower, (b) repay or prepay any Indebtedness owed by such Domestic Subsidiary to Borrower or any other Domestic Subsidiary of Borrower, (c) make loans or advances to Borrower or any other Domestic Subsidiary of Borrower, or (d) transfer, lease or license any Collateral to Borrower or any other Domestic Subsidiary of Borrower, except, in each case of this Section 6.9, for Permitted Subsidiary Distribution Restrictions.

***6.10.* Subordinated Debt**. Make or permit any voluntary or optional prepayment of any Subordinated Debt not otherwise expressly permitted pursuant to the applicable intercreditor, subordination or other similar agreement to which such Subordinated Debt is subject.

6.11. Amendments or Waivers of Organizational Documents. Amend, restate, supplement or otherwise modify, or waive, any provision of its Operating Documents in a manner that could reasonably be expected to result in a Material Adverse Change.

6.12. Compliance.

(a) Become an "investment company" under the Investment Company Act of 1940 or undertake as one of its important activities extending credit to purchase or carry margin stock (as defined in Regulation U of the Board of Governors of the Federal Reserve System), or use the proceeds of any Credit Extension for that purpose;

(b) No ERISA Affiliate shall cause or suffer to exist (i) any event that would result in the imposition of a Lien on any assets or properties of any Credit Party or a Subsidiary of a Credit Party with respect to any Plan or Multiemployer Plan or (ii) any other ERISA Event that, in each case of this clause (b), could reasonably be expected to, individually or in the aggregate, result in a Material Adverse Change; or

(c) Permit the occurrence of any other event with respect to any present pension, profit sharing or deferred compensation plan that could reasonably be expected to result in a Material Adverse Change.

6.13. Compliance with Sanctions and Anti-Money Laundering Laws. The Collateral Agent and each Lender hereby notifies each Credit Party that pursuant to the requirements of Sanctions and Anti- Money Laundering Laws, and such Person's policies and practices, the Collateral Agent and each Lender is required to obtain, verify and record certain information and documentation that identifies each Credit Party and its principals, which information includes the name and address of each Credit Party and its principals and such other information that will allow the Collateral Agent and each Lender to identify such party in accordance with Sanctions and Anti- Money Laundering Laws. No Credit Party will, nor will any Credit Party permit any of its Subsidiaries or controlled Affiliates to, directly or indirectly, knowingly enter into any documents or contracts with any Blocked Person. Each Credit Party shall promptly (but in any event within three (3) Business Days) notify the Collateral Agent and each Lender in writing upon any Responsible Officer of Borrower having knowledge that any Credit Party or any Subsidiary or Affiliate of any Credit Party is a Blocked Person or (a) is convicted on, (b) pleads *nolo contendere* to, (c) is indicted on, or (d) is arraigned and held over on charges involving money laundering or predicate crimes to

money laundering. No Credit Party will, nor will any Credit Party permit any of its Subsidiaries or controlled Affiliates to, directly or indirectly, (i) conduct any business or engage in any transaction or dealing with any Blocked Person, including the making or receiving of any contribution of funds, goods or services to or for the benefit of any Blocked Person, (ii) deal in, or otherwise engage in any transaction relating to, any property or interests in property blocked pursuant to Sanctions, or (iii) engage in or conspire to engage in any transaction that evades or avoids or violates, or has the purpose of evading or avoiding, or attempts to violate, any of the prohibitions set forth in applicable Sanctions or Anti-Money Laundering Laws.

6.14. Amendments or Waivers of Current Company IP Agreements. (a) Waive, amend, cancel or terminate, exercise or fail to exercise, any material rights constituting or relating to any of the Current Company IP Agreements or (b) breach, default under, or take any action or fail to take any action that, with the passage of time or the giving of notice or both, would constitute a default or event of default under any of the Current Company IP Agreements, in each case of this Section 6.14, which could, individually or taken together with any other such waivers, amendments, cancellations, terminations, exercises or failures, reasonably be expected to result in a Material Adverse Change.

6.15. **Minimum Liquidity**. The Credit Parties shall not permit their consolidated Liquidity, tested monthly as of the last day of each month, to be less than $100,000,000. Upon the request of the Collateral Agent, Borrower will provide the Collateral Agent with bank statements or internal cash reports with respect to each Credit Party's cash accounts.

7. EVENTS OF DEFAULT

Any one of the following shall constitute an event of default (an "**Event of Default**") under this Agreement:

7.1. Payment Default. Any Credit Party fails to (a) make any payment of any principal of the Term Loans when and as the same shall become due and payable, whether at the due date thereof (including pursuant to Section 2.2(c)) or at a date fixed for prepayment (whether voluntary or mandatory) thereof or by acceleration thereof or otherwise, or (b) within five (5) Business Days after the same becomes due, any payment of interest or premium pursuant to Section 2.2, including any applicable Additional Loan Consideration, Makewhole Amount or Prepayment Premium, or any other Obligations (which five (5) Business Day cure period shall not apply to any such payments due on the Term Loan Maturity Date, such earlier date pursuant to Section 2.2(c)(ii) hereof or the date of acceleration pursuant to Section 8.1(a) hereof). A failure to pay any such interest, premium or Obligations pursuant to the foregoing clause (b) prior to the end of such five (5) Business Day-period shall not constitute an Event of Default (unless such payment is due on the Term Loan Maturity Date, such earlier date pursuant to Section 2.2(c)(ii) hereof or the date of acceleration pursuant to Section 8.1(a) hereof).

7.2. Covenant Default.

(a) The Credit Parties: (i) fail or neglect to perform any obligation in Sections 5.2(b)(i), 5.2(b)(iii), 5.4, 5.5, 5.10, 5.12, 5.13 or 5.14 or (ii) violate any covenant in Section 6; or

(b) The Credit Parties fail or neglect to perform, keep, or observe any other term, provision, condition, covenant or agreement contained in this Agreement or any Loan Documents on its part to be performed, kept or observed and such failure continues for thirty (30) days (or for ninety (90) days in the case of Section 5.2(a)(i)(y), and provided further that the failure to perform, keep, or observe Section 5.2(a)(i)(y) shall be deemed cured and such resulting Default shall be deemed to no longer exist, when the underlying cause that led to such failure and resulting Default has been cured or remediated), after the earlier of the date on which (i) a Responsible Officer of any Credit Party becomes aware of such failure and (ii) written notice thereof shall have been given to the Borrower by the Collateral Agent. Cure periods provided under this Section 7.2(b) shall not apply, among other things, to any of the covenants referenced in clause (a) above.

7.3. Material Adverse Change. A Material Adverse Change of the type described in clause (ii) or clause (iii) of the definition thereof occurs.

7.4. Attachment; Levy; Restraint on Business.

(a) (i) The service of process seeking to attach, by trustee or similar process, any funds of any Credit Party or of any entity under the control of any Credit Party (including a Subsidiary) in excess of $10,000,000 on deposit or otherwise maintained with the Collateral Agent, or (ii) a notice of lien or levy is filed against a material portion of the Collateral by any Governmental Authority, and the same under sub-clauses (i) and (ii) hereof are not, within thirty (30) days after the occurrence thereof, discharged or stayed (whether through the posting of a bond or otherwise); provided, however, that no Credit Extensions shall be made during any thirty (30) day cure period; or

(b) (i) Any material portion of Collateral is attached, seized, levied on, or comes into possession of a trustee or receiver, or (ii) any court order enjoins, restrains, or prevents Borrower and its Subsidiaries from conducting any material part of their business, taken as a whole.

7.5. Insolvency.

(a) An involuntary proceeding shall be commenced or an involuntary petition shall be filed in a court of competent jurisdiction seeking: (i) relief in respect of any Credit Party, or of a substantial part of the property of any Credit Party, under Title 11 of the United States Code, as now constituted or hereafter amended, or any other federal, state or foreign bankruptcy, insolvency, receivership or similar law; (ii) the appointment of a receiver, trustee, custodian, sequestrator, conservator or similar official for any Credit Party or for a substantial part of the property or assets of any Credit Party; or (iii) the winding-up or liquidation of any Credit Party, and such proceeding or petition shall continue undismissed or unstayed for sixty (60) days or an order or decree approving or ordering any of the foregoing shall be entered; or

(b) Any Credit Party shall: (i) voluntarily commence any proceeding or file any petition seeking relief under Title 11 of the United States Code, as now constituted or hereafter amended, or any other federal, state or foreign bankruptcy, insolvency, receivership or similar law; (ii) consent to the institution of, or fail to contest in a timely and appropriate manner, any proceeding or the filing of any petition described in clause (a) above; (iii) apply for or consent to the appointment of a receiver, trustee, custodian, sequestrator, conservator or similar official for any Credit Party or for a substantial part of the property or assets of any Credit Party; (iv) file an answer admitting the material allegations of a petition filed against it in any such proceeding; (v) make a general assignment for the benefit of creditors; (vi) become unable, admit in writing its inability or fail generally to pay its debts as they become due; (vii) take any action for the purpose of effecting any of the foregoing; or (viii) wind up or liquidate (except as otherwise expressly permitted hereunder).

7.6. Other Agreements. Any Credit Party fails to pay any Indebtedness (other than the Indebtedness represented by this Agreement and the other Loan Documents) within any applicable grace period after such payment is due and payable (including at final maturity) or after the acceleration of any such Indebtedness by the holder(s) thereof because of a default, in each case, if the total amount of such Indebtedness unpaid or accelerated exceeds $10,000,000.

7.7. Judgments. One or more final, non-appealable judgments, orders, or decrees for the payment of money in an amount in excess of $10,000,000 (but excluding any final judgments, orders, or decrees for the payment of money that are covered by independent third-party insurance as to which liability has not been denied by such insurance carrier or by an indemnification claim against a solvent and unaffiliated Person that is not a Credit Party as to which such Person has not denied liability for such claim), shall be rendered against one or more Credit Parties and the same are not, within thirty (30) days after the entry thereof, discharged or execution thereof stayed or bonded pending appeal, or such judgments are not discharged prior to the expiration of any such stay.

7.8. Misrepresentations. Any Credit Party or any Person acting for any Credit Party makes or is deemed to make any representation, warranty, or other statement now or later in this Agreement, any other Loan Document or in any writing delivered to the Collateral Agent or any Lender or to induce the Collateral Agent or any Lender to enter this Agreement or any other Loan Document, and such representation, warranty, or other statement is incorrect in any material respect (or, to the extent any such representation, warranty or other statement is qualified by materiality or Material Adverse Change, in any respect) when made or deemed to be made.

7.9. Loan Documents; Collateral. Any material provision of any Loan Document shall for any reason cease to be valid and binding on or enforceable against any Credit Party, or any Credit Party shall so state in writing or bring an action to limit its obligations or liabilities thereunder; or any Collateral Document shall for any reason (other than pursuant to the terms thereof) cease to create a valid security interest in any material portion of the Collateral purported to be covered thereby or such security interest shall for any reason (other than pursuant to the terms of the Loan Documents) cease to be a perfected and first priority security interest in any material portion of the Collateral subject thereto, subject only to Permitted Liens, in each case, other than as a direct result of any action by the Collateral Agent or any Lender or failure of the Collateral Agent or any Lender to perform an obligation thereof under the Loan Documents.

7.10. ERISA Event. An ERISA Event occurs that, individually or taken together with any other ERISA Events, results or could reasonably be expected to result in a Material Adverse Change or the imposition of a Lien on any Collateral.

8. RIGHTS AND REMEDIES UPON AN EVENT OF DEFAULT

8.1. Rights and Remedies. While an Event of Default occurs and continues, the Collateral Agent may, or at the request of the Required Lenders, will, without notice or demand:

(a) declare all Obligations (including, for the avoidance of doubt, the Makewhole Amount or Prepayment Premium that is payable pursuant to Section 2.2(e) and Section 2.2(f), as applicable) immediately due and payable (but if an Event of Default described in Section 7.5 occurs all Obligations, including the Makewhole Amount and Prepayment Premium that is payable pursuant to Section 2.2(e) and Section 2.2(f), as applicable, are automatically and immediately due and payable without any action by the Collateral Agent or any Lender), whereupon all Obligations for principal, interest, premium or otherwise (including, for the avoidance of doubt, the Makewhole Amount and Prepayment Premium that is payable pursuant to Section 2.2(e) and Section 2.2(f), as applicable) shall become due and payable by Borrower without presentment, demand, protest or other notice of any kind, which are all expressly waived by the Credit Parties hereby;

(b) stop advancing money or extending credit for Borrower's benefit under this Agreement;

(c) settle or adjust disputes and claims directly with Account Debtors for amounts on terms and in any order that the Collateral Agent considers advisable, notify any Person owing Borrower money of the Collateral Agent's security interest, for the benefit of the Lenders and the other Secured Parties, in such funds, and verify the amount of the Collateral Accounts;

(d) make any payments and do any acts it considers necessary or reasonable to protect the Collateral or the Collateral Agent's security interest, for the benefit of Lenders and the other Secured Parties, in the Collateral. Borrower shall assemble the Collateral if the Collateral Agent or the Required Lenders requests and make it available as the Collateral Agent designates or the Required Lenders designate. The Collateral Agent or its agents or representatives may enter premises where the Collateral is located, take and maintain possession of any part of the Collateral, and pay, purchase, contest, or compromise any Lien that appears to be prior or superior to its security interest, for the benefit of Lenders and the other Secured Parties, and pay all expenses incurred. Borrower grants the Collateral Agent a license to enter and occupy (and for its agents or representatives to enter and occupy) any of its premises, without charge, to exercise any of the Collateral Agent's or any Lender's rights or remedies;

(e) apply to the Obligations (i) any balances and deposits of Borrower it holds, or (ii) any amount held by the Collateral Agent owing to or for the credit or the account of Borrower;

(f) ship, reclaim, recover, store, finish, maintain, repair, prepare for sale, advertise for sale, and sell the Collateral;

(g) place a "hold" on any account maintained with the Collateral Agent or deliver a notice of exclusive control, any entitlement order, or other directions or instructions pursuant to any Control Agreement or similar agreements providing control of any Collateral;

(h) demand and receive possession of Borrower's Books regarding Collateral; and

(i) exercise all rights and remedies available to the Collateral Agent or any Lender under the Collateral Documents or any other Loan Documents or at law or equity, including all remedies provided under the Code (including disposal of the Collateral pursuant to the terms thereof).

The Collateral Agent and each Lender agrees that in connection with any foreclosure or other exercise of rights under this Agreement or any other Loan Document with respect to any Intellectual Property included in the Collateral, the rights of the licensees under any license of such Intellectual Property will not be terminated, limited or otherwise adversely affected so long as no default exists thereunder in a way that would permit the licensor to terminate such license (commonly termed a non-disturbance). Without limitation to any other provision herein or in any other Loan Document, while an Event of Default occurs and continues, at the Collateral Agent's or the Required Lenders' request, Borrower shall, promptly following the receipt of such request, take such actions as are required or necessary to allow the Collateral Agent to collect, receive, appropriate and realize upon Borrower's rights and interests in, to and under any Current Company IP Agreement constituting Collateral, including in connection with any foreclosure or other exercise of the Collateral Agent's or any Lender's rights with respect thereto (including, for the avoidance of doubt, using reasonable best efforts to obtain the written consent of any counterparty to the exercise by the Collateral Agent or any Lender of any and all rights and remedies under this Agreement or any other Loan Document with respect to any Current Company IP Agreement constituting Collateral, in form and substance reasonably satisfactory to the Collateral Agent).

8.2. Power of Attorney. Borrower hereby irrevocably appoints the Collateral Agent and any Related Party thereof as its lawful attorney-in-fact, exercisable upon the occurrence and during the continuance of an Event of Default, to: (a) endorse Borrower's name on any checks or other forms of payment or security; (b) sign Borrower's name on any invoice or bill of lading for any Account or drafts against Account Debtors; (c) settle and adjust disputes and claims about the Collateral Accounts directly with depository banks where the Collateral Accounts are maintained, for amounts and on terms the Collateral Agent determines reasonable; (d) make, settle, and adjust all claims under Borrower's products liability or general liability insurance policies maintained in the United States regarding Collateral; (e) pay, contest or settle any Lien, charge, encumbrance, security interest, and adverse claim in or to the Collateral, or any judgment based thereon, or otherwise take any action to terminate or discharge the same; and (f) transfer the Collateral into the name of the Collateral Agent or a third party as the Code permits. Borrower hereby appoints the Collateral Agent and any Related Party thereof as its lawful attorney-in-fact to file or record any documents necessary to perfect or continue the perfection of the Collateral Agent's security interest, for the benefit of Lenders and the other Secured Parties, in the Collateral regardless of whether an Event of Default has occurred until all Obligations (other than inchoate indemnity obligations) have been satisfied in full and no Lender is under any further obligation to make Credit Extensions hereunder. The foregoing appointment of the Collateral Agent and any Related Party thereof as Borrower's attorney in fact, and all of the Collateral Agent's (or such Related Party's) rights and powers, coupled with an interest, are irrevocable until all Obligations (other than inchoate indemnity obligations) have been fully repaid and performed and each Lender's obligation to provide Credit Extensions terminates.

8.3. Application of Payments and Proceeds Upon Default. If an Event of Default has occurred and is continuing, the Collateral Agent shall apply any funds in its possession, whether from Borrower account balances, payments, proceeds realized as the result of any collection of Collateral Accounts or disposition of any other Collateral, or otherwise, to the Obligations in such order as the Collateral Agent shall determine in its sole discretion. Any surplus shall be paid to Borrower or other Persons legally entitled thereto; Borrower shall remain liable to Lenders for any deficiency. If the Collateral Agent or any Lender directly or indirectly enters into a deferred payment or other credit transaction with any purchaser at any sale of Collateral, the Collateral Agent or such Lender, as applicable, shall have the option, exercisable at any time, of either reducing the Obligations by the principal amount of the purchase price or deferring the reduction of the Obligations until the actual receipt by the applicable Lender(s) of cash therefor.

8.4. Collateral Agent's Liability for Collateral. So long as the Collateral Agent complies with Requirements of Law regarding the safekeeping of the Collateral in the possession or under the control of the Collateral Agent, the Collateral Agent shall not be liable or responsible for: (a) the safekeeping of the Collateral; (b) any loss or damage to the Collateral; or (c) any act or default of any other Person. In no event shall the Collateral Agent or any Lender have any liability for any diminution in the value of the Collateral for any reason. Borrower bears all risk of loss, damage or destruction of the Collateral.

8.5. No Waiver; Remedies Cumulative. The Collateral Agent's or any Lender's failure, at any time or times, to require strict performance by Borrower of any provision of this Agreement or any other Loan Document shall not waive, affect, or diminish any right of the Collateral Agent or any Lender thereafter to demand strict performance and compliance herewith or therewith. No waiver hereunder shall be effective unless signed by the party granting the waiver and then is only effective for the specific instance and purpose for which it is given. Each of the Collateral Agent's and Lender's rights and remedies under this Agreement and the other Loan Documents are cumulative. Each of the Collateral Agent and Lenders has all rights and remedies provided under the Code, by law, or in equity. The exercise by the Collateral Agent or any Lender of one right or remedy is not an election and shall not preclude the Collateral Agent or any Lender from exercising any other remedy under this Agreement or other remedy available at law or in equity, and the waiver by the Collateral Agent or any Lender of any Event of Default is not a continuing waiver. The Collateral Agent's or any Lender's delay in exercising any remedy is not a waiver, election, or acquiescence.

8.6. Demand Waiver; Makewhole Amount; Prepayment Premium. Borrower waives demand, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension, or renewal of accounts, documents, instruments, chattel paper, and guarantees held by the Collateral Agent on which Borrower is liable. Borrower acknowledges and agrees that if the maturity of all Obligations shall be accelerated pursuant to Section 8.1(a) by reason of the occurrence of an Event of Default, the applicable Makewhole Amount and Prepayment Premium that is payable pursuant to Section 2.2(e) and Section 2.2(f) shall become due and payable by Borrower upon such acceleration, whether such acceleration is automatic or is effected by the Collateral Agent's or any Lender's declaration thereof, as provided in Section 8.1(a), and Borrower shall pay the applicable Makewhole Amount and Prepayment Premium that is payable pursuant to Section 2.2(e) and Section 2.2(f) as compensation to Lenders for the loss of its investment opportunity and not as a penalty, and Borrower waives any right to object thereto in any voluntary or involuntary bankruptcy, insolvency or similar proceeding or otherwise.

9. NOTICES

All notices, consents, requests, approvals, demands, or other communication by any party to this Agreement or any other Loan Document must be in writing and shall be deemed to have been validly served, given, or delivered: (a) upon the earlier of actual receipt and three (3) Business Days after deposit in the U.S. mail, first class, registered or certified mail return receipt requested, with proper postage prepaid; (b) upon transmission, when sent by electronic mail or facsimile transmission; (c) one (1) Business Day after deposit with a reputable overnight courier with all charges prepaid; or (d) when delivered, if hand-delivered by messenger, all of which shall be addressed to the party to be notified and sent to the address, facsimile number, or email address (if any) indicated below. Any party to this Agreement may change its mailing or electronic mail address or facsimile number by giving all other parties hereto written notice thereof in accordance with the terms of this Section 9.

If to Borrower or any other Credit Party:

Sarepta Therapeutics, Inc.
215 First Street, Suite 415
Cambridge, MA 02142
Attention: Kevin Tan
Telephone: [**]
Email: [**]

Sarepta Therapeutics, Inc.
215 First Street, Suite 415
Cambridge, MA 02142
Attention: Matthew Gall
Telephone: [**]
Email: [**]

Sarepta Therapeutics, Inc.
215 First Street, Suite 415
Cambridge, MA 02142
Attention: David Tyronne Howton
Telephone: [**]
Email: [**]

with a copy to (which shall not constitute notice) to:

Ropes & Gray LLP
Prudential Tower, 800 Boylston Street
Boston, MA 02199-3600
Attn: Kevin T. Jarboe
Telephone: [**]
Facsimile: [**]
Email: [**]

If to the Collateral Agent: BioPharma Credit PLC

c/o Beaufort House
51 New North Road
Exeter EX4 4EP
United Kingdom
Attn: Company Secretary
Tel: [**]
Fax: [**]
Email: [**]

with copies (which shall not constitute notice) to:

Pharmakon Advisors LP
110 East 59th Street, #3300
New York, NY 10022
Attn: Pedro Gonzalez de Cosio
Phone: [**]
Fax: [**]
Email: [**]

and

Akin Gump Strauss Hauer & Feld LLP

One Bryant Park
New York, NY 10036-6745
Attn: Geoffrey E. Secol
Phone: [**]
Fax: [**]
Email: [**]

If to any Lender: To the address set forth on Exhibit D attached hereto.

10. CHOICE OF LAW, VENUE, AND JURY TRIAL WAIVER

THIS AGREEMENT AND THE OTHER LOAN DOCUMENTS AND ANY CLAIMS, CONTROVERSY, DISPUTE OR CAUSE OF ACTION (WHETHER IN CONTRACT OR TORT OR OTHERWISE) BASED UPON, ARISING OUT OF OR RELATING TO THIS AGREEMENT OR ANY OTHER LOAN DOCUMENT AND THE TRANSACTIONS CONTEMPLATED HEREBY AND THEREBY SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE LAW OF THE STATE OF NEW YORK. Each party hereto submits to the exclusive jurisdiction of the courts of the State of New York sitting in New York County, and of the United States District Court of the Southern District of New York, and any appellate court from any thereof, and agrees that all claims in respect of any such action, litigation or proceeding may be heard and determined in such New York State court or, to the fullest extent permitted by Requirements of Law, in such Federal court; provided, however, that nothing in this Agreement shall be deemed to operate to preclude the Collateral Agent or any Lender from bringing suit or taking other legal action in any other jurisdiction to realize on the Collateral or any other security for the Obligations, or to enforce a judgment or other court order in favor of the Collateral Agent or any Lender. Each party hereto expressly submits and consents in advance to such jurisdiction in any action or suit commenced in any such court, and each party hereto hereby waives any objection that it may have based upon lack of personal jurisdiction, improper venue, or *forum non conveniens* and hereby consents to the granting of such legal or equitable relief as is deemed appropriate by such court. Each party hereto hereby waives personal service of the summons, complaints, and other process issued in such action or suit and agrees that service of such summons, complaints, and other process may be made by registered or certified mail addressed to such party at the address set forth in (or otherwise provided in accordance with the terms of) Section 9 of this Agreement and that service so made shall be deemed completed upon the earlier to occur of such party's actual receipt thereof or three (3) days after deposit in the U.S. mails, proper postage prepaid.

TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, EACH PARTY HERETO WAIVES ITS RIGHT TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION ARISING OUT OF OR BASED UPON THIS AGREEMENT, THE LOAN DOCUMENTS OR ANY CONTEMPLATED TRANSACTION, INCLUDING CONTRACT, TORT, BREACH OF DUTY AND ALL OTHER CLAIMS. THIS WAIVER IS A MATERIAL INDUCEMENT FOR ALL PARTIES HERETO TO ENTER INTO THIS AGREEMENT. EACH PARTY HERETO HAS REVIEWED THIS WAIVER WITH ITS COUNSEL.

11. GENERAL PROVISIONS

11.1. Successors and Assigns.

(a) This Agreement binds and is for the benefit of the parties hereto and their respective successors and permitted assigns.

(b) No Credit Party may transfer, pledge or assign this Agreement or any other Loan Document or any rights or obligations hereunder or thereunder without the prior written consent of each Lender. No Lender may at any time sell, transfer, assign or pledge this Agreement or any other Loan Document or any of its rights or obligations hereunder or thereunder, or grant a participation in all or any part of, or any interest in, such Lender's obligations, rights or benefits under this Agreement and the other Loan Documents, including with respect to any Term Loan (or any portion thereof), to any third party without Borrower's prior written consent, not to be unreasonably withheld, delayed or conditioned (any such sale, transfer, assignment, pledge or grant of a participation, a "**Lender Transfer**"); provided, however, that, subject to clause (d) below, after the occurrence and during the continuance of an Event of Default, each Lender may make a Lender Transfer to any third party without Borrower's consent; provided, further, that no Borrower consent shall be required in connection with any Lender

Transfer (i) by any Lender to any other Lender, any Subsidiary of any Lender or any Controlled Investment Affiliate of any Lender, or (ii) by any Pharmakon Lender to any third party other than a Competitor of Borrower so long as after giving effect to such Lender Transfer, one or more Pharmakon Lenders continue to hold in the aggregate at least sixty percent (60.0%) of each of (x) the outstanding aggregate principal amount of the Term Loans, (y) at any time prior to the Tranche A Closing Date, the Tranche A Commitments and (z) at any time prior to the Tranche B Closing Date, the Tranche B Commitments (so long as the Tranche B Commitments are greater than zero as of such time) and, (x) with respect to any such Lender Transfer of all or any portion of the Tranche A Commitments, the applicable Pharmakon Lender executes and delivers to Borrower a side letter agreeing that no such Lender Transfer will relieve such Pharmakon Lender of its obligation to fund its Applicable Percentage of the Tranche A Commitments hereunder, if and to the extent the transferee fails to fund its portion of the Tranche A Commitment in breach of this Agreement, or (y) with respect to any such Lender Transfer of all or any portion of the Tranche B Commitments, the applicable Pharmakon Lender executes and delivers to Borrower a side letter agreeing that no such Lender Transfer will relieve such Pharmakon Lender of its obligation to fund its Applicable Percentage of the Tranche B Commitments hereunder, if and to the extent the transferee fails to fund its portion of the Tranche B Commitment in breach of this Agreement.

(c) In the case of a Lender Transfer in the form of a participation granted by any Lender to any third party, (i) such Lender's obligations under this Agreement shall remain unchanged, (ii) such Lender shall remain solely responsible to the other parties hereto for the performance of its obligations hereunder, (iii) Borrower shall continue to deal solely and directly with such Lender in connection with such Lender's rights and obligations under this Agreement and (iv) any agreement or instrument pursuant to which such Lender sells such participation shall provide that such Lender shall retain the sole right to enforce this Agreement and to approve any amendment, modification, or other modification hereto, in each case subject to the terms and conditions of this Agreement. Borrower agrees that each participant shall be entitled to the benefits of Sections 2.5 and 2.6 (subject to the requirements and limitations therein, including the requirements under Section 2.6(d) (it being understood that the documentation required under Section 2.6(d) shall be delivered to the applicable Lender)) to the same extent as if it were a Person that had acquired its interest by assignment pursuant to clause (b) above; provided that, with respect to any participation, such participant shall not be entitled to receive any greater payment under Sections 2.5 or 2.6 than the applicable Lender (i.e., the party that participated the interest) would have been entitled to receive, except to the extent of any entitlement to receive a greater payment resulting from a Change in Law that occurs after such participant acquired the applicable participation.

(d) No Lender shall make a Lender Transfer to a Competitor of Borrower, unless an Event of Default under Section 7.1, Section 7.3 or Section 7.5 has occurred and is continuing.

(e) The Collateral Agent shall record any Lender Transfer in the Register. Each Lender shall provide Borrower and the Collateral Agent with written notice of a Lender Transfer delivered no later than five (5) Business Days prior to the date on which such Lender Transfer is consummated. For the avoidance of doubt, if any Lender sells a participation, such Lender shall, acting solely for this purpose as a non-fiduciary agent of Borrower, maintain a register on which it enters the name and address of each participant and principal amounts (and stated interest) of each participant's interest in the Term Loan(s) or other obligations under the Loan Documents (the "**Participant Register**"); provided, however, that such Lender shall have no obligation to disclose all or any portion of the Participant Register (including the identity of any participant or any information relating to a participant's interest in any commitments, loans or its other obligations under any Loan Document) to any Person except to the extent that such disclosure is necessary to establish that such commitment, loan, letter of credit or other obligation is in registered form under Section 5f.103-1(c) or Proposed Section 1.163-5(b) of the Treasury Regulations (or, in each case, any amended or successor version), or as otherwise required thereunder. The entries in the Participant Register shall be conclusive absent manifest error, and the Collateral Agent and each Lender shall treat each Person whose name is recorded in the Participant Register as the owner of such participation for all purposes of this Agreement notwithstanding any notice to the contrary.

(f) Any attempted transfer, pledge or assignment of this Agreement or any other Loan Document or any rights or obligations hereunder or thereunder in violation of this Section 11.1 shall be null and void *ab initio* and of no effect.

11.2. Indemnification.

(a) Each of the Credit Parties agrees to indemnify and hold harmless each of the Collateral Agent, Lenders and its and their respective Affiliates (and its or their respective successors and assigns) and each manager, member, partner, controlling Person, director, officer, employee, agent or sub-agent, advisor and affiliate thereof (each such Person, an "**Indemnified Person**") from and against any and all Indemnified Liabilities; provided, however, that (i) no Credit Party shall have any obligation to any Indemnified Person hereunder with respect to any Indemnified Liabilities to the extent such Indemnified Liabilities arise from the bad faith, gross negligence or willful misconduct of that Indemnified Person (or its Affiliates or controlling Persons or their respective directors, officers, managers, partners, members, agents, sub-agents or advisors), in each case, as determined by a final, non-appealable judgment of a court of competent jurisdiction, (ii) no Credit Party shall have any obligation to any Indemnified Person hereunder with respect to any Indemnified Liabilities if and to the extent such Indemnified Liabilities arise from a material breach of any obligation of such Indemnified Person hereunder, (iii) no Credit Party shall have any obligation to any Indemnified Person hereunder with respect to any Indemnified Liabilities if and to the extent such Indemnified Liabilities arise from any claim by one Indemnified Person against another Indemnified Person that does not relate to any act or omission of any Credit Party, and (iv) no Credit Party shall be liable for any settlement of any claim or proceeding effected by any Indemnified Person without the prior written consent of such Credit Party (which consent shall not be unreasonably withheld, conditioned or delayed), but if settled with such consent or if there shall be a final judgment against an Indemnified Person, each of the Credit Parties shall, jointly and severally with each other Credit Parties, indemnify and hold harmless such Indemnified Person from and against any loss or liability by reason of such settlement or judgment in the manner set forth in this Agreement. This Section 11.2(a) shall not apply with respect to Taxes other than any Taxes that represent liabilities, obligations, losses, damages, penalties, claims, costs, expenses and disbursements arising from any non-Tax claim.

(b) To the extent permitted by Requirements of Law, no party to this Agreement shall assert, and each party to this Agreement hereby waives, any claim against any other party hereto (and its or their successors and assigns), and each manager, member, partner, controlling Person, director, officer, employee, agent or sub-agent, advisor and affiliate thereof, on any theory of liability, for special, indirect, consequential or punitive damages (as opposed to direct or actual damages) (whether or not the claim therefor is based on contract, tort or duty imposed by any applicable legal requirement) arising out of, in connection with, arising out of, as a result of, or in any way related to, this Agreement or any Loan Document or any agreement or instrument contemplated hereby or thereby or referred to herein or therein, the transactions contemplated hereby or thereby, the Term Loans or the use of the proceeds thereof or any act or omission or event occurring in connection therewith, and each party to this Agreement hereby waives, releases and agrees not to sue upon any such claim or any such damages, whether or not accrued and whether or not known or suspected to exist in its favor.

(c) Any action taken by any Credit Party under or with respect to any Loan Document, even if required under any Loan Document or at the request of the Collateral Agent or any Lender, shall be at the expense of such Credit Party, and neither the Collateral Agent nor any Secured Party shall be required under any Loan Document to reimburse any Credit Party or any Subsidiary of any Credit Party therefor except as expressly provided therein. In addition, and without limiting the generality of Section 2.4, Borrower agrees to pay or reimburse upon demand each of the Collateral Agent and Lenders (and their respective successors and assigns) and each of their respective Related Parties for any and all fees, expenses and disbursements of the kind or nature described in clause (ii) of the definition of "Lender Expenses" (including, for the avoidance of doubt, the limitations specified therein) incurred by it.

11.3. Severability of Provisions. In case any provision in or obligation hereunder or under any other Loan Document shall be invalid, illegal or unenforceable in any jurisdiction, the validity, legality and enforceability of the remaining provisions or obligations, or of such provision or obligation in any other jurisdiction, shall not in any way be affected or impaired thereby.

11.4. Correction of Loan Documents. The Collateral Agent or Required Lenders may correct patent errors and fill in any blanks in the Loan Documents consistent with the agreement of the parties hereto so long as the Collateral Agent or Required Lenders, as applicable, provides the Credit Parties and the other parties hereto with written notice of such correction and allows the Credit Parties at least ten (10) days to object to such correction in writing delivered to the Collateral Agent. In the event of such objection, such correction shall not be made except by an amendment to this Agreement in accordance with Section 11.5.

11.5. Amendments in Writing; Integration.

(a) No amendment, restatement or modification of any provision of this Agreement or any other Loan Document, or waiver, discharge or termination of any obligation hereunder or thereunder, no approval or consent hereunder or thereunder (including any consent to any departure by Borrower or any other Credit Party herefrom or therefrom), shall in any event be effective unless the same shall be in writing and signed by Borrower (on its own behalf and on behalf of each other Credit Party) and the Required Lenders; provided, however, that no such amendment, restatement, modification, waiver, discharge, termination, approval or consent shall, unless in writing and signed by the Collateral Agent and the Required Lenders, affect the rights or duties of, or any amounts payable to, the Collateral Agent under this Agreement or any other Loan Document. Any such waiver, approval or consent granted shall be limited to the specific circumstance expressly described in it, and shall not apply to any subsequent or other circumstance, whether similar or dissimilar, or give rise to, or evidence, any obligation or commitment to grant any further waiver, approval or consent.

(b) This Agreement and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements. All prior agreements, understandings, representations, warranties, and negotiations among the parties hereto about the subject matter of this Agreement and the Loan Documents merge into this Agreement and the Loan Documents.

11.6. Counterparts. This Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Agreement.

11.7. Survival. All covenants, representations and warranties made in this Agreement continue in full force and effect until all Obligations (other than inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement) have been paid in full and satisfied. The obligation of Borrower or any other the Credit Parties in Section 2.4 to pay or reimburse Lender Expenses, in Section 2.6 with respect to Taxes and withholding and in Section 11.2 to indemnify Indemnified Persons shall survive until the statute of limitations with respect to such claim or cause of action shall have run.

11.8. Confidentiality. Any information regarding the Credit Parties and their Subsidiaries and their businesses provided to the Collateral Agent or any Lender by or on behalf of any Credit Party pursuant to the Loan Documents shall be deemed "Confidential Information"; provided, however, that Confidential Information does not include information that is either: (i) in the public domain or in the possession of the Collateral Agent, any Lender or any of their respective Affiliates prior to the disclosure hereunder to the Collateral Agent, any Lender or any of their respective Affiliates, or becomes part of the public domain after disclosure to the Collateral Agent, any Lender or any of their respective Affiliates, in each case, other than as a result of a breach by the Collateral Agent, any Lender or any of their respective Affiliates of the obligations under this Section 11.8; or (ii) disclosed to the Collateral Agent, any Lender or any of their respective Affiliates by a third party if the Collateral Agent, such Lender or such Affiliate, as applicable, does not know that the third party is prohibited from disclosing the information. Neither the Collateral Agent nor any Lender shall disclose any Confidential Information to a third party or use Confidential Information for any purpose other than the exercise of its rights and the performance of its duties or obligations under the Loan Documents. The foregoing in this Section 11.8 notwithstanding, the Collateral Agent and each Lender may disclose Confidential Information: (a) to any of its Subsidiaries or Affiliates; (b) to prospective transferees, purchasers or participants of any interest in the Credit Extensions (including, for the avoidance of doubt, in connection with any proposed Lender Transfer); (c) as required by law, regulation, subpoena, or other order, provided, that (x) prior to any disclosure under this clause (c), the Collateral Agent or such Lender, as applicable, agrees to endeavor to provide Borrower with prior written notice thereof and with respect to any law, regulation, subpoena or other order, to the extent that the Collateral Agent or such Lender is permitted to provide such prior notice to Borrower pursuant to the terms hereof, and (y) any disclosure under this clause (c) shall be limited solely to that portion of the Confidential Information as may be specifically compelled by such law, regulation, subpoena or other order; (d) to the extent requested by regulators having jurisdiction over the Collateral Agent or such Lender or as otherwise required in connection with the Collateral Agent's or such Lender's examination or audit by such regulators; (e) as the Collateral Agent or such Lender considers reasonably necessary in exercising remedies under the Loan Documents; (f) to third-party service providers of the Collateral Agent or such Lender; and (g) to any of the Collateral Agent's or such Lender's Related Parties; provided, however, that the third parties to which Confidential Information is disclosed pursuant to clauses (a), (b), (f) and (g) are bound by obligations of confidentiality and non-use that are no less restrictive than those contained herein.

The provisions of this Section 11.8 shall survive the termination of this Agreement.

11.9. Attorneys' Fees, Costs and Expenses. In any action or proceeding between any Credit Party and the Collateral Agent or any Lender arising out of or relating to the Loan Documents, the prevailing party shall be entitled to recover its reasonable attorneys' fees and other costs and expenses incurred, in addition to any other relief to which it may be entitled.

11.10. Right of Set-Off. In addition to any rights now or hereafter granted under Requirements of Law and not by way of limitation of any such rights, upon the occurrence of an Event of Default and at any time thereafter during the continuance of any Event of Default, each Lender is hereby authorized by each Credit Party at any time or from time to time, without prior notice to any Credit Party, any such notice being hereby expressly waived by Borrower (on its own behalf and on behalf of each other Credit Party), to set off and to appropriate and to apply any and all deposits (general or special, including Indebtedness evidenced by certificates of deposit, whether matured or unmatured, but not including trust accounts) and any other Indebtedness at any time held or owing by such Lender to or for the credit or the account of any Credit Party against and on account of the obligations and liabilities of any Credit Party to such Lender hereunder and under the other Loan Documents, including all claims of any nature or description arising out of or connected hereto or with any other Loan Document, irrespective of whether or not (a) the Collateral Agent or such Lender shall have made any demand hereunder or (b) the principal of or the interest on the Term Loans or any other amounts due hereunder shall have become due and payable pursuant to Section 2 and although such obligations and liabilities, or any of them, may be contingent or unmatured. Each Lender agrees promptly to notify Borrower and the Collateral Agent after any such set off and application made by such Lender; provided, that the failure to give such notice shall not affect the validity of such set off and application.

11.11. Marshalling; Payments Set Aside. Neither the Collateral Agent nor any Lender shall be under any obligation to marshal any assets in favor of any Credit Party or any other Person or against or in payment of any or all of the Obligations. To the extent that any Credit Party makes a payment or payments to any Lender, or the Collateral Agent or any Lender enforces any Liens or exercises its rights of setoff, and such payment or payments or the proceeds of such enforcement or setoff or any part thereof are subsequently invalidated, declared to be fraudulent or preferential, set aside or required to be repaid to a trustee, receiver or any other party under any bankruptcy law, any other state or federal law, common law or any equitable cause, then, to the extent of such recovery, the obligation or part thereof originally intended to be satisfied, and all Liens, rights and remedies therefor or related thereto, shall be revived and continued in full force and effect as if such payment or payments had not been made or such enforcement or setoff had not occurred.

11.12. Electronic Execution of Documents. The words "execution," "signed," "signature" and words of like import in any Loan Document shall be deemed to include electronic signatures or the keeping of records in electronic form, each of which shall be of the same legal effect, validity and enforceability as a manually executed signature or the use of a paper-based recordkeeping systems, as the case may be, to the extent and as provided for in any Requirements of Law, including any state law based on the Uniform Electronic Transactions Act.

11.13. Captions. Section headings herein are included herein for convenience of reference only and shall not constitute a part hereof for any other purpose or be given any substantive effect.

11.14. Construction of Agreement. The parties hereto mutually acknowledge that they and their respective attorneys have participated in the preparation and negotiation of this Agreement. In cases of uncertainty, this Agreement shall be construed without regard to which of the parties hereto caused the uncertainty to exist.

11.15. Third Parties. Nothing in this Agreement, whether express or implied, is intended to: (a) except as expressly provided in Section 11.2(a), confer any benefits, rights or remedies under or by reason of this Agreement on any Persons other than the express parties to it and their respective successors and permitted assigns; (b) relieve or discharge the obligation or liability of any Person not an express party to this Agreement; or (c) give any Person not an express party to this Agreement any right of subrogation or action against any party to this Agreement.

11.16. No Advisory or Fiduciary Duty. The Collateral Agent and each Lender may have economic interests that conflict with those of the Credit Parties. Each Credit Party agrees that nothing in the Loan Documents or otherwise will be deemed to create an advisory, fiduciary or agency relationship or fiduciary or other implied duty between any Lender or the Collateral Agent, on the one hand, and such Credit Party, its Subsidiaries, and any of their respective stockholders or affiliates, on the other hand. Each Credit Party acknowledges and agrees that (i) the transactions contemplated by the Loan Documents are arm's-length commercial transactions between each Lender and the Collateral Agent, on the one hand, and such Credit Party, its Subsidiaries and their respective affiliates, on the other hand, (ii) in connection therewith and with the process leading to such transaction, the Collateral Agent and each Lender is acting solely as a principal and not the advisor, agent or fiduciary of such Credit Party, its

Subsidiaries or their respective affiliates, management, stockholders, creditors or any other Person, (iii) neither the Collateral Agent nor any Lender has assumed an advisory or fiduciary responsibility in favor of any Credit Party, its Subsidiaries or their respective affiliates with respect to the transactions contemplated hereby or the process leading thereto (irrespective of whether the Collateral Agent or any Lender or any of their respective affiliates has advised or is currently advising such Credit Party, its Subsidiaries or their respective affiliates on other matters) or any other obligation to such Credit Party, its Subsidiaries or their respective affiliates except the obligations expressly set forth in the Loan Documents and (iv) each Credit Party, its Subsidiaries and their respective affiliates have consulted their own legal and financial advisors to the extent each deemed appropriate. Each Credit Party further acknowledges and agrees that it is responsible for making its own independent judgment with respect to such transactions and the process leading thereto. Each Credit Party agrees that it will not claim that the Collateral Agent or any Lender has rendered advisory services of any nature or respect, or owes a fiduciary or similar duty to such Credit Party, its Subsidiaries or their respective affiliates in connection with such transaction or the process leading thereto.

12. COLLATERAL AGENT

12.1. Appointment and Authority. Each of the Lenders hereby irrevocably appoints BioPharma Credit PLC to act on its behalf as the Collateral Agent hereunder and under the other Loan Documents and authorizes the Collateral Agent to take such actions on its behalf and to exercise such powers as are delegated to the Collateral Agent by the terms hereof or thereof, together with such actions and powers as are reasonably incidental thereto. Except for Section 12.6 and Section 12.8, the provisions of this Section 12 are solely for the benefit of the Collateral Agent and the Lenders, and neither Borrower nor any other Credit Party shall have rights as a third party beneficiary of any of such provisions. Subject to Section 12.8 and Section 11.5, any action required or permitted to be taken by the Collateral Agent hereunder shall be taken with the prior approval of the Required Lenders, except for such actions as are expressly permitted in the Loan Documents to be taken by the Collateral Agent.

12.2. Rights as a Lender. The Person serving as the Collateral Agent hereunder shall have the same rights and powers in its capacity as a Lender as any other Lender and may exercise the same as though it were not the Collateral Agent and the term "Lender" or "Lenders" shall, unless otherwise expressly indicated or unless the context otherwise requires, include the Person serving as the Collateral Agent hereunder in its individual capacity. Such Person and its Affiliates may lend money to, own securities of, act as the financial advisor or in any other advisory capacity for and generally engage in any kind of business with Borrower or any Subsidiary or other Affiliate thereof as if such Person were not the Collateral Agent hereunder and without any duty to account therefor to the Lenders.

12.3. Exculpatory Provisions.

(a) The Collateral Agent shall not have any duties or obligations to the Lenders except those expressly set forth herein and in the other Loan Documents to which it is a party. Without limiting the generality of the foregoing, with respect to the Lenders, the Collateral Agent:

(i) shall not be subject to any fiduciary or other implied duties, regardless of whether a Default or Event of Default has occurred and is continuing;

(ii) shall not have any duty to take any discretionary action or exercise any discretionary powers, except discretionary rights and powers expressly contemplated hereby or by the other Loan Documents to which it is a party that the Collateral Agent is required to exercise as directed in writing by the Required Lenders (or such other number or percentage of the Lenders as shall be expressly provided for herein or in such other Loan Documents), provided that the Collateral Agent shall not be required to take any action that, in its opinion or the opinion of its counsel, may expose the Collateral Agent to liability or that is contrary to any Loan Document or Requirements of Law; and

(iii) shall not, except as expressly set forth herein and in the other Loan Documents to which it is a party, have any duty to disclose, and shall not be liable for the failure to disclose, any information relating to Borrower or any of its Affiliates that is communicated to or obtained by the Person serving as the Collateral Agent or any of its Affiliates in any capacity.

(b) The Collateral Agent shall not be liable for any action taken or not taken by it (i) with the consent or at the request of the Required Lenders (or such other number or percentage of the Lenders as shall be necessary, or as the Collateral Agent shall believe in good faith shall be necessary, under the circumstances as provided in Section 11.5) or (ii) in the absence of its own gross negligence or willful misconduct as determined by a court of competent jurisdiction by final and nonappealable judgment. The Collateral Agent shall be deemed not to have knowledge of any Default or Event of Default unless and until notice describing such Default or Event of Default is given to the Collateral Agent in writing by Borrower or a Lender.

(c) The Collateral Agent shall not be responsible for or have any duty to ascertain or inquire into (i) any statement, warranty or representation made in or in connection with this Agreement or any other Loan Document, (ii) the contents of any certificate, report or other document delivered hereunder or thereunder or in connection herewith or therewith, (iii) the performance or observance of any of the covenants, agreements or other terms or conditions set forth herein or therein or the occurrence of any Default or Event of Default, (iv) the validity, enforceability, effectiveness or genuineness of this Agreement, any other Loan Document or any other agreement, instrument or document or (v) the satisfaction of any condition set forth in Section 3 or elsewhere herein, other than to confirm receipt of items expressly required to be delivered to the Collateral Agent.

12.4. Reliance by Collateral Agent. The Collateral Agent shall be entitled to rely upon, and shall not incur any liability for relying upon, any notice, request, certificate, consent, statement, instrument, document or other writing (including any electronic message, internet or intranet website posting or other distribution) believed by it to be genuine and to have been signed, sent or otherwise authenticated by the proper Person. The Collateral Agent also may rely upon any statement made to it orally or by telephone and believed by it to have been made by the proper Person, and shall not incur any liability for relying thereon. The Collateral Agent may consult with legal counsel (who may be counsel for Borrower), independent accountants and other experts selected by it, and shall not be liable for any action taken or not taken by it in accordance with the advice of any such counsel, accountants or experts.

12.5. Delegation of Duties. The Collateral Agent may perform any and all of its duties and exercise its rights and powers hereunder or under any other Loan Document by or through any one or more sub-agents appointed by the Collateral Agent. The Collateral Agent and any such sub-agent may perform any and all of its duties and exercise its rights and powers by or through their respective Related Parties. The exculpatory provisions of this Section 12 shall apply to any such sub-agent and to the Related Parties of the Collateral Agent and any such sub-agent. The Collateral Agent shall not be responsible for the negligence or misconduct of any sub-agent except to the extent that a court of competent jurisdiction determines in a final and nonappealable judgment that the Collateral Agent acted with gross negligence or willful misconduct in the selection of such sub-agent.

12.6. Resignation of Collateral Agent. The Collateral Agent may at any time give notice of its resignation to the Lenders and Borrower. Upon the receipt of any such notice of resignation, the Required Lenders shall have the right, with the Borrower's prior written consent so long as no Event of Default has occurred and is continuing, to appoint a successor; provided, however, that Borrower's consent shall not be required in the case of any such appointment of a Pharmakon Lender or any Related Party of a Pharmakon Lender (and such Pharmakon Lender shall consult with Borrower regarding such appointment prior to the effectiveness thereof). If no successor shall have been so appointed by the Required Lenders and shall have accepted such appointment within thirty (30) days after the retiring Collateral Agent gives notice of its resignation, then the retiring Collateral Agent may, on behalf of the Lenders, with Borrower's prior written consent so long as no Event of Default has occurred and is continuing, appoint a successor Collateral Agent; provided that, whether or not a successor has been appointed or has accepted such appointment, such resignation shall become effective upon delivery of the notice thereof. Upon the acceptance of a successor's appointment as Collateral Agent hereunder, such successor shall succeed to and become vested with all of the rights, powers, privileges and duties of the retiring (or retired) Collateral Agent, and the retiring Collateral Agent shall be discharged from all of its duties and obligations under the Loan Documents (if not already discharged therefrom as provided above in this Section 12.6), other than its obligations under Section 11.8. After the retiring Collateral Agent's resignation, the provisions of this Section 12 and Section 10 shall continue in effect for the benefit of such retiring Collateral Agent, its sub-agents and their respective Related Parties in respect of any actions taken or omitted to be taken by any of them while the retiring Collateral Agent was acting as Collateral Agent. Upon any resignation by the Collateral Agent, all payments, communications and determinations provided to be made by, to or through the Collateral Agent shall instead be made by, to or through each Lender (in the case of such payments and communications) or the Required Lenders (in the case of such determinations) directly, until such time as a Person accepts an appointment as Collateral Agent in accordance with this Section 12.6.

12.7. Non-Reliance on Collateral Agent and Other Lenders. Each Lender acknowledges that it has, independently and without reliance upon the Collateral Agent or any other Lender or any of their respective Related Parties and based on such documents and information as it has deemed appropriate, made its own credit analysis and decision to enter into this Agreement and make Credit Extensions hereunder. Each Lender also acknowledges that it will, independently and without reliance upon the Collateral Agent or any other Lender or any of their respective Related Parties and based on such documents and information as it shall from time to time deem appropriate, continue to make its own decisions in taking or not taking action under or based upon this Agreement, any other Loan Document or any related agreement or any document furnished hereunder or thereunder.

12.8. Collateral and Guaranty Matters. Each Lender agrees that any action taken by the Collateral Agent or the Required Lenders in accordance with the provisions of this Agreement or of the other Loan Documents, and the exercise by the Collateral Agent or Required Lenders of the powers set forth herein or therein, together with such other powers as are reasonably incidental thereto, shall be authorized and binding upon all of the Lenders. Without limiting the generality of the foregoing, the Lenders irrevocably authorize the Collateral Agent, and the Collateral Agent agrees, upon the request of Borrower:

(a) to release any Lien on any property granted to or held by the Collateral Agent under any Collateral Document (i) upon payment in full of the Obligations (other than inchoate indemnity obligations), (ii) that is sold, transferred, disposed or to be sold, transferred, disposed as part of or in connection with any sale, transfer or other disposition (other than any sale to a Credit Party) permitted hereunder, (iii) subject to Section 11.5, if approved, authorized or ratified in writing by the Required Lenders, or (iv) to the extent such property is owned by a Guarantor upon the release of such Guarantor from its obligations under the Loan Documents pursuant to clause (c) below;

(b) to subordinate any Lien on any property granted to or held by the Collateral Agent under any Loan Document to the holder of any Lien on such property that is permitted by clause (d), (i), (n), (o), (q) and (v) of the definition of "Permitted Liens" (solely with respect to modifications, replacements, extensions or renewals of Liens permitted under clause (d), (i), (n), (o) and (q) of the definition of "Permitted Liens");

(c) to release any Guarantor from its obligations under the Loan Documents if such Person ceases to be a Subsidiary (or becomes an Excluded Subsidiary) as a result of a transaction permitted hereunder or upon payment in full of the Obligations (other than inchoate indemnity obligations);

(d) to enter into non-disturbance and similar agreements in connection with the licensing of Intellectual Property permitted pursuant to the terms of this Agreement; and

(e) to enter into a subordination, intercreditor, or other similar agreement with respect to any Indebtedness that constitutes Subordinated Debt to the extent such Subordinated Debt is permitted under the definition of "Permitted Indebtedness".

Upon request by the Collateral Agent at any time the Required Lenders will confirm in writing the Collateral Agent's authority to release or subordinate its interest in particular types or items of property, or to release any Guarantor from its obligations under the Security Agreement pursuant to this Section 12.8.

In each case as specified in this Section 12.8, the Collateral Agent will (and each Lender irrevocably authorizes the Collateral Agent to), at Borrower's expense, (A) deliver to Borrower any Collateral in the Collateral Agent's possession in connection with the release of the Collateral Agent's Lien thereon and (B) execute and deliver to the applicable Credit Party such documents as such Credit Party may reasonably request (i) to evidence the release or subordination of such item of Collateral from the Liens and security interests granted under the Collateral Documents, (ii) to enter into non-disturbance or similar agreements in connection with the licensing of Intellectual Property, (iii) to enter into a subordination, intercreditor, or other similar agreement with respect to any Indebtedness that constitutes Subordinated Debt to the extent such Subordinated Debt is permitted under the definition of "Permitted Indebtedness" or (iv) to evidence the release of any Guarantor from its obligations under the Loan Documents, in each case in accordance with the terms of the Loan Documents and this Section 12.8 and in form and substance reasonably acceptable to the Collateral Agent.

Without limiting the generality of Section 12.10 below, the Collateral Agent shall deliver to the Lenders notice of any action taken by it under this Section 12.8 promptly after the taking thereof; provided that delivery of or failure to deliver any such notice shall not affect the Collateral Agent's rights, powers, privileges and protections under this Section 12.

12.9. Reimbursement by Lenders. To the extent that Borrower for any reason fails to indefeasibly pay any amount required under Section 2.4 to be paid by it to the Collateral Agent (or any sub-agent thereof) or any Related Party of any of the foregoing, each Lender severally agrees to pay to the Collateral Agent (or any such sub-agent) or such Related Party, as the case may be, such Lender's *pro rata* share (based upon the percentages as used in determining the Required Lenders as of the time that the applicable unreimbursed expense or indemnity payment is sought) of such unpaid amount; provided that the unreimbursed expense or indemnified loss, damage, liability or related expense, as the case may be, was incurred by or asserted against the Collateral Agent (or any such sub-agent) in its capacity as such or against any Related Party of any of the foregoing acting for the Collateral Agent (or any sub-agent) in connection with such capacity.

12.10. Notices and Items to Lenders. The Collateral Agent shall deliver to the Lenders each notice, report, statement, approval, direction, consent, exemption, authorization, waiver, certificate, filing or other item received by it pursuant to this Agreement or any other Loan Document (including any item received by it pursuant to Section 3 or set forth on Schedule 5.14 of the Disclosure Letter); provided, that any delivery of or failure to deliver any such notice, report, statement, approval, direction, consent, exemption, authorization, waiver, certificate, filing or item shall not otherwise alter or effect the rights of the Lenders or the Collateral Agent under this Agreement or any other Loan Document or the validity of such item. In addition, to the extent the Collateral Agent or the Required Lenders deliver any notices, approvals, authorizations, directions, consents or waivers to Borrower pursuant to this Agreement or any other Loan Document, the Collateral Agent or the Required Lenders, as applicable, will also deliver such notice, approval, authorization, direction, consent or waiver to the other Lenders on or about the same time such notice, approval, authorization, direction, consent or waiver is provided to Borrower; provided, that the delivery of or failure to deliver such notice, approval, authorization, direction, consent or waiver to the other Lenders shall not in any way effect the obligations of Borrower, or the rights of the Collateral Agent or the Required Lenders, in respect of such notice, approval, authorization, direction, consent or waiver or the validity thereof.

13. DEFINITIONS

13.1. Definitions. For the purposes of and as used in the Loan Documents: (a) references to any Person include its successors and assigns and, in the case of any Governmental Authority, any Person succeeding to its functions and capacities; (b) except as the context otherwise requires (including to the extent otherwise expressly provided in any Loan Document), (i) references to any law, statute, treaty, order, policy, rule or regulation include any amendments, supplements and successors thereto and (ii) references to any contract, agreement, instrument or other document include any amendments, restatements, supplements or modifications thereto or thereof from time to time to the extent permitted by the provisions thereof; (c) the word "shall" is mandatory; (d) the word "may" is permissive; (e) the word "or" has the inclusive meaning represented by the phrase "and/or"; (f) the words "include", "includes" and "including" are not limiting; (g) the singular includes the plural and the plural includes the singular; (h) numbers denoting amounts that are set off in parentheses are negative unless the context dictates otherwise; (i) each authorization herein shall be deemed irrevocable and coupled with an interest; (j) all accounting terms shall be interpreted, and all determinations relating thereto shall be made, in accordance with Applicable Accounting Standards; (k) references to any time of day shall be to New York time; (l) the words "herein", "hereof", "hereby", "hereto" and "hereunder" refer to this Agreement as a whole; and (m) unless otherwise expressly provided, references to specific sections, articles, clauses, sub-clauses, annexes and exhibits are to this Agreement and references to specific schedules are to the Disclosure Letter. As used in this Agreement, the following capitalized terms have the following meanings:

"**Account**" means any "account" as defined in the Code with such additions to such term as may hereafter be made, and includes all accounts receivable, book debts, and other sums owing to Credit Parties.

"**Account Debtor**" means any "account debtor" as defined in the Code with such additions to such term as may hereafter be made.

"**Acquisition**" means (a) any Stock Acquisition, or (b) any Asset Acquisition.

"**Additional Consideration**" is defined in Section 2.7(b).

"**Additional Commitment Consideration**" is defined in Section 2.7(a).

"**Additional Loan Consideration**" is defined in Section 2.7(b).

"**Additional Tranche A Commitment Consideration**" is defined in Section 2.7(a).

"**Additional Tranche B Commitment Consideration**" is defined in Section 2.7(a).

"**Adverse Proceeding**" means any action, suit, proceeding, hearing (whether administrative, judicial or otherwise), governmental investigation or arbitration (whether or not purportedly on behalf of any Credit Party or any of its Subsidiaries) at law or in equity, or before or by any Governmental Authority, domestic or foreign (including any Environmental Claims), whether pending or, to the Knowledge of Borrower, threatened against or adversely affecting any Credit Party or any of its Subsidiaries or any property of any Credit Party or any of its Subsidiaries.

"**Affiliate**" means, with respect to any Person, each other Person that owns or controls directly or indirectly the Person, any Person that controls or is controlled by or is under common control with the Person, and each of that Person's senior executive officers, directors, partners and, for any Person that is a limited liability company or limited liability partnership, that Person's managers and members. As used in this definition, "control" means (a) direct or indirect beneficial ownership of at least fifty percent (50%) (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of the voting share capital or other equity interest in a Person or (b) the power to direct or cause the direction of the management of such Person by contract or otherwise. In no event shall the Collateral Agent or any Lender be deemed to be an Affiliate of Borrower or any of its Subsidiaries.

"**Agreement**" is defined in the preamble hereof.

"**Anti-Money Laundering Laws**" is defined in Section 4.18(b).

"**Applicable Accounting Standards**" means with respect to Borrower and its Subsidiaries, generally accepted accounting principles in the United States as set forth in the opinions and pronouncements of the Accounting Principles Board of the American Institute of Certified Public Accountants and statements and pronouncements of the Financial Accounting Standards Board or in such other statements by such other Person as may be approved by a significant segment of the accounting profession, which are applicable to the circumstances as of the date of determination, consistently applied.

"**Applicable Percentage**" means, at any time, (a) with respect to the Tranche A Loan or the Tranche A Loan Amount, the percentage equal to a fraction, the numerator of which is (i) on or prior to the Tranche A Closing Date, the amount of such Lender's Tranche A Commitment at such time and the denominator of which is the Tranche A Loan Amount at such time or (ii) thereafter, the outstanding principal amount of such Lender's portion of the Tranche A Loan at such time, and the denominator of which is the aggregate outstanding principal amount of the Tranche A Term Loan at such time, (b) with respect to the Tranche B Loan or the Tranche B Loan Amount, the percentage equal to a fraction, the numerator of which is (i) on or prior to the Tranche B Closing Date, the amount of such Lender's Tranche B Commitment at such time and the denominator of which is the Tranche B Loan Amount at such time or (ii) thereafter, the outstanding principal amount of such Lender's portion of the Tranche B Loan at such time, and the denominator of which is the aggregate outstanding principal amount of the Tranche B Term Loan at such time, and (c) with respect to the Term Loans and the Term Loan Commitments, the percentage equal to a fraction, the numerator of which is, the sum of the amount of such Lender's outstanding Term Loan Commitments and the amount of such Lender's portion of the outstanding principal amount of the Term Loans at such time, and the denominator of which is the sum of the amount of all outstanding Term Loan Commitments and the aggregate outstanding principal amount of the Term Loans at such time.

"**Asset Acquisition**" means, with respect to Borrower or any of its Subsidiaries: (a) any purchase, inbound license or other acquisition of all or substantially all of the assets of any other Person (or of any business unit, line of business or division of such Person); or (b) any other purchase, inbound license or other acquisition of any properties or assets or businesses of any other Person for any purpose other than for administrative expenses and other ordinary course expenses related to day-to-day operations.

"**Bankruptcy Code**" means Title 11 of the United States Code entitled "Bankruptcy," as now and hereafter in effect, or any successor statute.

"**Blocked Person**" means an individual or entity that is, or is owned or controlled by individuals or entities that are: (i) the subject or target of any sanctions administered or enforced by the U.S. Department of the Treasury's Office of Foreign Assets Control, the U.S. Department of State, the European Union, Her Majesty's Treasury or other relevant sanctions authority , or (ii) located, organized or resident in a country or territory that is the subject of Sanctions, including currently, Crimea, Cuba, Iran, North Korea, and Syria.

"**Board of Directors**" means, with respect to any Person, (i) in the case of any corporation, the board of directors of such Person, (ii) in the case of any limited liability company, the board of managers of such Person, or if there is none, the Board of Directors of the managing member of such Person, (iii) in the case of any partnership, the Board of Directors of the general partner of such Person and (iv) in any other case, the functional equivalent of the foregoing.

"**Board of Governors**" means the Board of Governors of the United States Federal Reserve System, or any successor thereto.

"**Books**" means all books and records including ledgers, records regarding a Credit Party's assets or liabilities, the Collateral, business operations or financial condition, and all computer programs or storage or any equipment containing such information.

"**Borrower**" is defined in the preamble hereof.

"**Borrowing Resolutions**" means, with respect to any Person, those resolutions adopted by such Person's Board of Directors and delivered by such Person to the Collateral Agent pursuant to Section 3.1 approving the Loan Documents to which such Person is a party and the transactions contemplated thereby (including the Term Loans), together with a certificate executed by its Secretary (or similar officer) on behalf of such Person certifying that (a) such Person has the authority to execute, deliver, and perform its obligations under each of the Loan Documents to which it is a party, (b) attaches as an exhibit to such certificate a true, correct, and complete copy of the resolutions then in full force and effect authorizing and ratifying the execution, delivery, and performance by such Person of the Loan Documents to which it is a party, (c) includes the name(s) and title(s) of the officers of such Person authorized to execute the Loan Documents to which such Person is a party on behalf of such Person, together with a sample of the true signature(s) of such Person(s), and (d) the Collateral Agent and each Lender may conclusively rely on such certificate with respect to the authority of such officers unless and until such Person shall have delivered to the Collateral Agent a further certificate canceling or amending such prior certificate.

"**Business Day**" means any day that is not a Saturday or a Sunday or a day on which banks are authorized or required to be closed in New York, New York, London or the Cayman Islands.

"**Capital Lease**" means, as applied to any Person, any lease of any property by that Person as lessee which, in accordance with Applicable Accounting Standards, is required to be accounted for as a capital lease on the balance sheet of that Person.

"**CFC**" means a "controlled foreign corporation" under Section 957 of the IRC.

"**Change in Control**" means: (a) a transaction or series of transactions (including any merger or consolidation with Borrower) in which any "person" or "group" (within the meaning of Section 13(d) and 14(d)(2) of the Exchange Act, but excluding any employee benefit plan of such Person or its Subsidiaries, and any Person acting in its capacity as trustee, agent or other fiduciary or administrator of any such plan) is or becomes the "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of a majority of shares of the then outstanding capital stock of Borrower ordinarily entitled to vote in the election of directors; (b) a sale of all or substantially all of the consolidated assets of Borrower and its Subsidiaries in one transaction or a series of transactions (whether by way of merger, stock purchase, asset purchase or otherwise); or (c) a merger or consolidation involving Borrower in which Borrower is not the surviving Person.

"**Change in Law**" means the occurrence, after the date of this Agreement, of any of the following: (a) the adoption or taking into effect of any law, treaty, order, policy, rule or regulation, (b) any change in any law, treaty, order, policy, rule or regulation or in the administration, interpretation or application thereof by any Governmental Authority or (c) the making or issuance of any request, guideline or directive (whether or not having the force of law) by any Governmental Authority; provided that notwithstanding anything herein to the contrary, (x) the Dodd-Frank Wall Street Reform and Consumer Protection Act and all requests, rules, guidelines or directives thereunder or issued in connection therewith and (y) all requests, rules, guidelines or directives promulgated by the Bank for International Settlements, the Basel Committee on Banking Supervision (or any successor or similar authority) or the United States or foreign regulatory authorities, in each case pursuant to Basel III, shall be deemed to be a "Change in Law", regardless of the date enacted, adopted or issued.

"**Closing Date**" means the Tranche A Closing Date or the Tranche B Closing Date, as applicable.

"**Code**" means the Uniform Commercial Code, as the same may, from time to time, be enacted and in effect in the State of New York; provided, that, to the extent that the Code is used to define any term herein or in any Loan Document and such term is defined differently in different Articles of the Code, the definition of such term contained in Article 9 of the Code shall govern; provided, further, that in the event that, by reason of mandatory provisions of law, any or all of the attachment, perfection, or priority of, or remedies with respect to, the Collateral Agent's Lien, for the benefit of Lenders and the other Secured Parties, on any Collateral is governed by the Uniform Commercial Code in effect in a jurisdiction other than the State of New York, the term "Code" shall mean the Uniform Commercial Code as enacted and in effect in such other jurisdiction solely for purposes of the provisions thereof relating to such attachment, perfection, priority, or remedies and for purposes of definitions relating to such provisions.

"**Collateral**" means, collectively, "Collateral" (as such term is defined in the Security Agreement) and all other property of whatever kind and nature subject or purported to be subject from time to time to a Lien under any Collateral Document, but in any event excluding all Excluded Property.

"**Collateral Account**" means any Deposit Account of a Credit Party maintained with a bank or other depository or financial institution located in the United States, any Securities Account of a Credit Party maintained with a securities intermediary located in the United States, or any Commodity Account of a Credit Party maintained with a commodity intermediary located in the United States, in each case, other than an Excluded Account.

"**Collateral Agent**" means BioPharma Credit PLC, in its capacity as Collateral Agent appointed under Section 12.1, and its successors in such capacity.

"**Collateral Documents**" means the Security Agreement, the Control Agreements, the IP Agreements and all other instruments, documents and agreements delivered by any Credit Party pursuant to this Agreement or any of the other Loan Documents, in each case, in order to grant to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, or perfect a Lien on any Collateral as security for the Obligations, and all amendments, restatements, modifications or supplements thereof or thereto.

"**Commodity Account**" means any "commodity account" as defined in the Code with such additions to such term as may hereafter be made.

"**Company IP**" means any and all of the following, as they exist in and throughout the Territory: (a) Current Company IP; (b) improvements, continuations, continuations-in-part, divisions, provisionals or any substitute applications, any patent issued with respect to any of the Current Company IP, any patent right claiming the composition of matter of, or the method of making or using, any Product in the Territory, any reissue, reexamination, renewal or patent term extension or adjustment (including any supplementary protection certificate) of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent; (c) trade secrets or trade secret rights, including any rights to unpatented inventions, know-how, show-how, operating manuals, confidential or proprietary information, research in progress, algorithms, data, databases, data collections, designs, processes, procedures, methods, protocols, materials, formulae, drawings, schematics, blueprints, flow charts, models, strategies, prototypes, techniques, and the results of experimentation and testing, including samples, in each case, as specifically related to any research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of any Product in the Territory; (d) any and all IP Ancillary Rights specifically relating to any of the foregoing; and (e) regulatory filings, submissions and approvals related to any research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of any Product in the Territory and all data provided in any of the foregoing.

"**Competitor**" means, at any time of determination, any Person that is an operating company directly and primarily engaged in the same or substantially the same line of business as the Borrower and its Subsidiaries, including without limitation those Persons identified in the Disclosure Letter, which Borrower may update from time to time.

"**Connection Income Taxes**" means Other Connection Taxes that are imposed on or measured by net income (however denominated) or that are franchise Taxes or branch profits Taxes.

"**Contingent Obligation**" means, for any Person, (a) any direct or indirect liability, contingent or not, of that Person for any indebtedness, lease, dividend, letter of credit or other obligation of another Person directly or indirectly guaranteed, endorsed, co-made, discounted or sold with recourse by that Person, or for which that Person is directly or indirectly liable (other than by endorsements of instruments in the course of collection) and (b) any obligation of that Person to pay an earn-out payment, milestone payment or similar contingent payment or contingent compensation to a counterparty incurred or created in connection with an Acquisition, in each case where such contingent payment or compensation becomes due and payable upon the occurrence of an event or the performance of an act (and not, for the avoidance of doubt, solely with the passage of time) except as otherwise expressly provided in clause (b) of the definition of "Indebtedness". The amount of a Contingent Obligation is the stated or determined amount of the primary obligation for which the Contingent Obligation is made or, if not determinable, the maximum reasonably anticipated liability for it reasonably determined by such Person in good faith; but the amount may not exceed the maximum of the obligations under any guarantee or other support arrangement. Notwithstanding anything to the contrary in the foregoing, any Permitted Bond Hedge Transaction and any Permitted Warrant Transaction, in each case, shall not constitute Contingent Obligations.

"**Control Agreement**" means, with respect to any Credit Party, any control agreement entered into among such Credit Party, the Collateral Agent and, in the case of a Deposit Account, the bank or other depository or financial institution located in the United States at which such Credit Party maintains such Deposit Account, or, in the case of a Securities Account or a Commodity Account, the securities intermediary or commodity intermediary located in the United States at which such Credit Party maintains such Securities Account or Commodities Account, in either case, pursuant to which the Collateral Agent obtains control (within the meaning of the Code) over such Collateral Account.

"**Controlled Investment Affiliate**" means, with respect to any Lender, any fund, investment vehicle or other Person (other than a natural person) that (a) is (or will be) engaged in making, purchasing, holding or otherwise investing in commercial loans and similar extensions of credit in the ordinary course of its activities and (b) controls, is controlled by, or under common control with, such Lender. For purposes of this definition "control" means (i) direct or indirect beneficial ownership of more than fifty percent (50%) (or such lesser percentage which is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of the voting share capital or other equity interest in a Person or (b) the power to direct or cause the direction of the management of such Person by contract or otherwise.

"**Copyrights**" means any and all copyright rights, copyright applications, copyright registrations and like protections in each work of authorship and derivative work thereof, whether published or unpublished and whether or not the same also constitutes a trade secret (and all related IP Ancillary Rights).

"**Convertible Indenture**" means that certain Indenture, dated as of November 14, 2017, between Borrower, as issuer, and U.S. Bank National Association, as trustee.

"**Convertible Notes**" means those certain 1.50% Convertible Senior Notes due 2024 issued pursuant to the Convertible Indenture.

"**Credit Extension**" means any Term Loan or any other extension of credit by any Lender for Borrower's benefit pursuant to this Agreement.

"**Credit Party**" means Borrower and each Guarantor.

"**Current Company IP**" is defined in Section 4.6(c).

"**Current Company IP Agreement**" means each of the: (a) Amended and Restated Exclusive License Agreement by and among The University of Western Australia, Sarepta Therapeutics, Inc., and Sarepta International CV dated April 10, 2013; (b) First Amendment to License Agreement by and among The University of Western Australia, Sarepta Therapeutics, Inc., and Sarepta International CV dated June 19, 2016; (c) Settlement Agreement between Sarepta Therapeutics, Inc., Sarepta International C.V. and The University of Western Australia on the one hand, and BioMarin Leiden Holding BV, BioMarin Nederlands BV and BioMarin Technologies BV on the other hand dated July 17, 2017; (d) License Agreement between Sarepta Therapeutics, Inc. and Sarepta International C.V. on the one hand and BioMarin Leiden Holding BV, BioMarin Nederlands BV and BioMarin Technologies BV on the other hand dated July 17, 2017; and (e) Non-Exclusive License Agreement between Royal Holloway and Bedford New College, on the one hand , and Sarepta Therapeutics, Inc., on the other hand, dated December 5, 2013.

"**Data Protection Laws**" means any and all foreign or domestic, statutes, ordinances, orders, rules, regulations, judgments, Governmental Approvals, or any other requirements of Governmental Authorities relating to the privacy, security, or confidentiality of personal data (including individually identifiable information) and other sensitive information, including HIPAA, Section 5 of the Federal Trade Commission Act (15 U.S.C. § 45), and GDPR.

"**Default**" means any breach of or default under any term, provision, condition, covenant or agreement contained in this Agreement or any other Loan Document or any other event, in each case that, with the giving of notice or the lapse of time or both, would constitute an Event of Default.

"**Deposit Account**" means any "deposit account" as defined in the Code with such additions to such term as may hereafter be made.

"**Disclosure Letter**" means the disclosure letter, dated the Effective Date, delivered by the Credit Parties to the Collateral Agent, as updated on the applicable Closing Date (if required and as permitted).

"**Disqualified Equity Interests**" means any Equity Interests that, by its terms (or by the terms of any security or other Equity Interests into which it is convertible or for which it is exchangeable), or upon the happening of any event or condition, (a) matures or is mandatorily redeemable, pursuant to a sinking fund obligation or otherwise (except as a result of a change of control, asset sale or similar event so long as any rights of the holders thereof upon the occurrence of a change of control, asset sale or similar event shall be subject to the prior repayment in full in cash of the Terms Loans and all other Obligations (other than inchoate indemnity obligations) and the termination of the Term Loan Commitments), (b) is redeemable at the option of the holder thereof, in whole or in part (except as a result of a change of control, asset sale or similar event so long as any rights of the holders thereof upon the occurrence of a change of control, asset sale or similar event shall be subject to the prior repayment in full in cash of the Terms Loans and all other Obligations (other than inchoate indemnity obligations) and the termination of the Term Loan Commitments), (c) provides for the scheduled payments of dividends or distributions in cash, or (d) is convertible into or exchangeable for (i) Indebtedness or (ii) any other Equity Interests that would constitute Disqualified Equity Interests, in each case of clauses (a) through (d), prior to the date that is 91 days after the Term Loan Maturity Date; provided that, if such Equity Interests is issued pursuant to any plan for the benefit of any employee, director, manager or consultant of the Borrower or its Subsidiaries or by any such plan to such employee, director, manager or consultant, such Equity Interests shall not constitute Disqualified Equity Interests solely because it may be required to be repurchased by the Borrower or its Subsidiaries in order to satisfy applicable statutory or regulatory obligations or as a result of the termination, death or disability of such employee, director, manager or consultant.

"**Dollars**," "**dollars**" or use of the sign "**$**" means only lawful money of the United States and not any other currency, regardless of whether that currency uses the "$" sign to denote its currency or may be readily converted into lawful money of the United States.

"**Domestic CFC Holdco**" means, with respect to any Credit Party, a Subsidiary of such Credit Party that (i) is organized, incorporated or formed under the laws of the United States or any state thereof and (ii) has no material assets other than equity in one or more Foreign Subsidiaries that are CFCs or in another Domestic CFC Holdco.

"**Domestic Subsidiary**" means, with respect to any Credit Party, a Subsidiary of such Credit Party that is organized, incorporated or formed under the laws of the United States or any state thereof (other than a Domestic CFC Holdco).

"**Effective Date**" is defined in the preamble hereof.

"**Environmental Claim**" means any investigation, notice, notice of violation, claim, action, suit, proceeding, demand, abatement order or other order or directive (conditional or otherwise), by any Governmental Authority or any other Person, arising (i) pursuant to or in connection with any actual or alleged violation of any Environmental Law; (ii) in connection with any Hazardous Material or any actual or alleged Hazardous Materials Activity; or (iii) in connection with any actual or alleged damage, injury, threat or harm to health, safety, natural resources or the environment.

"**Environmental Laws**" means any and all current or future, foreign or domestic, statutes, ordinances, orders, rules, regulations, judgments, Governmental Approvals, or any other requirements of Governmental Authorities relating to (i) environmental matters, including those relating to any Hazardous Materials Activity; (ii) the generation, use, storage, transportation or disposal of Hazardous Materials; or (iii) occupational safety and health, industrial hygiene, land use or the protection of human, plant or animal health or welfare, in each case, in any manner applicable to any Credit Party or any of its Subsidiaries or any Facility.

"**Equity Interests**" means, with respect to any Person, any and all shares, interests, participations or other equivalents (however designated) of capital stock of a corporation, any and all equivalent ownership interests in such Person (other than a corporation), including partnership interests and membership interests, and any and all warrants, rights or options to purchase or other arrangements or rights to acquire (by purchase, conversion, dividend, distribution or otherwise) any of the foregoing (and all other rights, powers, privileges, interests, claims and other property in any manner arising therefrom or relating thereto); provided that Equity Interests shall not include any Permitted Convertible Indebtedness.

"**ERISA**" means the Employee Retirement Income Security Act of 1974, and its regulations.

"**ERISA Affiliate**" means, with respect to any Person, any trade or business (whether or not incorporated) that, together with such Person, is treated as a single employer under Section 414(b) or (c) of the IRC or, solely for purposes of Section 302 of ERISA or Section 412 of the IRC, Section 412(m) or (o) of the IRC.

"**ERISA Event**" means (a) any "reportable event," as defined in Section 4043 of ERISA or the regulations issued thereunder, with respect to a Plan (other than an event for which the 30-day notice period is waived by regulation); (b) with respect to a Plan, the failure by Borrower or its Subsidiaries or their ERISA Affiliates to satisfy the minimum funding standard of Section 412 of the IRC and Section 302 of ERISA, whether or not waived; (c) the failure by Borrower or its Subsidiaries or their ERISA Affiliates to make by its due date a required installment under Section 430(j) of the IRC with respect to any Plan or to make any required contribution to a Multiemployer Plan; (d) the filing pursuant to Section 412(c) of the IRC or Section 302(c) of ERISA of an application for a waiver of the minimum funding standard with respect to any Plan; (e) the incurrence by Borrower or any of its ERISA Affiliates of any liability under Title IV of ERISA with respect to the termination of any Plan; (f) the receipt by Borrower or its Subsidiaries or any of their respective ERISA Affiliates from the Pension Benefit Guaranty Corporation (referred to and defined in ERISA) or a plan administrator of any notice relating to the intention to terminate any Plan or Plans under Section 4041 or 4041A of ERISA or to appoint a trustee to administer any Plan under Section 4042 of ERISA, or the occurrence of any event or condition which could reasonably be expected to constitute grounds under ERISA for the termination of, or the appointment of a trustee to administer, any Plan under Section 4041 Section 4042 of ERISA; (g) the incurrence by Borrower or its Subsidiaries or any of their respective ERISA Affiliates of any liability with respect to the withdrawal from any Plan or Multiemployer Plan; (h) the receipt by Borrower or its Subsidiaries or any of their respective ERISA Affiliates of any notice, concerning the imposition of Withdrawal Liability or a determination that a Multiemployer Plan is, or is expected to be, insolvent or in reorganization, within the meaning of Section 4245 or Section 4241, respectively, of ERISA; (i) the "substantial cessation of operations" by Borrower or its Subsidiaries or their ERISA Affiliates within the meaning of Section 4062(e) of ERISA with respect to a Plan; or (j) the occurrence of a nonexempt prohibited transaction (within the meaning of Section 4975 of the IRC or Section 406 of ERISA) which could reasonably be expected to result in material liability to Borrower or its Subsidiaries.

"**Event of Default**" is defined in Section 7.

"**Exchange Act**" means the Securities Exchange Act of 1934.

"**Exchange Act Documents**" is defined in Section 4.8(a).

"**Excluded Accounts**" is defined in Section 5.5.

"**Excluded Equity Interests**" means, collectively: (i) any Equity Interests in any Subsidiary with respect to which the grant to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of a security interest in and Lien upon, and the pledge to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of, such Equity Interests, to secure the Obligations (and any guaranty thereof) are validly prohibited by Requirements of Law; (ii) any Equity Interests in any Subsidiary with respect to which the grant to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of a security interest in and Lien upon, and the pledge to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of, such Equity Interests, to secure the Obligations (and any guaranty thereof) require the consent, approval or waiver of any Governmental Authority or other third party and such consent, approval or waiver has not been obtained by Borrower following Borrower's commercially reasonable efforts to obtain the same; (iii) any Equity Interests in any Subsidiary that is a non-Wholly-Owned Subsidiary that the grant to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of a security interest in and Lien upon, and the pledge to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of, such Equity Interests, to secure the Obligations (and any guaranty thereof) are validly prohibited by, or would give any third party (other than Borrower or an Affiliate of Borrower) the right to terminate its obligations under, the Operating Documents or the joint venture agreement or shareholder agreement with respect to, or any other contract with such third party relating to such non-Wholly-Owned Subsidiary, including any contract evidencing Indebtedness of such non-Wholly-Owned Subsidiary (other than customary non-assignment provisions which are ineffective under Article 9 of the Code or other Requirements of Law), but only, in each case, to the extent, and for so long as such Operating Document, joint venture agreement, shareholder agreement or other contract is in effect; (iv) any Equity Interests in any other Subsidiary with respect to which, Borrower and the Collateral Agent reasonably determine by mutual agreement that the cost of granting the Collateral Agent, for the benefit of Lenders and the other Secured Parties, a security interest in and Lien upon, and pledging to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, such Equity Interests, to secure the Obligations (and any guaranty thereof) are excessive, relative to the value to be afforded to the Secured Parties thereby, and (v) any voting Equity Interests in excess of sixty-five percent (65.0%) of the issued and outstanding voting Equity Interests of any Foreign Subsidiary that is a CFC or any Domestic CFC Holdco directly owned by any Credit Party. For purposes of the foregoing, "**voting Equity Interests**" means, with respect to any issuer, the issued and outstanding shares of each class of Equity Interests of such issuer entitled to vote in the election of directors or similar governing body of such issuer.

"**Excluded License**" means an exclusive license or sublicense, to a Person other than a Subsidiary of Borrower, of any Intellectual Property within the Territory covering any Product that is tantamount to a sale of substantially all rights to the Intellectual Property covering such Product because it conveys to the licensee or sublicensee exclusive rights to practice such Intellectual Property in the Territory for consideration that is not based upon future development or commercialization of any Products in the Territory (other than pursuant to so-called earn-out payments) or services by the licensee or sublicensee (other than transition services), such as, for example, consideration of only upfront advances or initial license fees or similar payments in consideration of such rights, with no anticipated subsequent payments or only de minimis payments to Borrower or any of its Subsidiaries (other than pursuant to so-called earn-out payments or transition services).

"**Excluded Property**" has the meaning set forth in the Security Agreement.

"**Excluded Subsidiaries**" means, collectively: (i) any Subsidiary with respect to which the grant to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of a security interest in and Lien upon, and the pledge to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of, such Subsidiary's properties and assets subject or purported to be subject from time to time to a Lien under any Collateral Document and the Equity Interests in such Subsidiary to secure the Obligations (and any guaranty thereof) are validly prohibited by Requirements of Law; (ii) any Subsidiary with respect to which the grant to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of a security interest in and Lien upon, and the pledge to the

Collateral Agent, for the benefit of Lenders and the other Secured Parties, of, such Subsidiary's properties and assets subject or purported to be subject from time to time to a Lien under any Collateral Document and the Equity Interests in such Subsidiary to secure the Obligations (and any guaranty thereof) require the consent, approval or waiver of any Governmental Authority or other third party (other than Borrower or an Affiliate of Borrower) and such consent, approval or waiver has not been obtained by Borrower or such Subsidiary following Borrower's and such Subsidiary's commercially reasonable efforts to obtain the same; (iii) any Subsidiary that is a non-Wholly-Owned Subsidiary; (iv) any Subsidiary that owns properties and assets with an aggregate fair market value (reasonably determined in good faith by a Responsible Officer of Borrower) of less than $5,000,000; (v) any Foreign Subsidiary; (vi) any Domestic Subsidiary that is a Subsidiary of a Foreign Subsidiary; (vii) Sarepta Securities Corp., a Massachusetts corporation; and (viii) any other Subsidiary with respect to which, Borrower and the Collateral Agent reasonably determine by mutual agreement that the cost of granting the Collateral Agent, for the benefit of Lenders and the other Secured Parties, a security interest in and Lien upon, and pledging to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, such Subsidiary's properties and assets subject or purported to be subject from time to time to a Lien under any Collateral Document and the Equity Interests of such Subsidiary to secure the Obligations (and any guaranty thereof) are excessive relative to the value to be afforded to the Secured Parties thereby.

"**Excluded Taxes**" means any of the following Taxes imposed on or with respect to Lender or required to be withheld or deducted from a payment to Lender, (a) Taxes imposed on or measured by net income (however denominated), franchise Taxes, and branch profits Taxes, in each case, (i) imposed by the United States or as a result of Lender being organized under the laws of, or having its principal office or its applicable lending office located in, the jurisdiction imposing such Tax (or any political subdivision thereof) or (ii) that are Other Connection Taxes, (b) U.S. federal withholding Taxes imposed on amounts payable to or for the account of Lender with respect to any Obligation pursuant to a law in effect on the date on which (i) Lender acquires such interest in any Obligation or (ii) Lender changes its lending office, except in each case to the extent that, pursuant to Section 2.6, amounts with respect to such Taxes were payable either to Lender's assignor immediately before Lender became a party hereto or to Lender immediately before it changed its lending office, (c) Taxes attributable to Lender's failure to comply with Section 2.6(d), and (d) any withholding Taxes imposed under FATCA.

"**Existing Convertible Indebtedness**" means unsecured Indebtedness of the Borrower evidenced by the Convertible Notes.

"**Facility**" means, with respect to any Credit Party, any real property (including all buildings, fixtures or other improvements located thereon) now, hereafter or heretofore owned, leased, operated or used by such Credit Party or any of its Subsidiaries or any of their respective predecessors or Affiliates, in each case, solely with respect to the manufacture, production, storage or distribution of any Product in the Territory.

"**FATCA**" means Sections 1471 through 1474 of the IRC, as of the date of this Agreement (including, for the avoidance of doubt, any agreements between the governments of the United States and the jurisdiction in which the applicable Lender is resident implementing such provisions), or any amended or successor version that is substantively comparable and not materially more onerous to comply with, and any current or future regulations promulgated thereunder or official interpretations thereof, any agreements entered into pursuant to Section 1471(b)(1) of the IRC, any intergovernmental agreement entered into in connection with the implementation of the foregoing sections of the IRC and any fiscal or regulatory legislation, regulations, rules or practices adopted pursuant to, or official interpretations implementing such Sections of the IRC or intergovernmental agreements.

"**FCPA**" is defined in Section 4.18(a).

"**FDA**" means the United States Food and Drug Administration.

"**FDA Good Clinical Practices**" means the applicable good clinical practice standards for pharmaceutical and biological products, as set forth in 21 C.F.R. Parts 50, 56 and 312.

"**FDA Good Laboratory Practices**" means the applicable good laboratory practice standards as set forth in 21 C.F.R. Part 58.

"**FDA Good Manufacturing Practices**" means the applicable good manufacturing practice standards as set forth in 21 C.F.R. Parts 210, 211 and 600.

"**FDA Laws**" means all applicable statutes (including the FDCA), rules and regulations implemented administered or enforced by the FDA.

"**FDCA**" is defined in Section 4.19(b).

"**Federal Reserve Board**" means the Board of Governors of the Federal Reserve System.

"**Foreign Lender**" means a Lender that is not a "United States person" as defined in Section 7701(a)(30) of the IRC.

"**Foreign Subsidiary**" means, with respect to any Credit Party, a Subsidiary of such Credit Party that is not a Domestic Subsidiary.

"**GDPR**" means the General Data Protection Regulation (EU) 2016/679.

"**Governmental Approval**" means any consent, authorization, approval, order, license, franchise, permit, certificate, accreditation, registration, filing or notice, of, issued by, from or to, or other act by or in respect of, any Governmental Authority.

"**Governmental Authority**" means any nation or government, any state or other political subdivision thereof, any agency (including Regulatory Agencies), government department, authority, instrumentality, regulatory body, court, central bank or other entity exercising executive, legislative, judicial, taxing, regulatory or administrative functions of or pertaining to government, any securities exchange and any self-regulatory organization.

"**Governmental Payor Programs**" means all governmental third party payor programs in which any Credit Party or its Subsidiaries participates, including Medicare, Medicaid, TRICARE or any other federal or state health care programs.

"**Guarantor**" means any Subsidiary that is a present or future guarantor of the Obligations.

"**Hazardous Materials**" means any chemical, material or substance, exposure to which is prohibited, limited or regulated by any Governmental Authority or which may or could pose a hazard to the health and safety of the owners, occupants or any Persons in the vicinity of any Facility or to the indoor or outdoor environment.

"**Hazardous Materials Activity**" means any past, current, proposed or threatened activity, event or occurrence involving any Hazardous Materials, including the use, manufacture, possession, storage, holding, presence, existence, location, Release, threatened Release, discharge, placement, generation, transportation, processing, construction, treatment, abatement, removal, remediation, disposal, disposition or handling of any Hazardous Materials, and any corrective action or response action with respect to any of the foregoing.

"**Health Care Laws**" means, collectively, the following, in each case to the extent applicable to any Credit Party or any of its Subsidiaries: (a) applicable federal, state or local laws, rules, regulations, orders, ordinances, statutes and requirements issued under or in connection with Medicare, Medicaid or any other Government Payor Program; (b) applicable federal and state laws and regulations governing the confidentiality of health information, including HIPAA; (c) applicable federal, state and local fraud and abuse laws of any Governmental Authority, including the federal Anti-Kickback Statute (42 U.S.C. § 1320a-7(b)), the civil False Claims Act (31 U.S.C. § 3729 et seq.), Sections 1320a-7 and 1320a-7a of Title 42 of the United States Code and the regulations promulgated pursuant to such statutes; (d) the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. No. 108-173) and the regulations promulgated thereunder; (e) the Physician Payment Sunshine Act (42 U.S.C. § 1320a-7h); (f) all applicable reporting and disclosure requirements under the Medicaid Drug Rebate Program (e.g., Monthly and Quarterly Average Manufacturer Price, Baseline Average Manufacturer Price, and Rebate Per Unit, as applicable), Medicare Part B (Quarterly Average Sales Price), Section 602 of the Veteran's Health Care Act (Public Health Service 340B Quarterly Ceiling Price), Section 603 of the Veteran's Health Care Act (Quarterly and Annual

Non-Federal Average Manufacturer Price and Federal Ceiling Price), Best Price, Federal Supply Schedule Contract Prices and Tricare Retail Pharmacy Refunds, and Medicare Part D; (g) applicable health care laws, rules, codes, statutes, regulations, orders, ordinances and requirements pertaining to Medicare or Medicaid; in each case, in any manner applicable to any Credit Party or any of its Subsidiaries; and (h) applicable federal, state or local laws, rules, regulations, ordinances, statutes and requirements relating to (i) the regulation of managed care, third party payors and Persons bearing the financial risk for the provision or arrangement of health care services, (ii) billings to insurance companies, health maintenance organizations and other Managed Care Plans or otherwise relating to insurance fraud and (iii) any insurance, health maintenance organization or managed care Requirements of Law; and (i) any other applicable health care laws, rules, codes, regulations, manuals, orders, ordinances, and statutes relating to the manufacture, sale and distribution of pharmaceutical products.

"**Hedging Agreement**" means any interest rate, currency, commodity or equity swap, collar, cap, floor or forward rate agreement, or other agreement or arrangement designed to protect a Person against fluctuations in interest rates, currency exchange rates or commodity or equity prices or values (including any option with respect to any of the foregoing and any combination of the foregoing agreements or arrangements), and any confirmation execution in connection with any such agreement or arrangement. Notwithstanding anything to the contrary in the foregoing, any Permitted Bond Hedge Transaction and any Permitted Warrant Transaction, in each case, shall not constitute Hedging Agreements of the Borrower.

"**HIPAA**" means the Health Insurance Portability and Accountability Act of 1996 (as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH) of 2009), any and all rules or regulations promulgated from time to time thereunder, and any state or federal laws with regards to the security, privacy, or notification of breaches of the confidentiality of health information which are not preempted pursuant to 45 C.F.R. Part 160, Subpart B.

"**Indebtedness**" means, with respect to any Person, without duplication: (a) all indebtedness for advanced or borrowed money of, or credit extended to, such Person; (b) all obligations issued, undertaken or assumed by such Person as the deferred purchase price of assets, properties, services or rights (other than (i) accrued expenses and trade payables entered into in the ordinary course of business consistent with past practice, (ii) obligations to pay for services provided by employees and individual independent contractors in the ordinary course of business consistent with past practice, (iii) liabilities associated with customer prepayments and deposits and (iv) prepaid or deferred revenue arising in the ordinary course of business consistent with past practice), including any obligation or liability to pay deferred purchase price or other similar deferred consideration for such assets, properties, services or rights, in each case of deferred consideration where such deferred consideration becomes due and payable upon the passage of time and excluding, for the avoidance of doubt, any Contingent Obligation described in clause (b) thereof unless and only to the extent any such Contingent Obligation is due and payable and not paid; (c) the face amount of all letters of credit issued for the account of such Person and, without duplication, all drafts drawn thereunder and all reimbursement or payment obligations with respect to letters of credit, surety bonds, performance bonds and other similar instruments issued by such Person; (d) all obligations of such Person evidenced by notes, bonds, debentures or other debt securities or similar instruments (including debt securities convertible into Equity Interests (including Permitted Convertible Indebtedness)), including obligations so evidenced incurred in connection with the acquisition of properties, assets or businesses; (e) all indebtedness of such Person created or arising under any conditional sale or other title retention agreement or incurred as financing, in either case with respect to property acquired by such Person (even though the rights and remedies of the seller or bank under such agreement in the event of default are limited to repossession or sale of such property); (f) all capital lease obligations of such Person; (g) the principal balance outstanding under any synthetic lease, off-balance sheet loan or similar off balance sheet financing product by such Person; (h) Disqualified Equity Interests; (i) all indebtedness referred to in clauses (a) through (h) above of other Persons secured by (or for which the holder of such indebtedness has an existing right, contingent or otherwise, to be secured by) any Lien upon or in assets or properties (including accounts and contracts rights) owned by such Person, even though such Person has not assumed or become liable for the payment of such indebtedness of such other Persons; and (j) all Contingent Obligations of such Person described in clause (a) of the definition thereof. Notwithstanding anything to the contrary in the foregoing, any Permitted Bond Hedge Transaction and any Permitted Warrant Transaction, in each case, shall not constitute Indebtedness.

"**Indemnified Liabilities**" means, collectively, any and all liabilities, obligations, losses, damages (including natural resource damages), penalties, claims, actions, judgments, suits, costs, reasonable and documented out-of-pocket fees, expenses and disbursements of any kind or nature whatsoever (including the reasonable and documented fees and disbursements of one counsel for Indemnified Persons plus, if required, one local legal counsel in each relevant material jurisdiction, and in the case of an actual or perceived conflict of interest, one additional counsel for such affected Indemnified Persons, in connection with any investigative, administrative or judicial proceeding or hearing commenced or threatened in writing by any Person, whether or not any such Indemnified Person shall have commenced such proceeding or hearing or be designated as a party or a potential party thereto, and any fees or expenses incurred by Indemnified Persons in enforcing the indemnity hereunder), whether direct, indirect or consequential and whether based on any federal, state or foreign laws, statutes, rules or regulations, on common law or equitable cause or on contract or otherwise, that may be imposed on, incurred by, or asserted against any such Indemnified Person, in any manner relating to or arising out of this Agreement or the other Loan Documents or the transactions contemplated hereby or thereby (including any Lender's agreement to make Credit Extensions or the use or intended use of the proceeds thereof, or any enforcement of any of the Loan Documents (including any sale of, collection from, or other realization upon any of the Collateral or the enforcement of any guaranty of the Obligations)).

"**Indemnified Person**" is defined in Section 11.2(a).

"**Indemnified Taxes**" means (a) Taxes, other than Excluded Taxes, imposed on or with respect to any payment made by or on account of any obligation of any Credit Party under any Loan Document and (b) to the extent not otherwise described in clause (a) above, Other Taxes.

"**Insolvency Proceeding**" means, with respect to any Person, any proceeding by or against such Person under the United States Bankruptcy Code, or any other bankruptcy or insolvency law, including assignments for the benefit of creditors, compositions, extensions generally with its creditors, or proceedings seeking reorganization, arrangement, or other relief.

"**Intellectual Property**" means all:

(a) Copyrights, Trademarks, and Patents;

(b) trade secrets and trade secret rights, including any rights to unpatented inventions, know-how, show-how and operating manuals;

(c) (i) all computer programs, including source code and object code versions, (ii) all data, databases and compilations of data, whether machine readable or otherwise, and (iii) all documentation, training materials and configurations related to any of the foregoing (collectively, "**Software**");

(d) all right, title and interest arising under any contract or Requirements of Law in or relating to Internet Domain Names;

(e) design rights; and

(f) IP Ancillary Rights (including all IP Ancillary Rights related to any of the foregoing);

in each case of clause (a) through (f), above, existing in the United States.

"**Interest Date**" means the last day of each calendar quarter.

"**Internet Domain Name**" means all right, title and interest (and all related IP Ancillary Rights) arising under any contract or Requirements of Law in or relating to Internet domain names.

"**Inventory**" means all "inventory" as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made, and includes all merchandise, raw materials, parts, supplies, packing and shipping materials, work in process and finished products, including such inventory as is temporarily out of a Credit Party's or Subsidiary's custody or possession or in transit and including any returned goods and any documents of title representing any of the above.

"**Investment**" means (a) any beneficial ownership interest in any Person (including Equity Interests), (b) any Acquisition or (c) the making of any advance, loan, extension of credit or capital contribution in or to, any Person.

"**IP Agreements**" means, collectively, (a) those certain Intellectual Property Security Agreements entered into by and between any Credit Party and the Collateral Agent, each dated as of the Tranche A Closing Date, and (b) any Intellectual Property Security Agreement entered into by and between any Credit Party and the Collateral Agent after the Tranche A Closing Date in accordance with the Loan Documents.

"**IP Ancillary Rights**" means, with respect to any Copyright, Trademark, Patent, Software, trade secrets or trade secret rights, including any rights to unpatented inventions, know-how, show-how and operating manuals, all income, royalties, proceeds and liabilities at any time due or payable or asserted under or with respect to any of the foregoing or otherwise with respect thereto, including all rights to sue or recover at law or in equity for any past, present or future infringement, misappropriation, dilution, violation or other impairment thereof, and, in each case, all rights to obtain any other intellectual property right ancillary to any Copyright, Trademark, Patent, Software, trade secrets or trade secret rights.

"**IRC**" means the Internal Revenue Code of 1986.

"**IRS**" is defined in Section 2.6(d)(i)

"**Knowledge**" of Borrower means the actual knowledge, after reasonable investigation, of the Responsible Officers of Borrower.

"**Lender**" means each Person signatory hereto as a "Lender" and its successors and assigns.

"**Lender Expenses**" means, collectively: (i) all reasonable and documented out-of-pocket fees and expenses of the Collateral Agent (and its successor, if any) and its Related Parties (A) incurred in connection with developing, preparing, negotiating, executing and delivering, and interpreting, investigating and administering, the Loan Documents (or any term or provision thereof), any commitment, proposal letter, letter of intent or term sheet therefor or any other document prepared in connection therewith, (B) incurred in connection with the consummation and administration of any transaction contemplated therein, (C) incurred in connection with the performance of any obligation or agreement contemplated therein, (D) incurred in connection with any modification or amendment of any term or provision of or any supplement to or the termination (in whole or in part) of, any Loan Document, (E) in connection with internal audit reviews and Collateral audits (in an aggregate amount not to exceed $200,000 during the term of this Agreement) or (F) otherwise incurred with respect to the Credit Parties in connection with the Loan Documents, including any filing or recording fees and expenses (but limited to the reasonable and documented out-of-pocket fees and expenses of one legal counsel to the Collateral Agent and its Related Parties (taken as a whole) (plus, if required, one local legal counsel to the Collateral Agent and its Related Parties (taken as a whole) in each relevant material jurisdiction)); and (ii) all reasonable and documented out-of-pocket costs and expenses incurred by the Collateral Agent and each Lender (and their respective successors and assigns) and their respective Related Parties (but limited, in the case of legal counsel, to the reasonable and documented out-of-pocket fees and expenses of one primary counsel for the Collateral Agent, the Lenders and their respective Related Parties (taken as a whole), and, of a single local counsel to the Collateral Agent, the Lenders and their respective Related Parties (taken as a whole) in each relevant material jurisdiction (and, in the case of an actual or perceived conflict of interest where the party affected by such conflict informs Borrower of such conflict and thereafter retains its own counsel, of one additional primary firm of counsel for all such affected parties (taken as a whole) and one additional firm of local counsel for all such affected parties (taken as a whole) in each relevant material jurisdiction)), in connection with (A) any refinancing or restructuring of the credit arrangements provided hereunder in the nature of a "work-out", (B) the enforcement or preservation of any right or remedy under any Loan Document, any Obligation, with respect to the Collateral or any other related right or remedy or (C) the commencement, defense, conduct of, intervention in, or the taking of any other action with respect to, any proceeding (including any Insolvency Proceeding) related to any Credit Party or any Subsidiary of any Credit Party in respect of any Loan Document or any Obligation, or otherwise in connection with any Loan Document or any Obligation (or the response to and preparation for any subpoena or request for document production relating thereto).

"**Lender Transfer**" is defined in Section 11.1(b).

"**Lien**" means a claim, mortgage, deed of trust, levy, charge, pledge, security interest or other encumbrance of any kind or assignment for security purposes, whether voluntarily incurred or arising by operation of law or otherwise against any property or assets.

"**Liquidity**" means (a) at any time prior to the date that is ninety (90) days (or such longer period as the Collateral Agent may agree in its sole discretion) following the Tranche A Closing Date, the sum of the Credit Parties' unrestricted cash and cash equivalents and (b) at all times thereafter, the sum of the Credit Parties' unrestricted cash and cash equivalents maintained in Collateral Accounts with respect to which Control Agreements are in effect.

"**Loan Documents**" means, collectively, this Agreement, the Disclosure Letter, the Term Loan Notes, the Security Agreement, the Perfection Certificate, any Control Agreement, any other Collateral Document, any guaranties executed by a Guarantor in favor of the Collateral Agent for the benefit of Lenders and the other Secured Parties in connection with this Agreement, and any other present or future agreement between or among a Credit Party, the Collateral Agent and any Lender in connection with this Agreement, including in each case, for the avoidance of doubt, any annexes, exhibits or schedules thereto.

"**Makewhole Amount**" means the Tranche A Makewhole Amount or the Tranche B Makewhole Amount (as applicable) or any combination thereof, as the context dictates.

"**Managed Care Plans**" means all health maintenance organizations, preferred provider organizations, individual practice associations, competitive medical plans and similar arrangements.

"**Manufacturing Agreement**" means any manufacturing or supply agreement entered into by any Credit Party or any of its Subsidiaries with third parties for the commercial supply in the Territory of any Product for any indication in the United States or for the commercial supply of the active pharmaceutical ingredient incorporated therein.

"**Margin Stock**" means "margin stock" within the meaning of Regulations U and X of the Federal Reserve Board as now and from time to time hereafter in effect.

"**Material Adverse Change**" means any material adverse change in or effect on: (i) the business, financial condition, properties or assets (including all or any portion of Collateral), liabilities (actual or contingent), operations, or performance of the Credit Parties, taken as a whole; (ii) the ability of the Credit Parties, taken as a whole, to fulfill the payment or performance obligations under this Agreement or any other Loan Document; or (iii) the binding nature or validity of, or the ability of the Collateral Agent or any Lender to enforce, the Loan Documents, taken as a whole, or any of its rights or remedies under the Loan Documents, taken as a whole.

"**Material Contract**" means any contract or other arrangement to which any Credit Party or any of its Subsidiaries is a party (other than the Loan Documents) or by which any of its assets or properties are bound, in each case relating to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of any Product in the Territory, for which the breach of, default or nonperformance under, cancellation or termination of or the failure to renew could reasonably be expected to result in a Material Adverse Change. For the avoidance of doubt, as of the Effective Date, each Current Company IP Agreement is a Material Contract.

"**Medicaid**" means the health care assistance program established by Title XIX of the SSA (42 U.S.C. 1396 et seq.).

"**Medicare**" means the health insurance program for the aged and disabled established by Title XVIII of the SSA (42 U.S.C. 1395 et seq.).

"**Multiemployer Plan**" means a multiemployer plan within the meaning of Section 4001(a)(3) or Section 3(37) of ERISA (a) to which Borrower or its Subsidiaries or their respective ERISA Affiliates is then making or accruing an obligation to make contributions; (b) to which Borrower or its Subsidiaries or their respective ERISA Affiliates has within the preceding five (5) plan years made contributions; or (c) with respect to which Borrower or its Subsidiaries could reasonably be expected to incur material liability.

"**Net Sales**" means, as of any date of determination and solely with respect to sales of the Products, the line item "product revenue, net" (which includes a reduction for product sales allowances) of Borrower and its Subsidiaries for the twelve (12) months prior to such date, determined on a consolidated basis in accordance with Applicable Accounting Standards.

"**Obligations**" means, collectively, the Credit Parties' obligations to pay when due any and all debts, principal, interest, Lender Expenses, the Additional Consideration, the Makewhole Amount (if applicable), the Prepayment Premium (if applicable) and any other fees, expenses, indemnities and amounts any Credit Party owes any Lender or the Collateral Agent now or later, under this Agreement or any other Loan Document, including interest accruing after Insolvency Proceedings begin (whether or not allowed), and to perform Borrower's duties under the Loan Documents.

"**OFAC**" is defined in Section 4.18(c).

"**Operating Documents**" means, collectively with respect to any Person such Person's formation documents as certified with the Secretary of State or other applicable Governmental Authority of such Person's jurisdiction of formation on a date that is no earlier than thirty (30) days prior to the date on which such documents are due to be delivered under this Agreement and, (a) if such Person is a corporation, its bylaws (or similar organizational regulations) in current form, (b) if such Person is a limited liability company, its limited liability company agreement (or similar agreement), and (c) if such Person is a partnership, its partnership agreement (or similar agreement), in each case, with all current amendments, restatements, supplements or modifications thereto.

"**ordinary course of business**" means, in respect of any transaction involving any Person, the ordinary course of such Person's business, undertaken by such Person in good faith and not for purposes of evading any covenant, prepayment obligation or restriction in any Loan Document.

"**Other Connection Taxes**" means, with respect to any Lender, Taxes imposed as a result of a present or former connection between such Lender and the jurisdiction imposing such Tax (other than connections arising solely from such Lender having executed, delivered, become a party to, performed its obligations under, received payments under, received or perfected a security interest under, engaged in any other transaction pursuant to or enforced any Loan Document, or sold or assigned an interest in any Term Loan or Loan Document) .

"**Other Taxes**" means all present or future stamp, court or documentary, intangible, recording, filing, mortgage or property Taxes, charges or similar levies or similar Taxes that arise from any payment made hereunder, from the execution, delivery, performance, enforcement or registration of, from the receipt or perfection of a security interest under, or otherwise with respect to, any Loan Document, except any such Taxes that are Other Connection Taxes imposed with respect to an assignment, grant of a participation, or other transfer.

"**Participant Register**" is defined in Section 11.1(e).

"**Patents**" means all patents and patent applications (including any continuations, continuations-in-part, divisions, provisionals or any substitute applications), any patent issued with respect to any of the foregoing patent applications, any reissue, reexamination, renewal or patent term extension or adjustment of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent. For the avoidance of doubt, patents and patent applications under this definition include all those filed with the U.S. Patent and Trademark Office or which could be nationalized in the United States.

"**Patriot Act**" is defined in Section 3.1(i).

"**Payment/Advance Request**" means a Payment/Advance Request in substantially the form attached hereto as Exhibit A.

"**Perfection Certificate**" is defined in Section 4.6.

"**Permitted Bond Hedge Transaction**" means any call or capped call option (or substantively equivalent derivative transaction) relating to Borrower's common stock (or other securities or property following a merger event or other change of the common stock of Borrower) purchased by Borrower in connection with the issuance of any Permitted Convertible Indebtedness; provided that the purchase price for such Permitted Bond Hedge Transaction, *less* the proceeds received by Borrower from the sale of any related Permitted Warrant Transaction, does not exceed the net proceeds received by Borrower from the issuance of such Permitted Convertible Indebtedness in connection with such Permitted Bond Hedge Transaction or result in the incurrence of additional Indebtedness by Borrower (other than such Permitted Convertible Indebtedness).

"**Permitted Convertible Indebtedness**" means (a) Indebtedness incurred by Borrower after the Effective Date having a feature which entitles the holder thereof to convert or exchange all or a portion of such Indebtedness into Equity Interests of Borrower; provided, that (i) such Permitted Convertible Indebtedness shall be unsecured, (ii) such Permitted Convertible Indebtedness shall not be guaranteed by any Subsidiary of Borrower, (iii) such Permitted Convertible Indebtedness shall not include covenants and defaults (other than covenants and defaults consistent with the covenants and defaults included in the Convertible Indenture) that are, taken as a whole, more restrictive on Borrower than the covenants and defaults that are, taken as a whole, contained herein (as reasonably determined by Borrower in its good faith judgment), (iv) immediately prior to and after giving effect to the incurrence of such Permitted Convertible Indebtedness, no Default or Event of Default shall have occurred and be continuing or could reasonably be expected to occur as a result therefrom, (v) such Permitted Convertible Indebtedness has a scheduled maturity date that is that is no earlier than twelve (12) months after the Term Loan Maturity Date and (vi) Borrower shall have delivered to the Collateral Agent a certificate of a Responsible Officer of Borrower certifying as to the foregoing, and (b) the Existing Convertible Indebtedness.

"**Permitted Distributions**" means, in each case subject to Section 6.8 if applicable:

(a) dividends, distributions or other payments by any Wholly-Owned Subsidiary on its Equity Interests to, or the redemption, retirement or purchase by any Wholly-Owned Subsidiary of its Equity Interests from, Borrower or any other Wholly-Owned Subsidiary;

(b) dividends, distributions or other payments by any non-Wholly-Owned Subsidiary on its Equity Interests to, or the redemption, retirement or purchase by any non-Wholly-Owned Subsidiary of its Equity Interests from, Borrower or any other Subsidiary or each other owner of such non-Wholly-Owned Subsidiary's Equity Interests based on their relative ownership interests of the relevant class of such Equity Interests;

(c) redemptions by Borrower in whole or in part any of its Equity Interests for another class of its Equity Interests or rights to acquire its Equity Interests or with proceeds from substantially concurrent equity contributions or issuances of new Equity Interests;

(d) any such payments arising from an Acquisition or other Investment by Borrower or any of its Subsidiaries;

(e) payments by any Credit Party or any Subsidiary of a Credit Party to any Credit Party or any Subsidiary of a Credit Party pursuant to Tax sharing agreements among the Credit Parties and their Subsidiaries on customary terms to the extent attributable to the ownership or operation of the Credit Party and their Subsidiaries;

(f) the payment of dividends by Borrower solely in non-cash pay and non-redeemable capital stock (including, for the avoidance of doubt, dividends and distributions payable solely in Equity Interests);

(g) cash payments in lieu of the issuance of fractional shares arising out of stock dividends, splits or combinations or in connection with the exercise of warrants, options or other securities convertible into or exchangeable for Equity Interests;

(h) in connection with any Acquisition or other Investment by Borrower or any of its Subsidiaries, (i) the receipt or acceptance of the return to Borrower or any of its Subsidiaries of Equity Interests of Borrower constituting a portion of the purchase price consideration in settlement of indemnification claims, or as a result of a purchase price adjustment (including earn-outs or similar obligations) and (ii) payments or distributions to equity holders pursuant to appraisal rights required under Requirements of Law;

(i) the distribution of rights pursuant to any shareholder rights plan or the redemption of such rights for nominal consideration in accordance with the terms of any shareholder rights plan;

(j) dividends, distributions or payments on its Equity Interests by any Subsidiary to any Credit Party;

(k) the conversion of convertible securities into other securities pursuant to the terms of such convertible securities or otherwise in exchange thereof;

(l) dividends, distributions or payments on its Equity Interests by any Subsidiary that is not a Credit Party to any other Subsidiary that is not a Credit Party;

(m) purchases of Equity Interests of Borrower or its Subsidiaries in connection with the exercise of stock options by way of cashless exercise, or in connection with the satisfaction of withholding tax obligations;

(n) issuance to directors, officers, employees or contractors of Borrower of common stock of Borrower upon the vesting of restricted stock, restricted stock units, or other rights to acquire common stock of Borrower pursuant to plans or agreements approved by Borrower's Board of Directors or stockholders;

(o) the repurchase, retirement or other acquisition or retirement for value of Equity Interests of Borrower or any of its Subsidiaries held by any future, present or former employee, consultant, officer or director (or spouse, ex-spouse or estate of any of the foregoing or trust for the benefit of any of the foregoing or any lineal descendants thereof) of Borrower or any of its Subsidiaries pursuant to any management equity plan or stock option plan or any other management or employee benefit plan or agreement, or any stock subscription or shareholder agreement or employment agreement; provided, however, that the aggregate payments made under this clause (n) do not exceed in any calendar year the sum of (i) $3,000,000 plus (ii) the amount of any payments received in such calendar year under key-man life insurance policies; and

(p) dividends or distributions on its Equity Interests by Borrower payable solely in additional shares of its common stock within sixty (60) days after the date of declaration thereof.

"**Permitted Hedging Agreement**" means a Hedging Agreement entered into in the ordinary course of business solely in connection with foreign exchange or interest rate hedging transactions and not for speculative purposes.

"**Permitted Indebtedness**" means:

(a) Indebtedness of the Credit Parties to Secured Parties under this Agreement and the other Loan Documents;

(b) Indebtedness existing on the Effective Date and shown on Schedule 12.1 of the Disclosure Letter;

(c) [reserved];

(d) Indebtedness not to exceed $15,000,000 in the aggregate at any time outstanding, consisting of (i) Indebtedness incurred to finance the purchase, construction, repair, or improvement of fixed assets and (ii) capital lease obligations;

(e) Indebtedness in connection with corporate credit cards, purchasing cards or bank card products;

(f) [reserved];

(g) Indebtedness assumed in connection with any Acquisition or Investment, so long as such Indebtedness was not incurred in connection with, or in anticipation of, such Acquisition or Investment;

(h) Indebtedness of Borrower or any of its Subsidiaries with respect to letters of credit outstanding (including in respect of any drawings thereunder) and secured solely by cash or cash equivalents entered into in the ordinary course of business;

(i) Indebtedness owed (i) by a Credit Party to another Credit Party, (ii) by a Subsidiary of Borrower that is not a Credit Party to another Subsidiary of Borrower that is not a Credit Party, (iii) by a Credit Party to a Subsidiary of Borrower that is not a Credit Party or (iv) by a Subsidiary of Borrower that is not a Credit Party to a Credit Party;

(j) Indebtedness consisting of Contingent Obligations described in clause (a) of the definition thereof (i) of a Credit Party of Permitted Indebtedness of another Credit Party, (ii) of a Subsidiary of Borrower which is not a Credit Party of Permitted Indebtedness of another Subsidiary of Borrower which is not a Credit Party, (iii) of a Subsidiary of Borrower which is not a Credit Party of Permitted Indebtedness of a Credit Party, or (iv) of a Credit Party of Permitted Indebtedness of a Subsidiary of Borrower which is not a Credit Party;

(k) Indebtedness in connection with any collaboration, development or similar arrangement not otherwise prohibited hereunder, in each case only if such Indebtedness is due and payable, in each instance, upon the occurrence of an event other than the passage of time;

(l) Indebtedness of any Person that becomes a Subsidiary (or of any Person not previously a Subsidiary that is merged or consolidated with or into a Subsidiary in a transaction permitted hereunder) of Borrower after the Effective Date, or Indebtedness of any Person that is assumed after the Effective Date by any Subsidiary in connection with an acquisition of assets by such Subsidiary; provided that such Indebtedness is not incurred in contemplation of such transaction;

(m) (i) Indebtedness with respect to workers' compensation claims, payment obligations in connection with health, disability or other types of social security benefits, unemployment or other insurance obligations, reclamation and statutory obligations or (ii) Indebtedness related to employee benefit plans, including annual employee bonuses, accrued wage increases and 401(k) plan matching obligations; in each case, incurred in the ordinary course of business consistent with past practice;

(n) Indebtedness in respect of performance bonds, bid bonds, appeal bonds, surety bonds and completion guarantees and similar obligations arising in the ordinary course of business consistent with past practice;

(o) Indebtedness in respect of netting services, overdraft protection and other cash management services, in each case in the ordinary course of business consistent with past practice;

(p) Indebtedness consisting of the financing of insurance premiums in the ordinary course of business consistent with past practice;

(q) Indebtedness consisting of guarantees resulting from endorsement of negotiable instruments for collection by any Credit Party in the ordinary course of business consistent with past practice;

(r) unsecured Indebtedness incurred in connection with any items of Permitted Distributions in clause (o) of the definition of "Permitted Distributions";

(s) Permitted Convertible Indebtedness; provided that the sum of (i) the principal amount of Permitted Convertible Indebtedness referred to in clause (a) of the definition thereof *plus* (ii) the principal amount of Indebtedness incurred pursuant to clause (y) below to purchase or construct a manufacturing plant of the Borrower or any Subsidiary shall not exceed $870,000,000 in the aggregate at any time outstanding;

(t) Permitted Hedging Agreements;

(u) [reserved];

(v) contingent liabilities in respect of any indemnification obligation, adjustment of purchase price, non-compete, or similar obligation incurred in connection with the consummation of one or more Acquisitions;

(w) Indebtedness arising from the honoring by a bank or other financial institution of a check, draft or similar instrument inadvertently (except in the case of daylight overdrafts) drawn against insufficient funds in the ordinary course of business; provided, however, that such Indebtedness is extinguished within five (5) Business Days of incurrence;

(x) Indebtedness of Subsidiaries that are not Credit Parties in an aggregate outstanding principal amount not to exceed $15,000,000 at any time;

(y) Indebtedness incurred to purchase or construct a manufacturing plant of the Borrower or any Subsidiary; provided that the sum of (i) the principal amount of such Indebtedness *plus* (ii) the principal amount of Permitted Convertible Indebtedness referred to in clause (a) of the definition thereof and incurred under clause (s) above shall not exceed $870,000,000 in the aggregate at any time outstanding;

(z) other Indebtedness of Borrower and its Subsidiaries in an aggregate outstanding principal amount not to exceed $10,000,000 at any time; and

(aa) subject to the proviso immediately below, extensions, refinancings, modifications, amendments, restatements and, solely in the case of any items of Permitted Indebtedness in clauses (b) or (s) of the definition of "Permitted Indebtedness" or Permitted Indebtedness constituting notes governed by an indenture, exchanges, of any items of Permitted Indebtedness in clauses (a) through (z) above, provided, that, in each case the principal amount thereof is not increased (other than by any reasonable amount of premium (if any), interest (including post-petition interest), fees, expenses, charges or additional or contingent interest reasonably incurred in connection with the same and the terms thereof), provided, further, and solely in the case of any Permitted Convertible Indebtedness or any Subordinated Debt permitted under the definition of "Permitted Indebtedness", in each case the maturity thereof is not shortened.

"**Permitted Licenses**" means: (a) a non-exclusive or an exclusive license (or covenant not to sue with respect to) as to a geography other than the Territory to Intellectual Property or a non-exclusive or an exclusive grant of rights for development, manufacture, production, commercialization, marketing, co-promotion, distribution, sale or similar commercial rights with respect to any Product as to a geography other than the Territory; (b) subject to satisfaction of the requirements set forth in the following sentence, a non-exclusive or an exclusive license as to geography within the Territory to Intellectual Property or a non-exclusive or an exclusive grant of rights for development, manufacture, production, commercialization, marketing, co-promotion, distribution, sale or similar commercial rights with respect to any Product as to geography within the Territory in the ordinary course of business, (c) a non-exclusive or an exclusive grant of manufacturing licenses to third parties in the ordinary course of business, (d) a non-exclusive or an exclusive license (or covenant not to sue with respect to) to Intellectual Property unrelated in any way to any Product or a non-exclusive or an exclusive grant of rights for development, manufacture, production, commercialization, marketing, co-promotion, distribution, sale or similar commercial rights unrelated in any way to any Product and (e) intercompany licenses or other similar arrangements among Credit Parties. Notwithstanding the foregoing, any license or grant of rights described in clause (b) above to a geography within the Territory shall not constitute a Permitted License hereunder if, as a result of such license or grant, one hundred percent (100%) of the Net Sales of any Product in the Territory would not be reported in the financial statements of Borrower and its Subsidiaries and such license or grant of rights prohibits or otherwise restricts the applicable Credit Party or Subsidiary from determining in its sole discretion the pricing of any Product in the Territory. Notwithstanding the foregoing, "Permitted Licenses" shall include any Excluded Licenses entered into after the Tranche A Closing Date that are consented to by the Collateral Agent or the Required Lenders, in writing.

"**Permitted Liens**" means:

(a) Liens securing the Obligations pursuant to any Loan Document;

(b) Liens existing on the Effective Date and set forth on Schedule 12.3 of the Disclosure Letter;

(c) Liens for Taxes, assessments or governmental charges (i) which are not yet delinquent or (ii) which are being contested in good faith and by appropriate proceedings promptly instituted and diligently conducted; provided that adequate reserves therefor have been set aside on the books of the applicable Person and maintained in conformity with Applicable Accounting Standards, if required; provided, further, that in the case of a Tax, assessment or charge that has or may become a Lien against any Collateral, such contest proceedings conclusively operate to stay the sale or forfeiture of any portion of any Collateral to satisfy such Tax, assessment or charge;

(d) pledges or deposits made in the ordinary course of business (other than Liens imposed by ERISA) in connection with workers' compensation, payroll taxes, unemployment insurance, old-age pensions, or other similar social security legislation, (ii) pledges or deposits made in the ordinary course of business consistent with past practice securing liability for reimbursement or indemnification obligations of (including obligations in respect of letters of credit or bank guarantees for the benefit of) insurance carriers providing property, casualty or liability insurance to Borrower or any of its Subsidiaries, (iii) statutory or common law Liens of landlords and pledges and deposits in the ordinary course of business securing liability to landlords (including obligations in respect of letters of credit or bank guarantees for the benefit of landlords) and other contractual obligations, and (iv) pledges or deposits to secure performance of tenders, bids, leases, statutory or regulatory obligations, surety and appeal bonds, government contracts, performance and return-of-money bonds and other obligations of like nature, in each case other than for borrowed money and entered into in the ordinary course of business consistent with past practice;

(e) Liens arising from attachments or judgments, orders, or decrees in circumstances not constituting an Event of Default under either Section 7.4 or 7.7;

(f) Liens (including the right of set-off) in favor of banks or other financial institutions incurred on deposits made in accounts held at such institutions in the ordinary course of business; provided that such Liens (i) are not given in connection with the incurrence of any Indebtedness, (ii) relate solely to obligations for administrative and other banking fees and expenses incurred in the ordinary course of business in connection with the establishment or maintenance of such accounts and (iii) are within the general parameters customary in the banking industry;

(g) Liens that are contractual rights of set-off (i) relating to pooled deposit or sweep accounts of Borrower or any of its Subsidiaries to permit satisfaction of overdraft or similar obligations incurred in the ordinary course of business consistent with past practice or (ii) relating to purchase orders and other agreements entered into with customers of Borrower or any of its Subsidiaries in the ordinary course of business consistent with past practice;

(h) Liens solely on any cash earnest money deposits made by Borrower or any of its Subsidiaries in connection with any Acquisition, Investment or other acquisition of assets or properties not otherwise prohibited under this Agreement;

(i) Liens existing on assets or properties at the time of its acquisition or existing on the assets or properties of any Person at the time such Person becomes a Subsidiary of Borrower, in each case after the Effective Date; provided that (i) neither such Lien was created nor the Indebtedness secured thereby was incurred in contemplation of such acquisition or such Person becoming a Subsidiary of Borrower, (ii) such Lien does not extend to or cover any other assets or properties (other than the proceeds or products thereof and other than after-acquired assets or properties subject to a Lien securing Indebtedness and other obligations incurred prior to such time and which Indebtedness and other obligations are permitted hereunder that requires, pursuant to its terms and conditions in effect at such time, a pledge of after-acquired assets or properties, it being understood that such requirement shall not be permitted to apply to any assets or properties to which such requirement would not have applied but for such acquisition) and (iii) the Indebtedness and other obligations secured thereby is permitted under Section 6.4 hereof;

(j) Liens on insurance policies and the proceeds thereof securing the financing of the premiums with respect thereto;

(k) Liens securing Indebtedness permitted under clause (d) of the definition of "Permitted Indebtedness" (including any extensions, refinancings, modifications, amendments or restatements of such Indebtedness permitted under clause (aa) of the definition of "Permitted Indebtedness"); provided, that such Lien does not extend to or cover any assets or properties other than those that are subject to such capital lease or acquired with such Indebtedness;

(l) rights of first refusal, voting, redemption, transfer or other restrictions (including call provisions and buy-sell provisions) with respect to the Equity Interests of any joint venture or other Persons that are not Subsidiaries;

(m) servitudes, easements, rights-of-way, restrictions and other similar encumbrances on real property imposed by Requirements of Law and encumbrances consisting of zoning or building restrictions, easements, licenses, restrictions on the use of property or minor defects or other irregularities in title which, in the aggregate, are not material, and which do not in any case materially detract from the value of the property subject thereto or interfere with the ordinary conduct of the business of any Credit Party or any Subsidiary of any Credit Party;

(n) to the extent constituting a Lien, escrow arrangements securing indemnification obligations associated with any Acquisition or Investment;

(o) licenses, sublicenses, leases or subleases of personal property (other than relating to Intellectual Property) granted to third parties in the ordinary course of business consistent with past practice, in each case which do not interfere in any material respect with the operations of the business of any Credit Party or any of its Subsidiaries;

(p) Permitted Licenses;

(q) Liens on cash or other current assets pledged to secure (i) Indebtedness in respect of corporate credit cards, purchasing cards or bank card products, (ii) Indebtedness in the form of letters of credit or bank guarantees, or (iii) Permitted Hedging Agreements;

(r) Liens on any properties or assets of Borrower or any of its Subsidiaries which do not constitute Collateral under the Loan Documents, including any of the Excluded Property, other than (i) any Company IP related to any research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of any Product in the Territory that does not constitute Collateral (if any), and (ii) any Equity Interests in any Credit Party or in Sarepta Securities Corp., a Massachusetts corporation;

(s) Liens on properties or assets of Borrower or any of its Subsidiaries imposed by law or regulation which were incurred in the ordinary course of business, including landlords', carriers', warehousemen's, mechanics', materialmen's, contractors', suppliers of materials', architects' and repairmen's Liens, and other similar Liens arising in the ordinary course of business consistent with past practice; provided that such Liens (i) do not materially detract from the value of such properties or assets subject thereto or materially impair the use of such properties or assets subject thereto in the operations of the business of Borrower or such Subsidiary or (ii) are being contested in good faith by appropriate proceedings, which conclusively operate to stay the sale or forfeiture of any portion of such properties or assets subject thereto and for which adequate reserves have been set aside on the books of the applicable Person and maintained in conformity with Applicable Accounting Standards, if required;

(t) mortgage on the manufacturing plant and the real property associated therewith to secure the Indebtedness permitted by clause (y) of the definition of Permitted Indebtedness; provided, that such mortgage does not extend to or secure any assets or properties other than such plant and real property and related fixtures;

(u) other Liens securing obligations incurred in compliance with the terms hereof and not exceeding $2,500,000 in the aggregate at any time outstanding; and

(v) subject to the provisos immediately below, the modification, replacement, extension or renewal of the Liens described in clauses (a) through (t) above; provided, however, that any such modification, replacement, extension or renewal must (i) be limited to the assets or properties encumbered by the existing Lien (and any additions, accessions, parts, improvements and attachments thereto and the proceeds thereof) and (ii) not increase the principal amount of any Indebtedness secured by the existing Lien (other than by any reasonable premium or other reasonable amount paid and fees and expenses reasonably incurred in connection therewith); provided, further, that to the extent any of the Liens described in clauses (a) through (t) above secure Indebtedness of a Credit Party, such Liens, and any such modification, replacement, extension or renewal thereof, shall constitute Permitted Liens if and only to the extent that such Indebtedness is permitted under Section 6.4 hereof.

"**Permitted Negative Pledges**" means:

(a) prohibitions or limitations with regards to specific properties or assets encumbered by Permitted Liens, if and only to the extent each such prohibition or limitation applies only to such properties or assets;

(b) prohibitions or limitations set forth in any lease, license or other similar agreement entered into in the ordinary course of business and not prohibited hereunder;

(c) prohibitions or limitations relating to Permitted Indebtedness, in the case of each such agreement if and only to the extent such prohibitions or limitations, taken as a whole, are not materially more restrictive than the prohibitions and limitations set forth in this Agreement and the other Loan Documents, taken as a whole (as reasonably determined by a Responsible Officer of Borrower in good faith);

(d) customary provisions restricting assignments, subletting, sublicensing or other transfer of properties or assets subject thereto set forth in leases, subleases, licenses (including Permitted Licenses) and other similar agreements that are not otherwise prohibited under this Agreement or any other Loan Document, if and only to the extent each such restriction applies only to the properties or assets subject to such leases, subleases, licenses or agreements, and customary provisions restricting assignment, pledges or transfer of any agreement entered into in the ordinary course of business consistent with past practice;

(e) prohibitions or limitations imposed by Requirements of Law;

(f) prohibitions or limitations that exist as of the Effective Date under any items of Permitted Indebtedness in clause (b) of the definition of "Permitted Indebtedness";

(g) customary prohibitions or limitations arising in connection with any Transfer not prohibited by Section 6.1 or contained in any agreement relating to any such Transfer pending the consummation of such Transfer;

(h) customary provisions in shareholders' agreements, joint venture agreements, organizational documents or similar binding agreements relating to, or any agreement evidencing Indebtedness of, any joint venture entity or non-Wholly-Owned Subsidiary and applicable solely to such joint venture entity or non-Wholly-Owned Subsidiary and the Equity Interests issued thereby;

(i) customary net worth provisions set forth in real property leases entered into by Subsidiaries of Borrower, so long as such net worth provisions could not reasonably be expected to impair the ability of Borrower or its Subsidiaries to meet their ongoing obligations (as reasonably determined by a Responsible Officer of Borrower in good faith);

(j) customary net worth provisions set forth in customer agreements entered into in the ordinary course of business consistent with past practice that are not otherwise prohibited under this Agreement or any other Loan Document, so long as such net worth provisions could not reasonably be expected to impair the ability of Borrower or its Subsidiaries to meet their ongoing obligations (as reasonably determined by a Responsible Officer of Borrower in good faith);

(k) restrictions on cash or other deposits (including escrowed funds) imposed by agreements entered into in the ordinary course of business consistent with past practice that are not otherwise prohibited under this Agreement or any other Loan Document;

(l) prohibitions or limitations set forth in any agreement in effect at the time any Person becomes a Subsidiary (but not any amendment, modification, restatement, renewal, extension, supplement or replacement expanding the scope of any such restriction or condition); provided that such agreement was not entered into in contemplation of such Person becoming a Subsidiary and each such prohibition or limitation does not apply to Borrower or any other Subsidiary (other than such Person and any other Person that is a Subsidiary of such first Person at the time such first Person becomes a Subsidiary);

(m) prohibitions or limitations imposed by any Loan Document;

(n) customary provisions set forth in joint venture agreements or agreements governing minority investments that are not otherwise prohibited by this Agreement or any other Loan Document, if and only to the extent each such prohibition or limitation applies only to the joint venture entity or minority investment that is the subject of such agreement;

(o) limitations imposed with respect to any license acquired in an Acquisition;

(p) customary provisions restricting assignments or other transfer of properties or assets subject thereto set forth in any agreement entered into in the ordinary course of business consistent with past practice, if and only to the extent each such restriction applies only to the properties or assets subject to such agreement;

(q) prohibitions or limitations imposed by any agreement evidencing any Permitted Indebtedness of the type described in any of clause (d) of the definition of "Permitted Indebtedness"; and

(r) prohibitions or limitations imposed by any amendments, modifications, restatements, renewals, extensions, supplements or replacements of any of the agreements referred to in clauses (a) through (q) above, except to the extent that any such amendment, modification, restatement, renewal, extension, supplement or replacement expands the scope of any such prohibition or limitation.

"**Permitted Subsidiary Distribution Restrictions**" means, in each case notwithstanding Section 6.8:

(a) prohibitions or limitations with regards to specific properties or assets encumbered by Permitted Liens, if and only to the extent each such prohibition or limitation applies only to such properties or assets;

(b) prohibitions or limitations set forth in any lease, license or other similar agreement not prohibited hereunder;

(c) prohibitions or limitations relating to Permitted Indebtedness, in the case of each such agreement if and only to the extent such prohibitions or limitations, taken as a whole, are not materially more restrictive than the prohibitions and limitations set forth in this Agreement and the other Loan Documents, taken as a whole (as reasonably determined by a Responsible Officer of Borrower in good faith);

(d) customary provisions restricting assignments, subletting, sublicensing or other transfer of properties or assets subject thereto set forth in leases, subleases, licenses (including Permitted Licenses) and other similar agreements that are not otherwise prohibited under this Agreement or any other Loan Document, if and only to the extent each such restriction applies only to the properties or assets subject to such leases, subleases, licenses or agreements, and customary provisions restricting assignment, pledges or transfer of any agreement entered into in the ordinary course of business consistent with past practice;

(e) prohibitions or limitations on the transfer or assignment of any properties, assets or Equity Interests set forth in any agreement entered into in the ordinary course of business consistent with past practice that is not otherwise prohibited under this Agreement or any other Loan Document, if and only to the extent each such prohibition or limitation applies only to such properties, assets or Equity Interests;

(f) prohibitions or limitations imposed by Requirements of Law;

(g) prohibitions or limitations that exist as of the Tranche A Closing Date under any items of Permitted Indebtedness in clause (b) of the definition of "Permitted Indebtedness";

(h) customary prohibitions or limitations arising in connection with any Transfer not prohibited by Section 6.1 or contained in any agreement relating to any such Transfer pending the consummation of such Transfer;

(i) customary provisions in shareholders' agreements, joint venture agreements, organizational documents or similar binding agreements relating to, or any agreement evidencing Indebtedness of, any joint venture entity or non-Wholly-Owned Subsidiary and applicable solely to such joint venture entity or non-Wholly-Owned Subsidiary and the Equity Interests issued thereby;

(j) customary net worth provisions set forth in real property leases entered into by Subsidiaries of Borrower, so long as such net worth provisions could not reasonably be expected to impair the ability of Borrower or its Subsidiaries to meet their ongoing obligations (as reasonably determined by a Responsible Officer of Borrower in good faith);

(k) customary net worth provisions set forth in customer agreements entered into in the ordinary course of business consistent with past practice that are not otherwise prohibited under this Agreement or any other Loan Document, so long as such net worth provisions could not reasonably be expected to impair the ability of Borrower or its Subsidiaries to meet their ongoing obligations (as reasonably determined by a Responsible Officer of Borrower in good faith);

(l) restrictions on cash or other deposits (including escrowed funds) imposed by agreements entered into in the ordinary course of business consistent with past practice that are not otherwise prohibited under this Agreement or any other Loan Document;

(m) prohibitions or limitations set forth in any agreement in effect at the time any Person becomes a Subsidiary (but not any amendment, modification, restatement, renewal, extension, supplement or replacement expanding the scope of any such restriction or condition); provided that such agreement was not entered into in contemplation of such Person becoming a Subsidiary and each such prohibition or limitation does not apply to Borrower or any other Subsidiary (other than such Person and any other Person that is a Subsidiary of such first Person at the time such first Person becomes a Subsidiary);

(n) prohibitions or limitations imposed by any Loan Document;

(o) customary provisions set forth in joint venture agreements or agreements governing minority investments that are not otherwise prohibited by this Agreement or any other Loan Document, if and only to the extent each such prohibition or limitation applies only to the joint venture entity or minority investment that is the subject of such agreement;

(p) customary provisions restricting assignments or other transfer of properties or assets subject thereto set forth in any agreement entered into in the ordinary course of business consistent with past practice, if and only to the extent each such restriction applies only to the properties or assets subject to such agreement;

(q) prohibitions or limitations imposed by any agreement evidencing any Permitted Indebtedness of the type described in any of clause (d) of the definition of "Permitted Indebtedness"; and

(r) prohibitions or limitations imposed by any amendments, modifications, restatements, renewals, extensions, supplements or replacements of any of the agreements referred to in clauses (a) through (q) above, except to the extent that any such amendment, modification, restatement, renewal, extension, supplement or replacement expands the scope of any such prohibition or limitation.

"**Permitted Warrant Transaction**" means any call option, warrant or right to purchase (or substantively equivalent derivative transaction) relating to Borrower's common stock (or other securities or property following a merger event or other change of the common stock of Borrower) or cash or any combination thereof (with the amount of such cash or such combination determined by reference to the market price of such common stock or other securities) sold by Borrower substantially concurrently with any purchase by Borrower of a related Permitted Bond Hedge Transaction.

"**Person**" means any individual, sole proprietorship, partnership, limited liability company, joint venture, company, trust, unincorporated organization, association, corporation, institution, public benefit corporation, firm, joint stock company, estate, entity or government agency.

"**Pharmakon Lender**" means BioPharma Credit PLC, BioPharma Credit Investments V (Master) LP and any of their respective Controlled Investment Affiliates.

"**PIK Interest**" is defined in Section 2.3(a)(iii).

"**Plan**" means any employee pension benefit plan (other than a Multiemployer Plan) subject to the provisions of Title IV of ERISA or Section 412 of the IRC or Section 302 of ERISA which is maintained or contributed to by Borrower or its Subsidiaries or their respective ERISA Affiliates or with respect to which Borrower or its Subsidiaries have any liability (including under Section 4069 of ERISA).

"**Prepayment Premium**" means the Tranche A Prepayment Premium or the Tranche B Prepayment Premium (as applicable) or any combination thereof, as the context dictates.

"**Product**" means, collectively, (a) any pharmaceutical composition, marketed, sold, offered for sale, produced, made, or manufactured by or on behalf of Borrower, in which eteplirsen is indicated to be administered for use in the treatment of Duchenne muscular dystrophy ("**DMD**") in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping or for any other use approved by the FDA, including EXONDYS 51® (eteplirsen) Injection; and (b) any pharmaceutical composition, marketed, sold, offered for sale, produced, made, or manufactured by or on behalf of Borrower, in which golodirsen is indicated to be administered for use in the treatment of DMD in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping or for any other use approved by the FDA, including VYONDYS 53® (golodirsen) (also known as SRP-4053); provided that Product does not contain a controlled substance (as that term is defined in the Controlled Substances Act (21 U.S.C. § 801 et seq.)).

"**Register**" is defined in Section 2.8(a).

"**Registered Organization**" means any "registered organization" as defined in the Code with such additions to such term as may hereafter be made.

"**Regulatory Agency**" means a U.S. Governmental Authority with responsibility for the approval of the marketing and sale of pharmaceuticals or other regulation of pharmaceuticals, including the FDA.

"**Regulatory Approval**" means all approvals, product or establishment licenses, registrations or authorizations of any Regulatory Agency necessary for the manufacture, use, storage, import, export, transport, offer for sale, or sale of any Product.

"**Related Parties**" means, with respect to any Person, such Person's Affiliates and the partners, directors, officers, employees, agents, trustees, administrators, managers, advisors and representatives of such Person and of such Person's Affiliates.

"**Release**" means any release, spill, emission, leaking, pumping, pouring, injection, escaping, deposit, disposal, discharge, dispersal, dumping, leaching or migration of any Hazardous Material into the indoor or outdoor environment (including the abandonment or disposal of any barrels, containers or other closed receptacles containing any Hazardous Material), including the movement of any Hazardous Material through the air, soil, surface water or groundwater, in each case, in the United States.

"**Required Lenders**" means, at any time of determination (a) prior to the Tranche A Closing Date, Lenders obligated with respect to greater than fifty percent (50%) of the Term Loan Commitments, and (b) thereafter, Lenders representing greater than fifty percent (50%) of the sum of the outstanding principal amount (including accrued and capitalized PIK Interest) of the Term Loans at such time *plus* the outstanding Term Loan Commitments at such time.

"**Requirements of Law**" means with respect to any Person, collectively, the common law and all federal, state, provincial, local, foreign, multinational or international laws, statutes, codes, treaties, standards, judgements, orders, writs and decrees or any other legal requirements of any Governmental Authority, in each case that are applicable to or binding upon such Person or any of its property or to which such Person or any of its property is subject.

"**Responsible Officers**" means, with respect to Borrower, collectively, the Chief Executive Officer, President or Vice President, Chief Commercial Officer, Chief Medical Officer, Chief Business Officer, General Counsel, Chief Financial Officer, Secretary or Assistant Secretary, Treasurer or Assistant Treasurer and Director of Global Treasury.

"**Sanctions**" is defined in Section 4.18(c).

"**SEC**" shall mean the Securities and Exchange Commission and any analogous Governmental Authority.

"**Secured Parties**" means each Lender, each other Indemnified Person and each other holder of any Obligation of a Credit Party.

"**Securities Account**" means any "securities account" as defined in the Code with such additions to such term as may hereafter be made.

"**Securities Act**" means the Securities Act of 1933.

"**Security Agreement**" means the Guaranty and Security Agreement, dated as of the Tranche A Closing Date, by and among the Credit Parties and the Collateral Agent, in form and substance substantially similar to Exhibit C attached hereto or in such form or substance as the Credit Parties and the Collateral Agent may otherwise agree.

"**Security Disclosure Letter**" means the "Security Disclosure Letter", as such term is defined in the Security Agreement.

"**Solvent**" means, with respect to any Person as of any date of determination, that, as of such date, (a) the value of the assets (including goodwill minus disposition costs) of such Person (both at fair value and present fair saleable value), on a going concern basis, is greater than the total amount of liabilities (including contingent and unliquidated liabilities) of such Person, (b) such Person is able to generally pay all liabilities (including trade debt) of such Person as such liabilities become absolute and mature in the ordinary course of business consistent with past practice and (c) such Person does not have unreasonably small capital after giving due consideration to the prevailing practice in the industry in which it is engaged or will be engaged. In computing the amount of contingent or unliquidated liabilities at any time, such liabilities shall be computed at the amount that, in light of all the facts and circumstances existing at such time, represents the amount that can reasonably be expected to become an actual or matured liability.

"**Specified Disputes**" is defined in Section 4.6(i).

"**SSA**" means the Social Security Act of 1935, codified at Title 42, Chapter 7, of the United States Code.

"**Stock Acquisition**" means the purchase or other acquisition by Borrower or any of its Subsidiaries of all of the Equity Interests (by merger, stock purchase or otherwise) in any other Person.

"**Subordinated Debt**" means any Indebtedness in the form of or otherwise constituting term debt incurred by any Credit Party or any Subsidiary thereof (including any Indebtedness incurred in connection with any Acquisition or other Investment) that: (a) is subordinated in right of payment to the Obligations at all times until all of the Obligations have been paid, performed or discharged in full and Borrower has no further right to obtain any Credit Extension hereunder pursuant to a subordination, intercreditor or other similar agreement that is in form and substance reasonably satisfactory to the Collateral Agent (which agreement shall include turnover provisions that are reasonably satisfactory to the Collateral Agent); (b) except as permitted by clause (d) below or otherwise permitted, is not subject to scheduled amortization, redemption (mandatory), sinking fund or similar payment and does not have a final maturity, in each case, before a date that is at least ninety-one (91) days following the Term Loan Maturity Date; (c) does not include covenants (including financial covenants) and agreements (excluding agreements with respect to maturity, amortization, pricing and other economic terms) that, taken as a whole, are more restrictive or onerous on the Credit Parties in any material respect than the comparable covenants and agreements, taken as a whole, in the Loan Documents (as reasonably determined by a Responsible Officer of Borrower in good faith); (d) is not subject to repayment or prepayment, including pursuant to a put option exercisable by the holder of any such Indebtedness, prior to the final maturity thereof except in the case of an event of default or change of control (or the equivalent thereof, however described); and (e) does not provide or otherwise include provisions having the effect of providing that a default or event of default (or the equivalent thereof, however described) under or in respect of such Indebtedness shall exist, or such Indebtedness shall otherwise become due prior to its scheduled maturity or the holder or holders thereof or any trustee or agent on its or their behalf shall be permitted (with or without the giving of notice, the lapse of time or both) to cause any such Indebtedness to become due, or to require the prepayment, repurchase, redemption or defeasance thereof, prior to its scheduled maturity, in any such case upon the occurrence of a Default or Event of Default hereunder unless and until the Obligations have been declared, or have otherwise automatically become, immediately due and payable pursuant to Section 8.1(a). Notwithstanding the foregoing, Permitted Convertible Indebtedness shall not constitute Subordinated Debt.

"**Subsidiary**" means, with respect to any Person, a corporation, partnership, limited liability company or other entity of which more than fifty percent (50.0%) of whose shares of stock or other ownership interests having ordinary voting power (other than stock or such other ownership interests having such power only by reason of the happening of a contingency) to elect a majority of the Board of Directors (or similar body) of such corporation, partnership or other entity are at the time owned, directly or indirectly through one or more intermediaries, or both, by such Person. Unless the context otherwise requires, each reference to a Subsidiary herein shall be a reference to a Subsidiary of a Credit Party.

"**Tax**" means any present or future taxes, levies, imposts, duties, deductions, withholdings (including backup withholding), assessments, fees or other charges imposed by any Governmental Authority, including any interest, additions to tax or penalties applicable thereto.

"**Term Loan**" means each of the Tranche A Loan and the Tranche B Loan, as applicable, and "**Term Loans**" means, collectively, the Tranche A Loan and the Tranche B Loan.

"**Term Loan Commitment**" mean each of the Tranche A Loan Commitment and the Tranche B Loan Commitment, as applicable, and "**Term Loan Commitments**" means, collectively, the Tranche A Loan Commitment and the Tranche B Loan Commitment.

"**Term Loan Maturity Date**" means the 48th-month anniversary of the Tranche A Closing Date.

"**Term Loan Note**" is defined in Section 2.8(b).

"**Term Loan Rate**" is defined in Section 2.3(a)(i).

"**Territory**" means the United States.

"**Third Party IP**" is defined in Section 4.6(l).

"**Trademark License**" means any agreement, whether written or oral, providing for the grant by or to a Person of any right to use any Trademark.

"**Trademarks**" means (a) all registrations and recordings of, and all applications in connection with, all trademarks, trade names, corporate names, company names, business names, fictitious business names, service marks, elements of package or trade dress of goods or services, logos and other source or business identifiers, in each case, in the United States Patent and Trademark Office or in any similar office or agency of the United States or any state thereof, together with the goodwill associated therewith and (b) all renewals thereof.

"**Trading Days**" means a day on which exchanges in the United States are open for the buying and selling of securities.

"**Tranche A Closing Date**" means the date on which the Tranche A Loan is advanced by Lenders, which, subject to the satisfaction of the conditions precedent to the Tranche A Loan set forth in Section 3.1, Section 3.3 and Section 3.5, shall be ten (10) Business Days following the Effective Date.

"**Tranche A Commitment**" means, with respect to any Lender, the commitment of such Lender to make the Credit Extensions relating to the Tranche A Loan on the Tranche A Closing Date in the aggregate principal amount set forth opposite such Lender's name on Exhibit D attached hereto.

"**Tranche A Loan**" is defined in Section 2.2(a)(i).

"**Tranche A Loan Amount**" means an original principal amount equal to Two Hundred and Fifty Million Dollars ($250,000,000.00).

"**Tranche A Makewhole Amount**" means, as of any date of prepayment of the Tranche A Loan occurring prior to the 2nd-year anniversary of the Tranche A Closing Date, an amount equal to the sum of all interest that would have accrued and been payable from such date of prepayment through the 2nd-year anniversary of the Tranche A Closing Date on the amount of principal (including accrued and capitalized PIK Interest) prepaid.

"**Tranche A Note**" means a promissory note in substantially the form attached hereto as Exhibit B-1, as it may be amended, restated, supplemented or otherwise modified from time to time.

"**Tranche A Prepayment Premium**" means, with respect to any prepayment of the Tranche A Loan by Borrower pursuant to Section 2.2(c) or as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a), an amount equal to the product of the amount of any principal (including accrued and capitalized PIK Interest) so prepaid, multiplied by:

(a) if such prepayment occurs prior to the 3rd-year anniversary of the Tranche A Closing Date, 0.02; and

(b) if such prepayment occurs on or after the 3rd-year anniversary of the Tranche A Closing Date but prior to the 4th-year anniversary of the Tranche A Closing Date, 0.01.

For the avoidance of doubt, no Tranche A Prepayment Premium shall be due and owing for any payment of principal of the Tranche A Loan made on the Term Loan Maturity Date.

"**Tranche B Closing Date**" means the date on which the Tranche B Loan is advanced by Lenders, which, as indicated in the Payment/Advance Request for the Tranche B Loan and subject to the satisfaction of the conditions precedent to the Tranche B Loan set forth in Section 3.2, Section 3.3 and Section 3.5, shall be seventy-five (75) days (or such shorter period as may be agreed to by Lenders) following the delivery by Borrower to the Collateral Agent of a completed Payment/Advance Request for the Tranche B Loan and, in no event, later than December 31, 2020.

"**Tranche B Commitment**" means, with respect to any Lender, the commitment of such Lender to make the Credit Extensions relating to the Tranche B Loan on the Tranche B Closing Date (and, for the avoidance of doubt, no later than December 31, 2020) in the aggregate principal amount set forth opposite such Lender's name on Exhibit D attached hereto; provided, however, that the parties hereto agree that such commitment, and any obligations of such Lender hereunder with respect thereto, shall terminate automatically without any further action by any party hereto and be of no further force and effect if (x) any prepayment, in whole or in part, of principal amount (including accrued and capitalized PIK Interest) of the Tranche A Loan is made pursuant to Section 2.2(c) or as a result of the acceleration of the maturity of the Tranche A Loan pursuant to Section 8.1(a) on or before the Tranche B Closing Date or (y) the Tranche B Closing Date does not occur on or before December 31, 2020 (in either of which case, for purposes of this Agreement, such Lender's Tranche B Commitment equals zero).

"**Tranche B Loan**" is defined in Section 2.2(a)(ii).

"**Tranche B Loan Amount**" means an original principal amount requested by the Borrower, in multiples of $50,000,000, not less than Fifty Million Dollars ($50,000,000.00) and not more than Two Hundred and Fifty Million Dollars ($250,000,000.00); provided, that if either of the events described clauses (x) or (y) in the proviso to the definition of "Tranche B Commitment" occurs, the Tranche B Loan Amount, for purposes of this Agreement, equals zero.

"**Tranche B Makewhole Amount**" means, as of any date of prepayment of the Tranche B Loan occurring prior to the 2nd-year anniversary of the Tranche B Closing Date, an amount equal to the sum of all interest that would have accrued and been payable from such date of prepayment through the 2nd-year anniversary of the Tranche B Closing Date on the amount of principal prepaid.

"**Tranche B Note**" means a promissory note in substantially the form attached hereto as Exhibit B-2, as it may be amended, restated, supplemented or otherwise modified from time to time.

"**Tranche B Prepayment Premium**" means, with respect to any prepayment of the Tranche B Loan by Borrower pursuant to Section 2.2(c) or as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a), an amount equal to the product of the amount of any principal so prepaid, multiplied by:

(a) if such prepayment occurs prior to the 3rd-year anniversary of the Tranche B Closing Date, 0.02; and

(b) if such prepayment occurs on or after the 3rd-year anniversary of the Tranche B Closing Date but prior to the 4th-year anniversary of the Tranche A Closing Date, 0.01.

For the avoidance of doubt, no Tranche B Prepayment Premium shall be due and owing for any payment of principal of the Tranche B Loan made on the Term Loan Maturity Date.

"**Transfer**" is defined in Section 6.1.

"**Treasury Regulations**" mean those regulations promulgated pursuant to the IRC.

"**TRICARE**" means a program of medical benefits covering former and active members of the uniformed services and certain of their dependents, financed and administered by the United States Departments of Defense, Health and Human Services and Transportation.

"**UKBA**" is defined in Section 4.18(a).

"**United States**" or "**U.S.**" means the United States of America, its fifty (50) states, and the District of Columbia.

"**Wholly-Owned Subsidiary**" means, with respect to any Person, a Subsidiary of such Person, all of the Equity Interests in which (other than directors' qualifying shares or nominee or other similar shares required pursuant to Requirements of Law) are owned by such Person or another Wholly-Owned Subsidiary of such Person. Unless the context otherwise requires, each reference to a Wholly-Owned Subsidiary herein shall be a reference to a Wholly-Owned Subsidiary of a Credit Party.

"**Withdrawal Liability**" means liability to a Multiemployer Plan as a result of a complete or partial withdrawal from such Multiemployer Plan, as such terms are defined in Part I of Subtitle E of Title IV of ERISA.

[Signature page follows.]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the Effective Date.

SAREPTA THERAPEUTICS, INC.,
as Borrower

By /s/ Sandesh Mahatme

Name: Sandesh Mahatme

Title: Executive Vice President, Chief Financial Officer, and Chief Business Officer

BIOPHARMA CREDIT PLC,
as Collateral Agent and Lender

By: Pharmakon Advisors, LP,
its Investment Manager

By: Pharmakon Management I, LLC,
its General Partner

By /s/ Pedro Gonzalez de Cosio
Name: Pedro Gonzalez de Cosio
Title: CEO and Managing Member

BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP,
as Lender

By: Pharmakon Advisors, LP,
its Investment Manager

By: Pharmakon Management I, LLC,
its General Partner

By /s/ Pedro Gonzalez de Cosio
Name: Pedro Gonzalez de Cosio
Title: CEO and Managing Member

EXHIBIT A – PAYMENT/ADVANCE REQUEST FORM

LOAN PAYMENT/ADVANCE REQUEST

The undersigned, being the duly elected and acting _____of SAREPTA THERAPEUTICS, INC., a Delaware corporation ("**Borrower**"), does hereby certify, solely in his/her capacity as an authorized officer of Borrower and not in his/her personal capacity, to each of BIOPHARMA CREDIT PLC (in its capacity as "**Collateral Agent**" and a "**Lender**") and BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP (a "**Lender**"), in connection with that certain Loan Agreement dated as of December 13, 2019 by and among Borrower, Lenders and the other parties thereto (the "**Loan Agreement**"; with other capitalized terms used below having the meanings ascribed thereto in the Loan Agreement) that, subject to the satisfaction (or waiver by Required Lenders) of the conditions precedent to the Tranche [A] [B] Loan[1] set forth in Section 3 of the Loan Agreement, on [the Tranche A Closing Date][2] [[_____, 20__] (the "**Tranche B Closing Date**")][3]:

1. the representations and warranties made by the Credit Parties in Section 4 of the Loan Agreement and in the other Loan Documents are true and correct in all material respects, unless any such representation or warranty is stated to relate to a specific earlier date, in which case such representation or warranty shall be true and correct in all material respects as of such earlier date (it being understood that any representation or warranty that is qualified as to "materiality," "Material Adverse Change," or similar language shall be true and correct in all respects on the Tranche [A][B] Closing Date[4] or as of such earlier date, as applicable);

2. no Default or Event of Default has occurred since the [Effective Date][5] [Tranche A Closing Date][6] or is occurring as of the date hereof;

3. all conditions referred to in Section 3 of the Loan Agreement to the making of the Tranche [A][B] Loan[7] to be made on the Tranche [A][B] Closing Date[8] have been satisfied (or waived in writing by the Required Lenders);

4. no Material Adverse Change has occurred since the [Effective Date][9] [Tranche A Closing Date][10]

5. the undersigned is a Responsible Officer of Borrower; and

6. the proceeds of the [Tranche A Loan][11] [Tranche B Loan][12] shall be disbursed as set forth on Attachment A hereto[13].

Dated: _____, 20__[14]

[Signature page follows]

---

1 As applicable.
2 To be included in Payment/Advance Request for Tranche A Loan only.
3 To be included in Payment/Advance Request for Tranche B Loan only.
4 As applicable.
5 To be included in Payment/Advance Request for Tranche A Loan only.
6 To be included in Payment/Advance Request for Tranche B Loan only.
7 As applicable.
8 As applicable.
9 To be included in Payment/Advance Request for Tranche A Loan only.
10 To be included in Payment/Advance Request for Tranche B Loan only.
11 To be included in Payment/Advance Request for Tranche A Loan only.
12 To be included in Payment/Advance Request for Tranche B Loan only.
13 To be prepared in coordination with Lenders (or by Lenders' counsel).
14 In Payment/Advance Request for Tranche B Loan, insert date no later than 75 days prior to the Tranche B Closing Date.

SAREPTA THERAPEUTICS, INC.,
as Borrower

By _____

Name: _____

Title: _____

[Signature page to Loan Payment/Advance Request (Tranche [A] [B] Loan)]

EXHIBIT B-1

THIS NOTE CONTAINS ORIGINAL ISSUE DISCOUNT, AS DEFINED IN SECTION 1273 OF THE INTERNAL REVENUE CODE OF 1986, AS AMENDED. PLEASE CONTACT PETER WALSH, 215 FIRST STREET, SUITE 415, CAMBRIDGE, MA, 02142, TELEPHONE: (617) 301-8680 TO OBTAIN INFORMATION REGARDING THE ISSUE PRICE OF THE NOTE, THE AMOUNT OF ORIGINAL ISSUE DISCOUNT IN THE NOTE AND THE YIELD TO MATURITY.

TRANCHE A NOTE

$____.00 Dated: [_____], 2019

FOR VALUE RECEIVED, the undersigned, SAREPTA THERAPEUTICS, INC., a Delaware corporation ("**Borrower**"), HEREBY PROMISES TO PAY to [BIOPHARMA CREDIT PLC] [BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP] ("**Lender**"), or its registered assignees, the principal amount of _____ ($_____.00), plus interest on the aggregate unpaid principal amount hereof at a per annum rate equal to eight and one-half percent (8.50%) per annum, and in accordance with the terms of the Loan Agreement dated as of December 13, 2019 by and among Borrower, Lender and the other parties thereto (as may be amended, restated, supplemented or otherwise modified from time to time, the "**Loan Agreement**"). If not sooner paid, the entire principal amount (including accrued and capitalized PIK Interest), all accrued, unpaid and uncapitalized interest hereunder, all due and unpaid Lender Expenses and any other amounts payable under the Loan Documents shall be due and payable on the Term Loan Maturity Date. Any capitalized term not otherwise defined herein shall have the meaning attributed to such term in the Loan Agreement.

All unpaid principal (including accrued and capitalized PIK Interest) with respect to the Tranche A Loan (and, for the avoidance of doubt, all accrued, unpaid and uncapitalized interest, all due and unpaid Lender Expenses and any other amounts payable under the Loan Documents) is due and payable in full on the Term Loan Maturity Date. Interest shall accrue on this Tranche A Note commencing on, and including, the date of this Tranche A Note, and shall accrue on this Tranche A Note, or any portion thereof, for the day on which this Tranche A Note or such portion is paid. Interest on this Tranche A Note shall be payable in accordance with Section 2.3 of the Loan Agreement.

Principal, interest and all other amounts due with respect to this Tranche A Note are payable in lawful money of the United States of America to Lender as set forth in the Loan Agreement and this Tranche A Note.

The Loan Agreement, among other things, (a) provides for the making of secured Term Loans by Lender to Borrower, and (b) contains provisions for acceleration of the maturity hereof upon the happening of certain stated events.

This Tranche A Note may not be prepaid except as set forth in Section 2.2(c) of the Loan Agreement or as expressly provided in Section 8.1 of the Loan Agreement.

This Tranche A Note and the obligation of Borrower to repay the unpaid principal amount of this Tranche A Note, interest thereon, and all other amounts due Lender under the Loan Agreement are secured pursuant to the Collateral Documents.

Presentment for payment, demand, notice of protest and all other demands and notices of any kind in connection with the execution, delivery, performance and enforcement of this Tranche A Note are hereby waived.

THIS TRANCHE A NOTE AND ANY CLAIMS, CONTROVERSY, DISPUTE OR CAUSE OF ACTION (WHETHER IN CONTRACT OR TORT OR OTHERWISE) BASED UPON, ARISING OUT OF OR RELATING TO THIS TRANCHE A NOTE SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE LAW OF THE STATE OF NEW YORK.

Note Register; Ownership of Note. The ownership of an interest in this Tranche A Note shall be registered on a record of ownership maintained by Collateral Agent. Notwithstanding anything else in this Tranche A Note to the contrary, the right to the principal of, and stated interest on, this Tranche A Note may be transferred only if the transfer is registered on such record of ownership and the transferee is identified as the owner of an interest in the obligation. Borrower shall be entitled to treat the registered holder of this Tranche A Note (as recorded on such record of ownership) as the owner in fact thereof for all purposes and shall not be bound to recognize any equitable or other claim to or interest in this Tranche A Note on the part of any other Person.

IN WITNESS WHEREOF, Borrower has caused this Tranche A Note to be duly executed by one of its officers thereunto duly authorized on the date hereof.

BORROWER:

SAREPTA THERAPEUTICS, INC.,
as Borrower

By _____

Name: _____

Title: _____

EXHIBIT B-2

THIS NOTE CONTAINS ORIGINAL ISSUE DISCOUNT, AS DEFINED IN SECTION 1273 OF THE INTERNAL REVENUE CODE OF 1986, AS AMENDED. PLEASE CONTACT PETER WALSH, 215 FIRST STREET, SUITE 415, CAMBRIDGE, MA, 02142, TELEPHONE: (617) 301-8680 TO OBTAIN INFORMATION REGARDING THE ISSUE PRICE OF THE NOTE, THE AMOUNT OF ORIGINAL ISSUE DISCOUNT IN THE NOTE AND THE YIELD TO MATURITY.

TRANCHE B NOTE

$_____.00 Dated: [_____], 20__

FOR VALUE RECEIVED, the undersigned, SAREPTA THERAPEUTICS, INC., a Delaware corporation ("**Borrower**"), HEREBY PROMISES TO PAY to [BIOPHARMA CREDIT PLC] [BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP] ("**Lender**"), or its registered assignees, the principal amount of _____ ($___,000,000.00), plus interest on the aggregate unpaid principal amount hereof at a per annum rate equal to eight and one-half percent (8.50%) per annum, and in accordance with the terms of the Loan Agreement dated as of December 13, 2019 by and among Borrower, Lender and the other parties thereto (as may be amended, restated, supplemented or otherwise modified from time to time, the "**Loan Agreement**"). If not sooner paid, the entire principal amount, all accrued and unpaid interest hereunder, all due and unpaid Lender Expenses and any other amounts payable under the Loan Documents shall be due and payable on the Term Loan Maturity Date. Any capitalized term not otherwise defined herein shall have the meaning attributed to such term in the Loan Agreement.

All unpaid principal with respect to the Tranche B Loan (and, for the avoidance of doubt, all accrued and unpaid interest, all due and unpaid Lender Expenses and any other amounts payable under the Loan Documents) is due and payable in full on the Term Loan Maturity Date. Interest shall accrue on this Tranche B Note commencing on, and including, the date of this Tranche B Note, and shall accrue on this Tranche B Note, or any portion thereof, for the day on which this Tranche B Note or such portion is paid. Interest on this Tranche B Note shall be payable in accordance with Section 2.3 of the Loan Agreement.

Principal, interest and all other amounts due with respect to this Tranche B Note are payable in lawful money of the United States of America to Lender as set forth in the Loan Agreement and this Tranche B Note.

The Loan Agreement, among other things, (a) provides for the making of secured Term Loans by Lender to Borrower, and (b) contains provisions for acceleration of the maturity hereof upon the happening of certain stated events.

This Tranche B Note may not be prepaid except as set forth in Section 2.2(c) of the Loan Agreement or as expressly provided in Section 8.1 of the Loan Agreement.

This Tranche B Note and the obligation of Borrower to repay the unpaid principal amount of this Tranche B Note, interest thereon, and all other amounts due Lender under the Loan Agreement are secured pursuant to the Collateral Documents.

Presentment for payment, demand, notice of protest and all other demands and notices of any kind in connection with the execution, delivery, performance and enforcement of this Tranche B Note are hereby waived.

THIS TRANCHE B NOTE AND ANY CLAIMS, CONTROVERSY, DISPUTE OR CAUSE OF ACTION (WHETHER IN CONTRACT OR TORT OR OTHERWISE) BASED UPON, ARISING OUT OF OR RELATING TO THIS TRANCHE B NOTE SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE LAW OF THE STATE OF NEW YORK.

Note Register; Ownership of Note. The ownership of an interest in this Tranche B Note shall be registered on a record of ownership maintained by Collateral Agent. Notwithstanding anything else in this Tranche B Note to the contrary, the right to the principal of, and stated interest on, this Tranche B Note may be transferred only if the transfer is registered on such record of ownership and the transferee is identified as the owner of an interest in the obligation. Borrower shall be entitled to treat the registered holder of this Tranche B Note (as recorded on such record of ownership) as the owner in fact thereof for all purposes and shall not be bound to recognize any equitable or other claim to or interest in this Tranche B Note on the part of any other Person.

IN WITNESS WHEREOF, Borrower has caused this Tranche B Note to be duly executed by one of its officers thereunto duly authorized on the date hereof.

BORROWER:

SAREPTA THERAPEUTICS, INC.,
as Borrower

By _____

Name: _____

Title: _____

EXHIBIT C

FORM OF SECURITY AGREEMENT

GUARANTY AND SECURITY AGREEMENT

Dated as of December 20, 2019

by

SAREPTA THERAPEUTICS, INC.

(as *Borrower*),

THE GUARANTORS PARTY HERETO,

and

EACH OTHER GRANTOR
FROM TIME TO TIME PARTY HERETO

in favor of

BIOPHARMA CREDIT PLC

(as *Collateral Agent* on behalf of Lenders and the other Secured Parties)

GUARANTY AND SECURITY AGREEMENT, dated as of December 20, 2019 by SAREPTA THERAPEUTICS, INC., a Delaware corporation ("Borrower"), the Guarantors party to the Loan Agreement (as defined below) as of the date hereof, and each other Person that becomes a party hereto pursuant to Section 8.6 (together with Borrower and such Guarantors, "Grantors"), in favor of BIOPHARMA CREDIT PLC, a public limited company incorporated under the laws of England and Wales (as the "Collateral Agent") on behalf of Lenders and each other Secured Party.

W I T N E S S E T H:

WHEREAS, pursuant to the Loan Agreement dated as of December 13, 2019 (as the same may be amended, restated, amended and restated, supplemented or otherwise modified from time to time, the "Loan Agreement") by and among Borrower, the Collateral Agent and the other parties thereto, Lenders agrees to make extensions of credit to Borrower upon the terms and subject to the conditions set forth therein;

WHEREAS, each Grantor other than Borrower agrees to guaranty, jointly and severally, the Obligations (as defined in the Loan Agreement) of Borrower;

WHEREAS, each Grantor will derive substantial direct and indirect benefits from the making of the extensions of credit under the Loan Agreement; and

WHEREAS, it is a condition precedent to the obligation of Lenders to extend credit to Borrower under the Loan Agreement that the Grantors shall have executed and delivered this Agreement to the Collateral Agent and each Lender for the benefit of Lenders and the other Secured Parties.

NOW, THEREFORE, in consideration of the mutual premises herein contained and for valuable consideration the receipt and sufficiency of which is hereby acknowledged and to induce the Collateral Agent, Lenders and the Credit Parties to enter into the Loan Agreement and to induce each Lender to make extensions of credit to Borrower thereunder, each Grantor hereby agrees with the Collateral Agent, each intending to be legally bound, as follows:

ARTICLE I

DEFINED TERMS

Section 1.1. Definitions. Capitalized terms used herein without definition are used as defined in the Loan Agreement.

(a) The following terms have the meanings given to them in the Code and terms used herein without definition that are defined in the Code have the meanings given to them in the Code (such meanings to be equally applicable to both the singular and plural forms of the terms defined): "account", "account debtor", "as-extracted collateral", "certificated security", "chattel paper", "check", "commercial tort claim", "commodity account", "commodity contract", "documents", "deposit account", "electronic chattel paper", "encumbrance", "entitlement holder", "equipment", "farm products", "financial asset", "fixture", "general intangible", "goods", "health-care-insurance receivable", "instruments", "inventory", "investment property", "letter of credit", "letter-of-credit right", "money", "proceeds", "promissory note", "record", "securities account", "security", "security entitlement", "supporting obligation", "tangible chattel paper" and "uncertificated security".

(b) The following terms shall have the following meanings:

"Agreement" means this Guaranty and Security Agreement, as it may be amended, restated, supplemented or otherwise modified from time to time.

"Applicable IP Office" means the United States Patent and Trademark Office or the United States Copyright Office, as the context dictates.

"Collateral" has the meaning specified in Section 3.1.

"Excluded Property" means, collectively:

(i) any "intent to use" United States Trademark applications for which a statement of use or an amendment to allege use has not been filed (but only until such statement is filed) solely to the extent, if any, that, and only during the period, if any, in which, the grant of a security interest therein would impair the validity or enforceability of such intent to use Trademark applications under applicable federal law;

(ii) any permit, lease, license, contract, instrument or other agreement held by any Grantor with respect to which, the grant to the Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, of a security interest therein and Lien thereupon, and the pledge to the Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, thereof, to secure the Obligations (and any guaranty thereof) are validly prohibited by the terms thereof, or would create a right of termination in favor of any other party thereto (other than Borrower or a controlled Affiliate of Borrower) but only, in each case, to the extent, and for so long as, such prohibition or term is not terminated or rendered unenforceable or otherwise deemed ineffective by the Code (including Sections 9-406(d), 9-407(a), 9-408(a) and 9-409 of the Code) or by any applicable Requirements of Law;

(iii) any permit, lease, license, contract, instrument or other agreement held by any Grantor with respect to which, the grant to the Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, of a security interest in and Lien thereupon, and the pledge to the Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, thereof, to secure the Obligations (and any guaranty thereof) require the consent, approval or waiver of any Governmental Authority or other third party (other than Borrower or a controlled Affiliate of Borrower) and such consent, approval or waiver has not been obtained by such Grantor or Borrower following their respective commercially reasonable efforts to obtain the same;

(iv) any other asset or property subject or purported to be subject to a Lien under any Collateral Document held by any Grantor with respect to which, the grant to the Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, of a security interest in and Lien thereupon, and the pledge to the Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, thereof, to secure the Obligations (and any guaranty thereof) require the consent, approval or waiver of any Governmental Authority or other third party (other than Borrower or a controlled Affiliate of Borrower) and such consent, approval or waiver has not been obtained by such Grantor or Borrower following their respective commercially reasonable efforts to obtain the same;

(v) any property or asset subject or purported to be subject to a Lien under any Collateral Document held by any Grantor that is a non-Wholly-Owned Subsidiary with respect to which, the grant to the Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, of a security interest therein and Lien thereupon, and the pledge to the Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, thereof, to secure the Obligations (and any guaranty thereof) are validly prohibited by, or would give any third party (other than Borrower or an Affiliate of Borrower) the right to terminate its obligations under, the Operating Documents of, the joint venture agreement or shareholder agreement with respect to, or any other contract with such third party relating to such non-Wholly-Owned Subsidiary (other than customary non-assignment provisions which are ineffective under Article 9 of the Code or other Requirements of Law), but only, in each case, to the extent, and for so long as such Operating Documents, joint venture agreement, shareholder agreement or other contract is in effect;

(vi) any asset or property subject or purported to be subject to a Lien under any Collateral Document held by any Grantor with respect to which, the cost, difficulty, burden or consequences (including adverse Tax consequences) of granting the Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, a security interest therein and Lien thereupon, and pledging to the Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, thereof, to secure the Obligations (and any guaranty thereof) are excessive relative to the value to be afforded to Secured Parties thereby;

(vii) any rights under any Federal or state governmental license, permit, franchise or authorization to the extent that the granting of a security interest therein is specifically prohibited or restricted by any Requirements of Law;

(viii) any asset or property subject to a Permitted Lien to the extent the documents governing such Permitted Lien or the Permitted Indebtedness secured thereby validly prohibit other Liens on such asset or property, or would create a right of termination in favor of any other party thereto (other than Borrower or a controlled Affiliate of Borrower) but only, in each case, to the extent, and for so long as, such prohibition or term is not terminated or rendered unenforceable or otherwise deemed ineffective by the Code (including Sections 9-406(d), 9-407(a), 9-408(a) and 9-409 of the Code) or by any applicable Requirements of Law;

(ix) leasehold interests in real property;

(x) fee interests in real property;

(xi) Vehicles;

(xii) any letter of credit with an amount less than $500,000 and all letter-of-credit rights with respect thereto;

(xiii) any Intellectual Property unrelated in any way to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of any Product in the Territory, including any similar or equivalent rights to those set forth in any of clauses (a) through (f) of the definition of "Intellectual Property" and, for the avoidance of doubt, any non-U.S. Intellectual Property;

(xiv) Excluded Equity Interests; and

(xv) Excluded Accounts;

provided, however, that "Excluded Property" shall not include any proceeds, products, substitutions or replacements of Excluded Property (unless such proceeds, products, substitutions or replacements would otherwise constitute Excluded Property).

"Fraudulent Transfer Laws" has the meaning set forth in Section 2.2.

"Guaranteed Obligations" has the meaning set forth in Section 2.1.

"Guarantor" means each Grantor other than Borrower.

"Guaranty" means the guaranty of the Guaranteed Obligations made by Guarantors as set forth in this Agreement.

"IP License" means all express and implied grants or rights to make, have made, use, sell, reproduce, distribute, modify, or otherwise exploit any Intellectual Property, as well as all covenants not to sue and co-existence agreements (and all related IP Ancillary Rights), whether written or oral, relating to any Intellectual Property.

"Maximum Guaranteed Amount" has the meaning set forth in Section 2.2.

"NDA" means a new drug application filed with the FDA pursuant to Section 505(b) of the U.S. Federal Food, Drug, and Cosmetic Act, along with all supplements and amendments thereto.

"Pledged Certificated Stock" means all of the Equity Interests (other than Excluded Equity Interests) in any Subsidiary evidenced by a certificate, instrument or other similar document (as defined in the Code), in each case owned by any Grantor, including a Grantor's right, title and interest resulting from its ownership of any such Equity Interests as a limited or general partner in any partnership that has issued Pledged Certificated Stock or as a member of any limited liability company that has issued Pledged Certificated Stock, and a Grantor's right, title and interest resulting from its ownership of any such Equity Interests in, to and under any Operating Document or shareholder agreement of any corporation, partnership or limited liability company to which it is a party, and any distribution of property made on, in respect of or in exchange for the foregoing from time to time, including all certificated Equity Interests listed on Schedule 1 of the Security Disclosure Letter. "Pledged Certificated Stock" includes, for the avoidance of doubt, any Pledged Uncertificated Stock that subsequently becomes certificated.

"Pledged Collateral" means, collectively, the Pledged Stock and the Pledged Debt Instruments.

"Pledged Debt Instruments" means all right, title and interest of any Grantor in instruments evidencing any Indebtedness owed to such Grantor, and any distribution of property made on, in respect of or in exchange for the foregoing from time to time, including all Indebtedness described on Schedule 3 of the Security Disclosure Letter, issued by the obligors named therein. "Pledged Debt Instruments" excludes any Excluded Property.

"Pledged Investment Property" means any investment property of any Grantor, and any distribution of property made on, in respect of or in exchange for the foregoing from time to time, other than any Pledged Stock or Pledged Debt Instruments. "Pledged Investment Property" excludes any Excluded Property.

"Pledged Stock" means all Pledged Certificated Stock and all Pledged Uncertificated Stock.

"Pledged Uncertificated Stock" means all of the Equity Interests (other than Excluded Equity Interests) in any Subsidiary that is not Pledged Certificated Stock, in each case owned by any Grantor, including Grantor's right, title and interest resulting from its ownership of any such Equity Interests as a limited or general partner in any partnership not constituting Pledged Certificated Stock or as a member of any limited liability company not constituting Pledged Certificated Stock, a Grantor's right, title and interest resulting from its ownership of any such Equity Interests in, to and under any Operating Document or shareholder agreement of any partnership or limited liability company to which it is a party, and any distribution of property made on, in respect of or in exchange for the foregoing from time to time, including in each case those interests set forth on Schedule 1 of the Security Disclosure Letter, to the extent such interests are not certificated.

"Secured Obligations" has the meaning set forth in Section 3.2.

"Security Disclosure Letter" means the security agreement disclosure letter, dated as of the date hereof, delivered by the Grantors to the Collateral Agent and each Lender.

"Vehicles" means rolling stock, motor vehicles, vessels, aircraft and other assets subject to certificates of title.

Section 1.2. Certain Other Terms.

(a) For the purposes of and as used in this Agreement: (i) references to any Person include its successors and assigns and, in the case of any Governmental Authority, any Person succeeding to its functions and capacities; (ii) each authorization herein shall be deemed irrevocable and coupled with an interest; and (iii) where the context requires, provisions relating to any Collateral when used in relation to a Grantor shall refer to such Grantor's Collateral or any relevant part thereof.

(b) Other Interpretive Provisions.

(i) Defined Terms. Unless otherwise specified herein or therein, all terms defined in this Agreement shall have the defined meanings when used in any certificate or other document made or delivered pursuant hereto.

(ii) This Agreement. The words "hereof", "herein", "hereunder" and words of similar import when used in this Agreement shall refer to this Agreement as a whole and not to any particular provision of this Agreement.

(iii) Certain Common Terms. The words "include", "included" and "including" are not limiting and mean "including without limitation." The word "or" has the inclusive meaning represented by the phrase "and/or". The word "shall" is mandatory. The word "may" is permissive. The singular includes the plural and the plural includes the singular.

(iv) Performance; Time. Whenever any performance obligation hereunder (other than a payment obligation) shall be stated to be due or required to be satisfied on a day other than a Business Day, such performance shall be made or satisfied on the next succeeding Business Day. In the computation of periods of time from a specified date to a later specified date, the word "from" means "from and including"; the words "to" and "until" each mean "to but excluding", and the word "through" means "to and including." If any provision of this Agreement refers to any action taken or to be taken by any Person, or which such Person is prohibited from taking, such provision shall be interpreted to encompass any and all means, direct or indirect, of taking, or not taking, such action.

(v) Contracts. Except as the context otherwise requires (including to the extent otherwise expressly provided herein), references to any contract, agreement, instrument or other document, including this Agreement and the other Loan Documents, shall be deemed to include any and all amendments, supplements or modifications thereto or restatements or substitutions thereof, in each case which are in effect from time to time, but only to the extent such amendments, supplements, modifications, restatements or substitutions are not prohibited by the terms of any Loan Document.

(vi) Laws. Except as the context otherwise requires (including to the extent otherwise expressly provided herein), references to any law, statute, treaty, order, policy, rule or regulation include any amendments, supplements and successors thereto, and references to any law, statute, treaty, order, policy, rule or regulation are to be construed as including all statutory and regulatory provisions related thereto or consolidating, amending, replacing, supplementing or interpreting such law, statute, treaty, order, policy, rule or regulation.

(vii) Excluded Property. Notwithstanding anything to the contrary herein, the representations, warranties and covenants set forth herein in relation to the assets of the Grantors shall not apply to any Excluded Property.

ARTICLE II

GUARANTY

Section 2.1. Guaranty. To induce Lenders to make the Term Loans to Borrower in accordance with the terms and conditions of the Loan Agreement, each Guarantor, jointly and severally with each other Guarantor, absolutely, unconditionally and irrevocably guarantees, as primary obligor and not merely as surety, the full and punctual payment when due, whether at stated maturity or earlier, by reason of acceleration, mandatory prepayment or otherwise in accordance with any Loan Document, of all the Obligations of Borrower existing on the date hereof or hereinafter incurred or created (the "Guaranteed Obligations"). This Guaranty by each Guarantor hereunder constitutes a guaranty of payment and not of collection. Each Guarantor hereby acknowledges and agrees that the Guaranteed Obligations, at any time and from time to time, may exceed the Maximum Guaranteed Amount of such Guarantor and may exceed the aggregate of the Maximum Guaranteed Amounts of all Guarantors, in each case without discharging, limiting or otherwise affecting the obligations of any Guarantor hereunder or the rights, powers and remedies of any Secured Party hereunder or under any other Loan Document.

Section 2.2. Limitation of Guaranty. Any term or provision of this Guaranty or any other Loan Document to the contrary notwithstanding, the maximum aggregate amount for which any Guarantor shall be liable hereunder (the "Maximum Guaranteed Amount") shall not exceed the maximum amount for which such Guarantor can be liable without rendering this Guaranty or any other Loan Document, as it relates to such Guarantor, subject to avoidance under applicable Requirements of Law relating to fraudulent conveyance or fraudulent transfer (including the Uniform Fraudulent Conveyance Act, the Uniform Fraudulent Transfer Act and Section 548 of title 11 of the United States Code or any applicable provisions of comparable Requirements of Law) (collectively, "Fraudulent Transfer Laws"). Any analysis of the provisions of this Guaranty for purposes of Fraudulent Transfer Laws shall take into account the right of contribution established in Section 2.7 below and, for purposes of such analysis, give effect to any discharge of intercompany debt as a result of any payment made under the Guaranty.

Section 2.3. Authorization; Other Agreements. The Collateral Agent, on behalf of Lenders and the other Secured Parties is hereby authorized, without notice, to or demand upon any Guarantor and without discharging or otherwise affecting the obligations of any Guarantor hereunder and without incurring any liability hereunder, from time to time, to do each of the following but subject in all cases to the terms and conditions of the other Loan Documents:

(a) (i) modify, amend, supplement or otherwise change, (ii) accelerate or otherwise change the time of payment or (iii) waive or otherwise consent to noncompliance with, any Guaranteed Obligation or any Loan Document;

(b) apply to the Guaranteed Obligations any sums by whomever paid or however realized to any Guaranteed Obligation in such order as provided in the Loan Documents;

(c) refund at any time any payment received by any Secured Party in respect of any Guaranteed Obligation;

(d) (i) sell, exchange, enforce, waive, substitute, liquidate, terminate, release, abandon, fail to perfect, subordinate, accept, substitute, surrender, exchange, affect, impair or otherwise alter or release any Collateral for any Guaranteed Obligation or any other guaranty therefor in any manner, (ii) receive, take and hold additional Collateral to secure any Guaranteed Obligation, (iii) add, release or substitute any one or more other Guarantors, makers or endorsers of any Guaranteed Obligation or any part thereof and (iv) otherwise deal in any manner with Borrower or any other Guarantor, maker or endorser of any Guaranteed Obligation or any part thereof; and

(e) settle, release, compromise, collect or otherwise liquidate the Guaranteed Obligations.

Section 2.4. Guaranty Absolute and Unconditional. Each Guarantor hereby waives and agrees not to assert any defense (other than the defense of indefeasible payment in full of the Guaranteed Obligations (other than inchoate indemnity obligations)), whether arising in connection with or in respect of any of the following clauses (a) through (f) or otherwise, and hereby agrees that its obligations under this Guaranty are irrevocable, absolute and unconditional and shall not be discharged as a result of or otherwise affected by any of the following clauses (a) through (f) (which may not be pleaded and evidence of which may not be introduced in any proceeding with respect to this Guaranty, in each case except as otherwise agreed in writing by the Collateral Agent):

(a) the invalidity or unenforceability of any obligation of Borrower or any other Guarantor under any Loan Document or any other agreement or instrument relating thereto (including any amendment, consent or waiver thereto), or any security for, or other guaranty of, any Guaranteed Obligation or any part thereof, or the lack of perfection or continuing perfection or failure of priority of any security for the Guaranteed Obligations or any part thereof;

(b) the absence of (i) any attempt to collect any Guaranteed Obligation or any part thereof from Borrower or any other Guarantor or other action to enforce the same or (ii) any action to enforce any Loan Document or any Lien thereunder;

(c) the failure by any Person to take any steps to perfect and maintain any Lien on, or to preserve any rights with respect to, any Collateral;

(d) any workout, insolvency, bankruptcy proceeding, reorganization, arrangement, liquidation or dissolution by or against Borrower, any other Guarantor or any of Borrower's other Subsidiaries or any procedure, agreement, order, stipulation, election, action or omission thereunder, including any discharge or disallowance of, or bar or stay against collecting, any Guaranteed Obligation (or any interest thereon) in or as a result of any such proceeding;

(e) any foreclosure, whether or not through judicial sale, and any other sale or other disposition of any Collateral or any election following the occurrence of an Event of Default and during the continuance thereof by the Collateral Agent, on behalf of Lenders and any other Secured Party, to proceed separately against any Collateral in accordance with the Collateral Agent's rights and the rights of any Lender or other Secured Party under any applicable Requirements of Law; or

(f) any other defense, setoff, counterclaim or any other circumstance that might otherwise constitute a legal or equitable discharge of Borrower, any other Guarantor or any other Subsidiary of Borrower, in each case other than the defense of indefeasible payment in full of the Guaranteed Obligations (other than inchoate indemnity obligations).

Section 2.5. Waivers. To the fullest extent permitted by Requirements of Law, each Guarantor hereby unconditionally and irrevocably waives and agrees not to assert any claim, defense (other than the defense of payment in full of the Guaranteed Obligations (other than inchoate indemnity obligations)), setoff or counterclaim based on diligence, promptness, presentment, requirements for any demand or notice hereunder, including any of the following: (a) any demand for payment or performance and protest and notice of protest; (b) any notice of acceptance; (c) any presentment, demand, protest or further notice or other requirements of any kind with respect to any Guaranteed Obligation (including any accrued but unpaid interest thereon) becoming immediately due and payable; and (d) any other notice in respect of any Guaranteed Obligation or any part thereof, and any defense arising by reason of any disability or other defense of Borrower or any other Guarantor. Until the indefeasible payment in full of the Guaranteed Obligations (other than inchoate indemnity obligations), each Guarantor further unconditionally and irrevocably agrees not to (x) enforce or otherwise exercise any right of subrogation or any right of reimbursement or contribution or similar right against Borrower or any other Guarantor by reason of any Loan Document or any payment made thereunder or (y) assert any claim, defense, setoff or counterclaim it may have against any other Credit Party or set off any of its obligations to such other Credit Party against obligations of such Credit Party to such Guarantor. No obligation of any Guarantor hereunder shall be discharged other than by complete performance.

Section 2.6. Reliance. Each Guarantor hereby assumes responsibility for keeping itself informed of the financial condition of Borrower, each other Guarantor and any other guarantor, maker or endorser of any Guaranteed Obligation or any part thereof, and of all other circumstances bearing upon the risk of nonpayment of any Guaranteed Obligation or any part thereof that reasonable and diligent inquiry would reveal, and each Guarantor hereby agrees that neither the Collateral Agent nor any Lender or other Secured Party shall have any duty to advise any Guarantor of information known to it regarding such condition or any such circumstances. In the event the Collateral Agent, in its sole discretion, undertakes at any time or from time to time to provide any such information to any Guarantor, such Person shall be under no obligation to (a) undertake any investigation not a part of its regular business routine, (b) disclose any information that any Lender or other Secured Party, pursuant to accepted or reasonable commercial finance or banking practices, wishes to maintain confidential or (c) make any future disclosures of such information or any other information to any Guarantor.

Section 2.7. Contribution. To the extent that any Guarantor shall be required hereunder to pay any portion of any Guaranteed Obligation exceeding the greater of (a) the amount of the value actually received by such Guarantor and its Subsidiaries from the Term Loans and other Obligations and (b) the amount such Guarantor would otherwise have paid if such Guarantor had paid the aggregate amount of the Guaranteed Obligations (excluding the amount thereof repaid by Borrower) in the same proportion as such Guarantor's net worth on the date enforcement is sought hereunder bears to the aggregate net worth of all Guarantors on such date, then such Guarantor shall be reimbursed by such other Guarantors for the amount of such excess, *pro rata*, based on the respective net worth of such other Guarantors on such date.

ARTICLE III

GRANT OF SECURITY INTEREST

Section 3.1. Collateral. For the purposes of this Agreement, the following tangible and intangible assets and property now owned or at any time hereafter acquired, developed or created by a Grantor or in which a Grantor now has or at any time in the future may acquire any right, title or interest, in each case, wherever located, is collectively referred to as the "Collateral":

(a) all accounts;

(b) all as-extracted collateral;

(c) all chattel paper, including electronic chattel paper or tangible chattel paper;

(d) all checks;

(e) all deposit accounts;

(f) all documents;

(g) all equipment;

(h) all fixtures;

(i) all general intangibles (including all Current Company IP Agreements);

(j) all goods;

(k) all instruments (including all promissory notes);

(l) any and all U.S. Intellectual Property and IP Licenses (including IP Licenses under the Current Company IP Agreements to which a Grantor is a party and the rights of such Grantor thereunder, and all of a Grantor's right, title and interest in, to and under any Internet Domain Names and Software) relating to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of any Product in the Territory, including any similar or equivalent rights to those set forth in any of clauses (a) through (f) of the definition of "Intellectual Property";

(m) all right title and interest in, to and under any NDA relating to the commercialization, marketing, offer for sale, distribution or sale of any Product in the Territory;

(n) all inventory;

(o) all investment property (including Pledged Collateral, Pledged Investment Property, Equity Interests, securities, securities accounts and security entitlements with respect thereto and financial assets carried therein, and all commodity accounts and commodity contracts);

(p) all money;

(q) all letters of credit, letter-of-credit rights and supporting obligations;

(r) the commercial tort claims with a predicted value of $500,000 or more (as reasonably determined by a Responsible Officer of Borrower in good faith and based upon reasonable assumptions) described on Schedule 4 of the Security Disclosure Letter;

(s) all books, records, ledger cards, files, correspondence, customer lists, blueprints, technical specifications, manuals, computer software, computer printouts, tapes, disks and other electronic storage media and related data processing software and similar items that at any time pertain to or evidence or contain information specifically relating to any of the other property described in the foregoing clauses (a) - (p) of this Section 3.1;

(t) all property of such Grantor held by the Collateral Agent for the benefit of Lenders and any other Secured Party, including all property of every description, in the custody of or in transit to the Collateral Agent for the benefit of Lenders and any other Secured Party for any purpose, including safekeeping, collection or pledge, for the account of such Grantor or as to which such Grantor may have any right or power, including cash;

(u) all proceeds, products, accessions, rents and profits of or in respect of any of the foregoing;

(v) to the extent not otherwise included, all personal property of such Grantor, whether tangible or intangible and wherever located, and all proceeds, products, accessions, rents, issues and profits of any and all of the foregoing and all collateral security, supporting obligations and guarantees given by any Person with respect to any of the foregoing; and

(w) to the extent not otherwise included, all other properties or assets of whatever kind and nature subject or purported to be subject from time to time to a Lien under any Collateral Document;

excluding, however, all Excluded Property.

Section 3.2. **Grant of Security Interest in Collateral.**

(a) Without limiting any other security interest granted to the Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, each Grantor, as collateral security for the prompt and complete payment and performance when due (whether at stated maturity, by acceleration or otherwise) of the Obligations of such Grantor (the "Secured Obligations"), hereby pledges, hypothecates and grants to the Collateral Agent, in favor and for the benefit of Lenders and the other Secured Parties, to secure the payment and performance in full of all of the Obligations for the benefit of Lenders and the other Secured Parties, a first priority Lien (subject only to Permitted Liens) on and continuing security interest in, all of its right, title and interest in, to and under the Collateral of such Grantor, wherever located, whether now owned or hereafter acquired or arising; provided, however, notwithstanding the foregoing, no Lien or security interest is hereby granted on, and "Collateral" shall not include, any Excluded Property; provided, further, that if and when any property or asset shall cease to be Excluded Property, a first priority Lien (subject only to Permitted Liens) on and security interest in such property or asset shall be deemed granted therein and, therefore, "Collateral" shall then include any such property or asset.

(b) Notwithstanding anything herein to the contrary, no Grantor or Subsidiary of any Grantor shall be required to take any action under laws outside the United States, or enter into agreements governed or purported to be governed by laws outside of the United States, to attach, maintain, perfect, protect or enforce any Lien of the Collateral Agent in favor and for the benefit of Lenders and the other Secured Parties on Collateral.

ARTICLE IV

REPRESENTATIONS AND WARRANTIES

To induce the Collateral Agent and Lenders to enter into the Loan Documents, each Grantor, jointly and severally with each other Grantor, represents and warrants each of the following to the Collateral Agent, each Lender and the other Secured Parties:

Section 4.1. Title; No Other Liens. Except for the Lien granted to the Collateral Agent for the benefit of Lenders and the other Secured Parties pursuant to this Agreement and any other Permitted Liens under any Loan Document (including Section 4.2 hereof), such Grantor owns or otherwise has the rights it purports to have in each item of the Collateral, free and clear of any and all Liens or claims of others. Such Grantor (a) is the record and beneficial owner of the Collateral pledged by it hereunder constituting instruments or certificates and (b) except for Permitted Subsidiary Distribution Restrictions, has rights in or the power to transfer each other item of Collateral in which a Lien is granted by it hereunder, free and clear of any other Lien other than any Permitted Liens.

Section 4.2. Perfection and Priority. Other than in respect of money and other Collateral subject to Section 9-311(a)(1) of the Code, the security interest granted to the Collateral Agent pursuant to this Agreement constitutes a valid and continuing first priority perfected security interest (subject, in the case of priority only, to Permitted Liens that are expressly permitted (if at all) by the terms of the Loan Agreement or this Agreement to, or that by operation of law, have superior priority to the Lien and security interest granted to the Collateral Agent for the benefit of Lenders and the other Secured Parties) in favor of and for the benefit of Lenders and the other Secured Parties in all Collateral, subject, for the following Collateral, to the occurrence of the following: (a) in the case of all Collateral in which a security interest may be perfected by filing a financing statement under the Code, the completion of the filings and other actions specified on Schedule 2 of the Security Disclosure Letter (which, in the case of all filings and other documents referred to on such schedule, have been duly authorized by the applicable Guarantor); (b) with respect to any account over which a Control Agreement is required pursuant to Section 5.5 of the Loan Agreement, the execution of Control Agreements; in the case of all United States Trademarks, Patents and Copyrights for which Code filings are insufficient to effectuate perfection, all appropriate filings having been made with the Applicable IP Office, as applicable; (d) in the case of all Pledged Certificated Stock, Pledged Debt Instruments and Pledged Investment Property, the delivery to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of such Pledged Certificated Stock, Pledged Debt Instruments and Pledged Investment Property consisting of instruments and certificates, in each case, properly endorsed for transfer to the Collateral Agent or in blank; (e) in the case of all Pledged Uncertificated Stock, the delivery to the Collateral Agent, for the benefit of the Lenders and the other Secured Parties, of an executed uncertificated stock control agreement among the issuer, the registered owner and the Collateral Agent in the form attached as Annex 4 hereto; and (f) in the case of all other instruments that are not Pledged Stock, if any, the delivery thereof to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of such instruments. Such Lien on and security interest in Pledged Stock shall be prior to all other Liens on such Collateral, subject to Permitted Liens having priority over the Collateral Agent's Lien by operation of law or as and to the extent expressly permitted (if at all) by any Loan Document. Except to the extent expressly not required pursuant to the terms of the Loan Agreement or this Agreement, all actions by each Grantor necessary or desirable to protect and perfect the first priority Lien on and security interest in the Collateral granted hereunder have been duly taken (subject to Section 3.2(b)).

Section 4.3. Pledged Stock.

(a) As of the Tranche A Closing Date, the Pledged Stock issued by any Subsidiary of any Grantor pledged by such Grantor hereunder (i) consist of the number and types of Equity Interests listed on Schedule 1 of the Security Disclosure Letter and constitutes that percentage of the issued and outstanding equity of all classes in each issuer thereof as set forth on Schedule 1 of the Security Disclosure Letter, (ii) has been duly authorized, validly issued and is fully paid and nonassessable (other than Pledged Stock in limited liability companies and partnerships), and (ii) constitutes the legal, valid and binding obligation of the obligor with respect thereto, enforceable in accordance with its terms. As of the date any Joinder Agreement or Pledge Amendment is delivered pursuant to Section 8.6, the Pledged Stock pledged by each applicable Grantor thereunder (x) is listed on

the applicable schedule attached to such Joinder Agreement or Pledge Amendment, as applicable, and constitutes that percentage of the issued and outstanding equity of all classes of each issuer thereof as set forth on such schedule, (y) has been duly authorized, validly issued and is fully paid and non-assessable (other than Pledged Stock in limited liability companies and partnerships) and (z) constitutes the legal, valid and binding obligation of the obligor with respect thereto, enforceable in accordance with its terms.

(b) As of, or substantially concurrently with, the Tranche A Closing Date, (i) all Pledged Certificated Stock has been delivered to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, in accordance with Section 5.2(a), and (ii) with respect to all Pledged Uncertificated Stock of Persons organized under the laws of the United States, uncertificated stock control agreements in the form attached as Annex 4 hereto have been delivered to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, in accordance with Section 5.2(a).

(c) Upon (i) the occurrence and during the continuance of an Event of Default and (ii) concurrent, written notice by the Collateral Agent to the relevant Grantor, the Collateral Agent for the benefit of Lenders and the other Secured Parties shall be entitled to exercise all of the rights of the Grantor granting the security interest in any Pledged Stock, and a transferee or assignee of such Pledged Stock shall become a holder of such Pledged Stock to the same extent as such Grantor and, upon the transfer of the entire interest of such Grantor, such Grantor shall, by operation of law, cease to be a holder of such Pledged Stock.

ARTICLE V

COVENANTS

Each Grantor agrees with the Collateral Agent to the following, until the indefeasible payment in full of the Obligations (other than inchoate indemnity obligations) and unless the Collateral Agent, on behalf of Lenders and the other Secured Parties, otherwise consents in writing:

Section 5.1. Maintenance of Perfected Security Interest; Further Documentation and Consents.

(a) Subject to the occurrence of the actions described in Section 4.2, which each Grantor shall promptly undertake, and except to the extent perfection is either (i) mutually agreed between Borrower and the Collateral Agent not to be required under this Agreement or the other Loan Documents or (ii) mutually agreed between Borrower and the Collateral Agent to be effected by filings of financing statements or amendments thereto to be made by the Collateral Agent or any Lender or its Related Party pursuant to Section 7.2, such Grantor shall maintain the security interest created by this Agreement as a perfected security interest having at least the priority described in Section 4.2 and shall take reasonable steps to warrant and defend the Collateral covered by such security interest and such priority against the claims and demands of all Persons (other than Secured Parties).

(b) Such Grantor shall furnish to the Collateral Agent at any time and from time to time statements and schedules further identifying and describing the Collateral and such other documents in connection with the Collateral as the Collateral Agent may reasonably request in writing, in all cases in reasonable detail and in form and substance reasonably satisfactory to the Collateral Agent.

(c) At any time and from time to time, upon the written request of the Collateral Agent, such Grantor shall, for the purpose of obtaining or preserving the full benefits of this Agreement and the other Collateral Documents and of the rights and powers herein and therein granted, (i) promptly and duly execute and deliver, and have recorded, such further documents, including an authorization to file (or, as applicable, the filing) of any financing statement or amendment under the Code (or other filings under similar Requirements of Law) in effect in any jurisdiction with respect to the security interest created hereby and (ii) take such further action as the Collateral Agent may reasonably request in writing that is consistent with the requirements hereof and of the other Loan Documents, including executing and delivering any Control Agreements required by Section 5.5 of the Loan Agreement with respect to the Collateral Accounts.

Section 5.2. Pledged Collateral.

(a) Delivery of Pledged Collateral. Such Grantor shall, promptly after acquiring any Pledged Collateral not owned on the Tranche A Closing Date: (i) deliver to the Collateral Agent, in suitable form for transfer and in form and substance reasonably satisfactory to the Collateral Agent, (A) all such Pledged Stock that is Pledged Certificated Stock, (B) all Pledged Debt Instruments in an amount greater than, individually, $75,000 and (C) all certificates and instruments evidencing Pledged Investment Property in an amount greater than, individually, $75,000, (ii) subject all Collateral Accounts required to be subject to a Control Agreement pursuant to the Loan Agreement to a Control Agreement; and (iii) cause the issuer of any such Pledged Stock that is Pledged Uncertificated Stock of Persons organized under the laws of the United States to execute an uncertificated stock control agreement in the form attached hereto as Annex 4, pursuant to which, *inter alia*, such issuer agrees to comply with the Collateral Agent's instructions with respect to such Pledged Uncertificated Stock without further consent by such Grantor, and, for the avoidance of doubt, if any such Pledged Uncertificated Stock becomes certificated, promptly (but in any event within thirty (30) days thereof) deliver to the Collateral Agent, in suitable form for transfer and in form and substance reasonably satisfactory to the Collateral Agent, all such certificates, instruments or other similar documents (as defined in the Code).

(b) Event of Default. During the continuance of any Event of Default and in connection with the exercise of rights or remedies hereunder or under any other Loan Document, the Collateral Agent shall have the right, at any time in its discretion, and upon concurrent, written notice by the Collateral Agent to the relevant Grantor, to (i) transfer to or to register in its name or in the name of its nominees any Pledged Stock and (ii) exchange any certificate or instrument representing or evidencing any Pledged Stock for certificates or instruments of smaller or larger denominations.

(c) Cash Distributions with respect to Pledged Collateral and Pledged Investment Property. Except as provided in Article VI and subject to any limitations set forth in the Loan Agreement, such Grantor shall be entitled to receive all cash distributions paid in respect of the Pledged Collateral and the Pledged Investment Property.

(d) Voting Rights. Except as provided in Article VI, such Grantor shall be entitled to exercise all voting, consent and corporate, partnership, limited liability company and similar rights with respect to the Pledged Collateral and Pledged Investment Property; provided, however, that no vote shall be cast, consent, waiver or ratification given or right exercised (or failed to be exercised) or other action taken (or failed to be taken) by such Grantor in any manner that would reasonably be expected to (i) violate or be inconsistent with any of the terms of this Agreement or any other Loan Document or (ii) have the effect of materially impairing such Collateral or the position or interests of the Secured Parties.

ARTICLE VI

REMEDIAL PROVISIONS

Section 6.1. Code and Other Remedies.

(a) Code Remedies. During the continuance of an Event of Default, the Collateral Agent, on behalf of Lenders and the other Secured Parties, may exercise, in addition to all other rights and remedies granted to it in this Agreement, any IP Agreement, any other Loan Document or in any other instrument or agreement securing, evidencing or relating to any Secured Obligation, all rights, powers and remedies of a secured party under the Code or any other Requirements of Law or in equity.

(b) Disposition of Collateral. During the continuance of an Event of Default, without limiting the generality of the foregoing, the Collateral Agent may (personally or through its agents or attorneys), without demand of performance or other demand, presentment, protest, advertisement or notice of any kind (except any notice required by Requirements of Law referred to below) to or upon any Grantor or any other Person (all and each of which demands, defenses, advertisements and notices are hereby waived): (i) enter upon the premises where any Collateral is located, without any obligation to pay rent, through self-help, without judicial process, without first obtaining a final judgment or giving Grantor or any other Person notice or opportunity for a hearing on the Collateral Agent's or any Lender's claim or action; (ii) collect, receive, appropriate and realize upon any Collateral; (iii) store, process, repair or recondition the Collateral or otherwise prepare any Collateral for disposition in any manner to the extent the Collateral Agent deems appropriate; and (iv) sell, assign, license out, convey, transfer, grant option or options to purchase or license and deliver any Collateral (or enter into contractual obligations to do any of the foregoing), in one or more parcels at public or private sale or sales, at any exchange, broker's board or office of the Collateral Agent or any Lender or other Secured Party or elsewhere upon such terms and conditions as it may deem advisable and at such prices as it may deem best, for cash or on credit or for future delivery without assumption of any credit risk. The Collateral Agent, on behalf of Lenders and the other Secured Parties, shall have the right, upon any such public sale or sales and, to the extent permitted by the Code and other Requirements of Law, upon any such private sale or sales, to purchase or license the whole or any part of the Collateral so sold or licensed, free of any right or equity of redemption of any Grantor, which right or equity is hereby waived and released. The Collateral Agent, as representative of all Lenders and other Secured Parties, shall be entitled, for the purpose of bidding and making settlement or payment of the purchase price for all or any portion of the Collateral sold at any such sale made in accordance with the Code, to use and apply any of the Secured Obligations as a credit on account of the purchase price for any Collateral payable by the Collateral Agent on behalf of Lenders and the other Secured Parties, at such sale. If the Collateral Agent on behalf of any Lender sells any of the Collateral upon credit, Grantor will be credited only with payments actually made by purchaser and received by such Lender and applied to indebtedness of the purchaser. In the event the purchaser fails to pay for the Collateral, the Collateral Agent may resell the Collateral and Grantor shall be credited with proceeds of the sale. Neither the Collateral Agent nor any Lender shall have an obligation to marshal any of the Collateral.

(c) Management of the Collateral. Each Grantor further agrees, that, during the continuance of any Event of Default, (i) at the Collateral Agent's request, it shall assemble the Collateral and make it available to the Collateral Agent at places that the Collateral Agent shall reasonably select, whether at such Grantor's premises or elsewhere, (ii) without limiting the foregoing, the Collateral Agent also has the right to require that such Grantor store and keep any Collateral pending further action by the Collateral Agent and, while any such Collateral is so stored or kept, provide such guards and maintenance services as shall be necessary to protect the same and to preserve and maintain such Collateral in good condition, normal wear and tear excepted, (iii) until the Collateral Agent is able to sell, assign, license out, convey or transfer any Collateral, the Collateral Agent shall have the right to hold or use such Collateral to the extent that it deems appropriate for the purpose of preserving the Collateral or its value or for any other purpose deemed appropriate by the Collateral Agent and (iv) the Collateral Agent may, if it so elects, seek the appointment of a receiver or keeper to take possession of any Collateral and to enforce any of the Collateral Agent's or any Lender's remedies, with respect to such appointment without prior notice or hearing as to such appointment. The Collateral Agent shall not have any obligation to any Grantor to maintain or preserve the rights of any Grantor as against other Persons with respect to any Collateral while such Collateral is in the possession of the Collateral Agent.

(d) Application of Proceeds. The Collateral Agent shall apply the cash proceeds received by it in respect of any sale of, any collection from, or other realization upon all or any part of the Collateral, after deducting all reasonable costs and expenses of every kind incurred in connection therewith or incidental to the care or safekeeping of any Collateral or in any way relating to the Collateral or the rights of Lenders and the other Secured Parties, including reasonable and documented out-of-pocket attorneys' fees and disbursements, to the payment in whole or in part of the Secured Obligations, as set forth in the Loan Agreement, and only after such application and after the payment by the Collateral Agent or Lenders of any other amount required by any Requirements of Law, need the Collateral Agent or any Lender account for the surplus, if any, to any Grantor.

(e) Direct Obligation. Neither the Collateral Agent nor any Lender or other Secured Party shall be required to make any demand upon, or pursue or exhaust any right or remedy against, any Grantor or any other Person with respect to the payment of the Obligations or to pursue or exhaust any right or remedy with respect to any Collateral therefor or any direct or indirect guaranty thereof. All of the rights and remedies of the Collateral Agent and Lenders and any other Secured Party shall be cumulative, may be exercised individually or concurrently and not exclusive of any other rights or remedies provided by any Requirements of Law. To the extent it may lawfully do so, each Grantor absolutely and irrevocably waives and relinquishes the benefit and advantage of, and covenants not to assert against the Collateral Agent, Lenders or any other Secured Party, any valuation, stay, appraisement, extension, redemption or similar laws and any and all rights or defenses it may have as a surety, now or hereafter existing, arising out of the exercise by any of them of any rights or remedies hereunder. If any notice of a proposed sale or other disposition of any Collateral shall be required by Requirements of Law, such notice shall be deemed reasonable and proper if given at least ten (10) days before such sale or other disposition.

(f) Commercially Reasonable. To the extent that applicable Requirements of Law impose duties on the Collateral Agent or any Lender or other Secured Party to exercise remedies in a commercially reasonable manner, each Grantor acknowledges and agrees that it is not commercially unreasonable for the Collateral Agent or any Lender to do any of the following:

(i) fail to incur significant costs, expenses or other liabilities reasonably deemed as such by the Collateral Agent or such Lender to prepare any Collateral for disposition or otherwise to complete raw material or work in process into finished goods or other finished products for disposition;

(ii) fail to obtain permits, licenses or other consents for access to any Collateral to sell or license or for the collection or sale or licensing of any Collateral, or, if not required by other Requirements of Law, fail to obtain permits, licenses or other consents for the collection or disposition of any Collateral;

(iii) fail to exercise remedies against account debtors or other Persons obligated on any Collateral or to remove Liens on any Collateral or to remove any adverse claims against any Collateral;

(iv) advertise dispositions of any Collateral through publications or media of general circulation, whether or not such Collateral is of a specialized nature, or to contact other Persons, whether or not in the same business as any Grantor, for expressions of interest in acquiring any such Collateral;

(v) exercise collection remedies against account debtors and other Persons obligated on any Collateral, directly or through the use of collection agencies or other collection specialists, hire one or more professional auctioneers to assist in the disposition of any Collateral, whether or not such Collateral is of a specialized nature, or, to the extent deemed appropriate by the Collateral Agent or such Lender, obtain the services of other brokers, investment bankers, consultants and other professionals to assist the Collateral Agent or such Lender in the collection or disposition of any Collateral, or utilize Internet sites that provide for the auction of assets of the types included in the Collateral or that have the reasonable capacity of doing so, or that match buyers and sellers of assets to dispose of any Collateral;

(vi) dispose of assets in wholesale rather than retail markets;

(vii) disclaim warranties, such as title, merchantability, possession, non-infringement or quiet enjoyment; or

(viii) purchase insurance or credit enhancements to insure the Collateral Agent or any Lender or other Secured Party against risks of loss, collection or disposition of any Collateral or to provide to the Collateral Agent and Lenders a guaranteed return from the collection or disposition of any Collateral.

Each Grantor acknowledges that the purpose of this Section 6.1 is to provide a non-exhaustive list of actions or omissions that are commercially reasonable when exercising remedies against any Collateral and that other actions or omissions by the Collateral Agent, Lenders or any other Secured Party shall not be deemed commercially unreasonable solely on account of not being indicated in this Section 6.1. Without limitation upon the foregoing, nothing contained in this Section 6.1 shall be construed to grant any rights to any Grantor or to impose any duties on the Collateral Agent or any Lender or other Secured Party that would not have been granted or imposed by this Agreement or by applicable Requirements of Law in the absence of this Section 6.1.

(g) IP Licenses. To the extent permitted, and only for the purpose of enabling the Collateral Agent to exercise rights and remedies under this Section 6.1 during the continuance of an Event of Default (including in order to take possession of, collect, receive, assemble, process, appropriate, remove, realize upon, sell, assign, license out, convey, transfer or grant options to purchase any Collateral) at such time as the Collateral Agent on behalf of Lenders and the other Secured Parties shall be lawfully entitled to exercise such rights and remedies, each Grantor hereby grants to the Collateral Agent (i) an irrevocable, nonexclusive, assignable, license in the Territory (exercisable without payment of royalty or other compensation to such Grantor), including the right to sublicense, use and practice any and all Intellectual Property now owned or held or hereafter acquired or held by such Grantor and access to all media in which any of the licensed items may be recorded or stored and to all Software and programs used for the compilation or printout thereof; provided, however, (A) that such licenses to be granted hereunder with respect to Trademarks shall be subject to the maintenance of quality standards with respect to the goods and services on which such Trademarks are used sufficient to preserve the validity of such Trademarks; (B) that such licenses granted with regard to trade secrets shall be subject to the requirement that the secret status of trade secrets be maintained and reasonable steps are taken to ensure that they are maintained; and (C) that the Collateral Agent shall have no greater rights than those of any such Grantor under such license or sublicense and (ii) an irrevocable license (without payment of rent or other compensation to such Grantor) to use, operate and occupy all real property owned by such Grantor.

Section 6.2. Accounts and Payments in Respect of General Intangibles.

(a) In addition to, and not in substitution for, any similar requirement in the Loan Agreement, if required by the Collateral Agent at any time during the continuance of an Event of Default, any payment of accounts or payment in respect of general intangibles relating to the Collateral, when collected by any Grantor, shall be promptly (and, in any event, within two (2) Business Days of such collection) deposited by such Grantor in the exact form received, duly indorsed by such Grantor to the Collateral Agent for the benefit of Lenders and the other Secured Parties, in a Collateral Account, subject to withdrawal by the Collateral Agent as provided in Section 6.4. Until so turned over, such payment shall be held by such Grantor in trust for the Collateral Agent for the benefit of Lenders and the other Secured Parties, segregated from other funds of such Grantor. Each such deposit of proceeds of accounts and payments in respect of general intangibles relating to the Collateral shall, upon the Collateral Agent's request, be accompanied by a report identifying in reasonable detail the nature and source of the payments included in the deposit.

(b) At any time during the continuance of an Event of Default:

(i) each Grantor shall, upon the Collateral Agent's request, assemble and hold for the benefit of Lenders and the other Secured Parties all original and other documents evidencing, and relating to, the contractual obligations and transactions that gave rise to any account or any payment in respect of general intangibles included in or otherwise relating to the Collateral, including all IP Licenses, original orders, invoices and shipping receipts and notify account debtors that the accounts or general intangibles have been collaterally assigned to the Collateral Agent for the benefit of Lenders and the other Secured Parties and that payments in respect thereof shall be made directly to the Collateral Agent for the benefit of Lenders and the other Secured Parties or to any Lender on behalf of itself and the other Secured Parties, as the Collateral Agent shall direct; and

(ii) each Grantor shall take all actions, deliver all documents and provide all information necessary or reasonably requested by the Collateral Agent to ensure any Internet Domain Name included in or otherwise relating to the Collateral is registered.

(c) Anything herein to the contrary notwithstanding, each Grantor shall remain liable under each account and each payment in respect of general intangibles included in the Collateral to observe and perform all the conditions and obligations to be observed and performed by it thereunder, all in accordance with the terms of any agreement giving rise thereto. Neither the Collateral Agent nor any Lender or other Secured Party shall have any obligation or liability under any agreement giving rise to an account or a payment in respect of a general intangible included in the Collateral by reason of or arising out of any Loan Document or the receipt by the Collateral Agent or any Lender or other Secured Party of any payment relating thereto, nor shall the Collateral Agent nor any Lender or other Secured Party be obligated in any manner to perform any obligation of any Grantor under or pursuant to any agreement giving rise to an account or a payment in respect of a general intangible included in the Collateral, to make any payment, to make any inquiry as to the nature or the sufficiency of any payment received by it or as to the sufficiency of any performance by any party thereunder, to present or file any claim, to take any action to enforce any performance or to collect the payment of any amounts that may have been assigned to it or to which it may be entitled at any time or times.

Section 6.3. Pledged Collateral.

(a) Voting Rights. During the continuance of an Event of Default, upon concurrent, written notice by the Collateral Agent to the relevant Grantor or Grantors, all rights of each Grantor to exercise or refrain from exercising the voting and other consensual rights which it would otherwise be entitled to exercise pursuant hereto shall cease and all such rights shall thereupon become vested in the Collateral Agent or a nominee on behalf of Lenders or the other Secured Parties, who shall thereupon have the sole right to exercise such voting and other consensual rights, including (i) the right to exercise any voting, consent, corporate and other right pertaining to the Pledged Collateral at any meeting of shareholders, partners or members, as the case may be, of the relevant issuer or issuers of Pledged Collateral or otherwise, and (ii) any right of conversion, exchange and subscription and any other right, privilege or option pertaining to the Pledged Collateral as if it were the absolute owner thereof (including the right to exchange at its discretion any Pledged Collateral upon the merger, amalgamation, consolidation, reorganization, recapitalization or other fundamental change in the corporate or equivalent structure of any issuer of Pledged Collateral, the right to deposit and deliver any Pledged Collateral with any committee, depositary, transfer agent, registrar or other designated agency upon such terms and conditions as the Collateral Agent (or such nominee) on behalf of Lenders or the other Secured Parties may determine), all without liability except to account for property actually received by it; provided, however, that the Collateral Agent (or such nominee) shall have no duty to any Grantor to exercise any such right, privilege or option and shall not be responsible for any failure to do so or delay in so doing.

(b) Proxies. During the continuance of an Event of Default, in order to permit the Collateral Agent on behalf of Lenders and the other Secured Parties to exercise the voting and other consensual rights that it may be entitled to exercise pursuant hereto and to receive all dividends and other distributions that it may be entitled to receive hereunder, (i) each Grantor shall promptly execute and deliver (or cause to be executed and delivered) to the Collateral Agent all such proxies, dividend payment orders and other instruments as the Collateral Agent may from time to time reasonably request and (ii) without limiting the effect of clause (i) above, such Grantor hereby grants to the Collateral Agent for the benefit of Lenders and the other Secured Parties an irrevocable proxy to vote all or any part of the Pledged Collateral and to exercise all other rights, powers, privileges and remedies to which a holder of the Pledged Collateral would be entitled (including giving or withholding written consents of shareholders, partners or members, as the case may be, calling special meetings of shareholders, partners or members, as the case may be, and voting at such meetings), which proxy shall be effective, automatically and without the necessity of any action (including any transfer of any Pledged Collateral on the record books of the issuer thereof) by any other Person (including the issuer of such Pledged Collateral or any officer or agent thereof) during the continuance of an Event of Default and which proxy shall only terminate upon (A) the cure of any and all Events of Default or (B) the indefeasible payment in full of the Secured Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted).

(c) Authorization of Issuers. Each Grantor hereby expressly and irrevocably authorizes and instructs, without any further instructions from such Grantor, each issuer of any Pledged Collateral pledged hereunder by such Grantor to, and each Grantor that is an issuer of Pledged Collateral so pledged hereunder hereby agrees to (i) comply with any instruction received by it from the Collateral Agent in writing that states that an Event of Default is continuing and is otherwise in accordance with the terms of this Agreement and each Grantor agrees that such issuer shall be fully protected from liabilities to such Grantor in so complying, and (ii) during the continuance of such Event of Default, unless otherwise permitted hereby or by the Loan Agreement, pay any dividend or make any other payment with respect to the Pledged Collateral directly to the Collateral Agent for the benefit of Lenders and the other Secured Parties or to any Lender on behalf of itself and the other Secured Parties, as the Collateral Agent shall direct.

Section 6.4. Proceeds to be Turned over to and Held by Collateral Agent. Unless otherwise expressly provided in the Loan Agreement or this Agreement, during the continuance of an Event of Default and, upon written notice by the Collateral Agent to the relevant Grantor or Grantors, all proceeds of any Collateral received by any Grantor hereunder in cash or Cash Equivalents shall be held by such Grantor in trust for Lenders and the other Secured Parties, segregated from other funds of such Grantor, and shall, promptly upon receipt by any Grantor, be turned over to the Collateral Agent for the benefit of Lenders and the other Secured Parties in the exact form received (with any necessary endorsement). All such proceeds of Collateral and any other proceeds of any Collateral received by the Collateral Agent in cash or Cash Equivalents shall be held by the Collateral Agent for the benefit of itself and the other Secured Parties in a Collateral Account. All proceeds being held by the Collateral Agent in a Collateral Account (or by such Grantor in trust for Lenders and the other Secured Parties) shall continue to be held as collateral security for the Secured Obligations and shall not constitute payment thereof until applied as provided in the Loan Agreement.

Section 6.5. Sale of Pledged Collateral.

(a) Each Grantor recognizes that the Collateral Agent may be unable to effect a public sale of any Pledged Collateral by reason of certain prohibitions contained in the Securities Act and applicable state or foreign securities laws or otherwise or may determine that a public sale is impracticable, not desirable or not commercially reasonable and, accordingly, may resort to one or more private sales thereof to a restricted group of purchasers that shall be obliged to agree, among other things, to acquire such securities for their own account for investment and not with a view to the distribution or resale thereof. Each Grantor acknowledges and agrees that any such private sale may result in prices and other terms less favorable than if such sale were a public sale and, notwithstanding such circumstances, agrees that any such private sale shall be deemed to have been made in a commercially reasonable manner. The Collateral Agent shall be under no obligation to delay a sale of any Pledged Collateral for the period of time necessary to permit the issuer thereof to register such securities for public sale under the Securities Act or under applicable state securities laws even if such issuer would agree to do so.

(b) Each Grantor agrees to use commercially reasonable efforts to do or cause to be done all such other acts as may be reasonably necessary to make such sale or sales of any portion of the Pledged Collateral pursuant to Section 6.1 and this Section 6.5 valid and binding and in compliance with all applicable Requirements of Law. Each Grantor further agrees that a breach of any covenant contained herein will cause irreparable injury to the Collateral Agent, Lenders and the other Secured Parties, that the Collateral Agent, Lenders and the other Secured Parties have no adequate remedy at law in respect of such breach and, as a consequence, that each and every covenant contained herein shall be specifically enforceable against such Grantor, and such Grantor hereby waives and agrees not to assert any defense against an action for specific performance of such covenants except for a defense that no Event of Default has occurred and is continuing under the Loan Agreement or a defense of indefeasible payment in full of the Guaranteed Obligations (other than inchoate indemnity obligations). Each Grantor waives any and all rights of contribution or subrogation upon the sale or disposition of all or any portion of the Pledged Collateral by the Collateral Agent on behalf of Lenders and the other Secured Parties.

Section 6.6. Deficiency. Each Grantor shall remain liable for any deficiency if the proceeds of any sale or other disposition of any Collateral are insufficient to pay the Secured Obligations and the reasonable and documented fees and disbursements of any attorney employed by the Collateral Agent or any Lender to collect such deficiency.

Section 6.7. Collateral Accounts. If any Event of Default shall have occurred and be continuing, the Collateral Agent may apply the balance from any Collateral Account of a Grantor or instruct the bank at which any Collateral Account is maintained to pay the balance of any Collateral Account to the Collateral Agent for the benefit of Lenders and the other Secured Parties or to any Lender on behalf of itself and the other Secured Parties, as the Collateral Agent shall direct, to be applied to the Secured Obligations in accordance with the terms hereof.

Section 6.8. Directions, Notices or Instructions. Neither the Collateral Agent nor any Lender or any Related Party thereof or any other Secured Party shall take any action under or issue any directions, notice or instructions pursuant to any Control Agreement or similar agreement unless an Event of Default has occurred and is continuing.

ARTICLE VII

ADDITIONAL RIGHTS OF COLLATERAL AGENT

Section 7.1. Collateral Agent's Appointment as Attorney-in-Fact.

(a) Each Grantor hereby irrevocably constitutes and appoints the Collateral Agent and any Related Party thereof, with full power of substitution, as its true and lawful attorney-in-fact with full irrevocable power and authority in the place and stead of such Grantor and in the name of such Grantor or in its own name, for the purpose of carrying out the terms of the Loan Documents, to take any appropriate action and to execute any document or instrument that may be necessary or desirable to accomplish the purposes of the Loan Documents, in each case during the continuance of an Event of Default, and, without limiting the generality of the foregoing, each Grantor hereby gives the Collateral Agent and its Related Party the power and right, on behalf of such Grantor, without notice to or assent by such Grantor, to do any of the following when an Event of Default shall be continuing:

(i) in the name of such Grantor, in its own name or otherwise, take possession of and indorse and collect any check, draft, note, acceptance or other instrument for the payment of moneys due under any account or general intangible or with respect to any other Collateral and file any claim or take any other action or proceeding in any court of law or equity or otherwise deemed appropriate by the Collateral Agent for the purpose of collecting any such moneys due under any account or general intangible or with respect to any other Collateral whenever payable;

(ii) in the case of any Intellectual Property (including any IP Ancillary Rights) or any IP Licenses included in the Collateral, execute, deliver and have recorded any document that the Collateral Agent may request to evidence, effect, publicize or record the Collateral Agent's security interest, in favor of and for the benefit of Lenders and the other Secured Parties, in such Intellectual Property or IP Licenses and the goodwill and general intangibles of such Grantor relating thereto or represented thereby and the Collateral Agent's (on behalf of Lenders and the other Secured Parties) rights and remedies with respect thereto;

(iii) pay or discharge taxes and Liens levied or placed on or threatened against any Collateral, effect any repair or obtain or pay any insurance called for by the terms of the Loan Agreement (including all or any part of the premiums therefor and the costs thereof);

(iv) execute, in connection with any sale provided for in Section 6.1 or 6.5, any document to effect or otherwise necessary or appropriate in relation to evidence the sale of any Collateral; or

(v) (A) direct any party liable for any payment under any Collateral to make payment of any moneys due or to become due thereunder directly to the Collateral Agent or as the Collateral Agent shall direct, (B) ask or demand for, and collect and receive payment of and receipt for, any moneys, claims and other amounts due or to become due at any time in respect of or arising out of any Collateral, (C) commence and prosecute any suit, action or proceeding at law or in equity in any court of competent jurisdiction to collect any Collateral and to enforce any other right in respect of any Collateral, (D) defend any actions, suits, proceedings, audits, claims, demands, orders or disputes brought against such Grantor with respect to any Collateral, (E) settle, compromise or adjust any such actions, suits, proceedings, audits, claims, demands, orders or disputes and, in connection therewith, give such discharges or releases as the Collateral Agent may deem appropriate, (F) assign or license any Intellectual Property included in the Collateral on such terms and conditions and in such manner as the Collateral Agent shall in its sole discretion determine, including the execution and filing of any document necessary to effectuate or record such assignment or license and (G) generally, sell, assign, license, convey, transfer or grant a Lien on, make any contractual obligation with respect to and otherwise deal with, any Collateral as fully and completely as though the Collateral Agent on behalf of Lenders and the other Secured Parties were the absolute owner thereof for all purposes and do, at the Collateral Agent's option, at any time or from time to time, all acts and things that the Collateral Agent deems necessary to protect, preserve or realize upon any Collateral and the Collateral Agent's, in favor of and for the benefit of Lenders and the other Secured Parties, security interests therein and to effect the intent of the Loan Documents, all as fully and effectively as such Grantor might do.

(vi) If any Grantor fails to perform or comply with any contractual obligation contained herein, the Collateral Agent, at its option, but without any obligation so to do, may perform or comply, or otherwise cause performance or compliance, with such contractual obligation.

(b) Without limiting the generality of Section 2.4 of the Loan Agreement, the Lender Expenses and any other reasonable and documented out-of-pocket expenses of the Collateral Agent and any Lender and other Secured Party incurred in connection with the taking of any actions pursuant to or as otherwise contemplated by this Section 7.1, together with, solely in the event any Grantor fails to pay any of the Obligations when due or upon the commencement and during the continuance of an Insolvency Proceeding of the Borrower or, at the election of the Required Lenders, upon the occurrence and during the continuance of any other Event of Default, interest thereon at the Default Rate, from the date of payment by such Person to the date reimbursed by the relevant Grantor, shall be payable by such Grantor to such Person in accordance with Section 2.4 of the Loan Agreement.

(c) Each Grantor hereby ratifies all that said attorneys shall lawfully do or cause to be done by virtue of this Section 7.1. All powers, authorizations and agencies contained in this Agreement are coupled with an interest and are irrevocable until the indefeasible payment in full of the Secured Obligations (other than inchoate indemnity obligations), this Agreement is terminated and the security interests created hereby are released.

Section 7.2. Authorization to File Financing Statements. Each Grantor authorizes the Collateral Agent and its Related Party, at any time and from time to time, without notice to any Grantor, to file or record financing statements, amendments thereto, and other filing or recording documents or instruments with respect to any Collateral in such form, in such jurisdictions and in such offices as the Collateral Agent reasonably determines appropriate to perfect or protect the security interests of the Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, under this Agreement or any other Loan Document (and the Collateral Agent's and each Lender's and each other Secured Party's rights in respect thereof), and such financing statements and amendments may describe the Collateral covered thereby as "all assets of the debtor" or words of similar effect and may include a notice that any disposition of the Collateral, by any Grantor or other Person, shall be deemed to violate the rights of the Collateral Agent and Lenders and other Secured Parties under the Code to the extent not permitted under this Agreement or any other Loan Document. A photographic or other reproduction of this Agreement shall be sufficient as a financing statement or other filing or recording document or instrument for filing or recording in any jurisdiction. Such Grantor also hereby ratifies its authorization for the Collateral Agent to have filed any initial financing statement or amendment thereto under the Code (or other similar laws) in effect in any jurisdiction if filed prior to the date hereof.

Section 7.3. Authority of Collateral Agent. Each Grantor acknowledges that, as between the Collateral Agent and the Grantors, the Collateral Agent shall be conclusively presumed to be acting as agent for each Lender and all of the other Secured Parties with full and valid authority so to act or refrain from acting, and no Grantor shall be under any obligation or entitlement to make any inquiry respecting such authority.

Section 7.4. Duty; Obligations and Liabilities.

(a) Duty of Collateral Agent. The Collateral Agent's sole duty with respect to the custody, safekeeping and physical preservation of the Collateral in its possession shall be to deal with it in the same manner as it deals with similar property for its own account. The powers conferred on the Collateral Agent hereunder are solely to protect each Lender's and the other Secured Parties' interest in the Collateral and shall not impose any duty upon the Collateral Agent to exercise any such powers. The Collateral Agent shall be accountable only for amounts that it receives as a result of the exercise of such powers, and neither it nor any of its Related Parties shall be responsible to any Grantor for any act or failure to act hereunder, except for its or their own gross negligence, bad faith or willful misconduct as finally determined by a court of competent jurisdiction. In addition, the Collateral Agent shall not be liable or responsible for any loss or damage to any Collateral, or for any diminution in the value thereof, by reason of the act or omission of any warehousemen, carrier, forwarding agency, consignee or other bailee if such Person has been selected by the Collateral Agent in good faith.

(b) Obligations and Liabilities with respect to Collateral. Neither the Collateral Agent nor Lenders or any other Secured Parties nor any of their respective Related Parties shall be liable for failure to demand, collect or realize upon any Collateral or for any delay in doing so or shall be under any obligation to sell or otherwise dispose of any Collateral upon the request of any Grantor or any other Person or to take any other action whatsoever with regard to any Collateral.

ARTICLE VIII

MISCELLANEOUS

Section 8.1. Reinstatement. Each Grantor agrees that, if any payment made by any Credit Party or other Person and applied to the Secured Obligations is at any time annulled, avoided, set aside, rescinded, invalidated, declared to be fraudulent or preferential or otherwise required to be refunded or repaid, or the proceeds of any Collateral are required to be returned by any Secured Party to such Credit Party, its estate, trustee, receiver or any other party, including any Grantor, under any bankruptcy law, state or federal law, common law or equitable cause, then, to the extent of such payment or repayment, any Lien or other Collateral securing such liability shall be and remain in full force and effect, as fully as if such payment had never been made. If, prior to any of the foregoing, (a) any Lien or other Collateral securing such Grantor's liability hereunder shall have been released or terminated by virtue of the foregoing or (b) any provision of the Guaranty hereunder shall have been terminated, cancelled or surrendered, such Lien, other Collateral or provision shall be reinstated in full force and effect and such prior release, termination, cancellation or surrender shall not diminish, release, discharge, impair or otherwise affect the obligations of such Grantor in respect of any Lien or other Collateral securing such obligation or the amount of such payment.

Section 8.2. Release of Collateral and Guarantee Obligations.

(a) When all Obligations (other than unasserted inchoate indemnity obligations) have been indefeasibly paid in full, the Collateral shall be released from the Lien created hereby and this Agreement and all obligations (other than those expressly stated to survive such termination) of each Lender and any other Secured Party and each Guarantor and Grantor hereunder shall terminate, all without delivery of any instrument or performance of any act by any party (except as required hereunder), and all rights of the Collateral Agent, Lenders and any other Secured Parties to the Collateral shall revert to the Grantors.

(b) In connection with any termination or release pursuant to this Section 8.2, the Collateral Agent shall, and to the extent required, each Secured Party hereby authorizes the Collateral Agent to, promptly execute and deliver to any Grantor all instruments, documents and agreements which such Grantor shall reasonably request in writing to evidence and confirm such termination or release (including termination statements under the Code and customary payoff letters), and will duly assign, transfer and deliver to such Grantor (or its designee), such of the Collateral that may be in the possession of the Collateral Agent, all without further consent or joinder of the Collateral Agent or any Lender or other Secured Party.

(c) Any termination or release pursuant to clauses (a) and (b) of this Section 8.2 is subject to reinstatement as provided in Section 8.1.

(d) Upon any disposition of property permitted by the Loan Agreement, the Liens granted herein shall be deemed to be automatically released and such property shall automatically revert to the applicable Grantor with no further action on the part of any Person.

(e) Upon (i) any sale or disposition of property of a Grantor to a Person other than a Grantor permitted by the Loan Agreement or (ii) the consummation of any other transaction permitted by the Loan Agreement as a result of which such Grantor becomes an Excluded Subsidiary or such Grantor is released from its Guaranty, the Liens granted herein shall be deemed to be automatically released and such property shall automatically revert to the applicable Grantor (or such other applicable Person) with no further action on the part of any Person.

(f) Upon any Collateral being or becoming Excluded Property, the security interests created pursuant to this Agreement on such Collateral shall be automatically released.

(g) Upon the release of the Liens on any Collateral or of a Grantor from all of its obligations as a Credit Party under the Loan Agreement and as a Grantor hereunder, any representation, warranty or covenant contained in any Loan Document relating to any such Collateral or such Grantor, as applicable, shall no longer be deemed to be made.

(h) Without limiting the generality of Section 2.4 of the Loan Agreement, the Lender Expenses and any other reasonable and documented out-of-pocket expenses of the Collateral Agent and any Lender and other Secured Party incurred in connection with the taking of any actions pursuant to or as otherwise contemplated by this Section 8.2 in accordance with Section 2.4 of the Loan Agreement.

Section 8.3. Independent Obligations. The obligations of each Grantor hereunder are independent of and separate from the Secured Obligations and the Guaranteed Obligations. Upon any Event of Default and during the continuance thereof, the Collateral Agent for the benefit of Lenders and the other Secured Parties may, at its sole election, proceed directly and at once, without notice, against any Grantor and any Collateral to collect and recover the full amount of any Secured Obligation or Guaranteed Obligation then due, without first proceeding against any other Grantor, any other Credit Party or any other Collateral and without first joining any other Grantor or any other Credit Party in any proceeding.

Section 8.4. No Waiver by Course of Conduct. Neither the Collateral Agent nor any Secured Party shall by any act (except by a written instrument pursuant to Section 8.5), delay, indulgence, omission or otherwise be deemed to have waived any right or remedy hereunder or to have acquiesced in any Default or Event of Default. No failure to exercise, nor any delay in exercising, on the part of the Collateral Agent or any Secured Party, any right, power or privilege hereunder shall operate as a waiver thereof. No single or partial exercise of any right, power or privilege hereunder shall preclude any other or further exercise thereof or the exercise of any other right, power or privilege. A waiver by the Collateral Agent or any Secured Party of any right or remedy hereunder on any one occasion shall not be construed as a bar to any right or remedy that the Collateral Agent or any Secured Party would otherwise have on any future occasion.

Section 8.5. Amendments in Writing. None of the terms or provisions of this Agreement may be waived, amended, supplemented or otherwise modified except in accordance with Section 11.5 of the Loan Agreement; provided, however, that annexes to this Agreement may be supplemented (but no existing provisions may be modified and no Collateral may be released) through Pledge Amendments and Joinder Agreements, in substantially the form of Annex 1 and Annex 2 attached hereto, respectively, in each case, duly executed by the Collateral Agent and each Grantor directly affected thereby.

Section 8.6. Additional Grantors and Guarantors; Additional Pledged Collateral.

(a) Joinder Agreements. If, at the option of Borrower or as required pursuant to Section 5.12 or Section 5.13 of the Loan Agreement, Borrower shall cause any Subsidiary (other than an Excluded Subsidiary) that is not a Grantor or Guarantor to become a Grantor and Guarantor hereunder, such Subsidiary shall execute and deliver to the Collateral Agent a Joinder Agreement substantially in the form of Annex 2 attached hereto and shall thereafter for all purposes be a party hereto and have the same rights, benefits and obligations as a Grantor party hereto on the Tranche A Closing Date.

(b) Pledge Amendments. To the extent any Pledged Collateral has not been delivered as of the Tranche A Closing Date, such Grantor shall, promptly after such Pledged Collateral is acquired, deliver a pledge amendment duly executed by the Grantor in substantially the form of Annex 1 attached hereto (each, a "Pledge Amendment"). Such Grantor authorizes the Collateral Agent to attach each Pledge Amendment to this Agreement.

Section 8.7. Notices. All notices, requests and demands to or upon the Collateral Agent or any Grantor hereunder shall be effected in the manner provided for in Section 9 of the Loan Agreement; provided, however, that any such notice, request or demand to or upon any Grantor shall be addressed to Borrower's notice address set forth in Section 9 of the Loan Agreement.

Section 8.8. Successors and Assigns. This Agreement shall be binding upon the successors and assigns of each Grantor and shall inure to the benefit of the Collateral Agent and each Secured Party and their respective successors and assigns; provided, however, that no Grantor may assign, transfer or delegate any of its rights or obligations under this Agreement without the prior written consent of the Collateral Agent.

Section 8.9. Counterparts. This Agreement may be executed in any number of counterparts and by different parties in separate counterparts, each of which when so executed shall be deemed to be an original and all of which taken together shall constitute one and the same agreement. Signature pages may be detached from multiple separate counterparts and attached to a single counterpart. Delivery of an executed signature page of this Agreement by facsimile transmission or by electronic transmission shall be as effective as delivery of a manually executed counterpart hereof.

Section 8.10. Severability. Any provision of this Agreement being held illegal, invalid or unenforceable in any jurisdiction shall not affect any part of such provision not held illegal, invalid or unenforceable, any other provision of this Agreement or any part of such provision in any other jurisdiction.

Section 8.11. SECTION 10 OF THE LOAN AGREEMENT IS HEREBY INCORPORATED BY REFERENCE, *MUTATIS MUTANDIS*.

[Signature Pages Follow]

IN WITNESS WHEREOF, each of the undersigned has caused this Guaranty and Security Agreement to be duly executed and delivered as of the date first above written.

SAREPTA THERAPEUTICS, INC.,
as Borrower and Grantor

By /s/ Sandesh Mahatme

Name: Sandesh Mahatme

Title: Executive Vice President, Chief Financial Officer, and Chief Business Officer

ACCEPTED AND AGREED
as of the date first above written:

BIOPHARMA CREDIT PLC,
as Collateral Agent

By: Pharmakon Advisors, LP,
its Investment Manager

By: Pharmakon Management I, LLC,
its General Partner

By /s/ Pedro Gonzalez de Cosio
Name: Pedro Gonzalez de Cosio
Title: Managing Member

ANNEX 1
TO GUARANTY AND SECURITY AGREEMENT

FORM OF PLEDGE AMENDMENT

This Pledge Amendment, dated as of _____, 20__, is delivered pursuant to Section 8.6 of the Guaranty and Security Agreement, dated as of December 20, 2019, by SAREPTA THERAPEUTICS, INC., as Borrower, the undersigned Grantor and the other Persons from time to time party thereto as Grantors in favor of BIOPHARMA CREDIT PLC, as Collateral Agent on behalf of Lenders and each of the other Secured Parties (as such agreement may be amended, restated, supplemented or otherwise modified from time to time, the "Guaranty and Security Agreement"). Capitalized terms used herein without definition are used as defined in the Guaranty and Security Agreement.

The undersigned hereby agrees that this Pledge Amendment may be attached to the Guaranty and Security Agreement and that the Pledged Collateral listed on Annex 1-A to this Pledge Amendment shall be and become part of the Collateral referred to in the Guaranty and Security Agreement and shall secure all Secured Obligations of the undersigned.

[GRANTOR]

By: _____
Name:
Title:

PLEDGED STOCK

ISSUER	CLASS	CERTIFICATE NO(S).	PAR VALUE	NUMBER OF SHARES, UNITS OR INTERESTS

PLEDGED DEBT INSTRUMENTS

COMMERCIAL TORT CLAIMS

ACKNOWLEDGED AND AGREED
as of the date first above written:

BIOPHARMA CREDIT PLC,
as Collateral Agent

By: Pharmakon Advisors, LP,
its Investment Manager

By: Pharmakon Management I, LLC,
its General Partner

By _____
Name: Pedro Gonzalez de Cosio
Title: Managing Member

ANNEX 2
TO
GUARANTY AND SECURITY AGREEMENT

FORM OF JOINDER AGREEMENT

This JOINDER AGREEMENT, dated as of _____ __, 20__, is delivered pursuant to Section 8.6 of the Guaranty and Security Agreement, dated as of December 20, 2019, by and among SAREPTA THERAPEUTICS, INC. ("Borrower") and the other Persons from time to time party thereto as Grantors, in favor of BIOPHARMA CREDIT PLC (together with its successors and permitted assigns, the "Collateral Agent") on behalf of Lenders and each of the other Secured Parties, (as such agreement may be amended, restated, supplemented or otherwise modified from time to time, the "Guaranty and Security Agreement"). Capitalized terms used herein without definition are used as defined in the Guaranty and Security Agreement.

By executing and delivering this Joinder Agreement, the undersigned, as provided in Section 8.6 of the Guaranty and Security Agreement, (a) hereby becomes a party to the Guaranty and Security Agreement as a "Grantor" and "Guarantor" thereunder with the same force and effect as if originally named as a Grantor and Guarantor therein and, without limiting the generality of the foregoing, hereby assumes all obligations and liabilities of a Grantor and a Guarantor thereunder and (b) as collateral security for the prompt and complete payment and performance when due (whether at stated maturity, by acceleration or otherwise) of the Secured Obligations of the undersigned, hereby pledges and hypothecates to the Collateral Agent for the benefit of Lenders and the other Secured Parties, and grants to the Collateral Agent for the benefit of Lenders and the other Secured Parties, a lien on and security interest in, all of its right, title and interest in, to and under the Collateral of the undersigned. The undersigned hereby agrees to be bound as a Grantor and a Guarantor for the purposes of the Guaranty and Security Agreement.

In connection with this Joinder Agreement, the undersigned has delivered to the Collateral Agent a completed Perfection Certificate duly executed by the undersigned. The information set forth in Annex 1-A[15] is hereby added to the information set forth in Schedules 1, 2 and 4 to the Security Disclosure Letter. By acknowledging and agreeing to this Joinder Agreement, the undersigned hereby agrees that this Joinder Agreement may be attached to the Guaranty and Security Agreement, the Perfection Certificate delivered herewith by the undersigned shall constitute a "Perfection Certificate" referred to in Section 4.6 of the Loan Agreement and that the Pledged Collateral listed on Annex 1-A to this Joinder Agreement shall be and become part of the Collateral referred to in the Guaranty and Security Agreement and shall secure all Secured Obligations of the undersigned.

The undersigned hereby represents and warrants that each of the representations and warranties contained in Article IV of the Guaranty and Security Agreement applicable to it is true and correct on and as the date hereof as if made on and as of such date.

In witness whereof, the undersigned has caused this Joinder Agreement to be duly executed and delivered as of the date first above written.

[Additional Grantor]

By: _____
Name:
Title:

[15] Use same Annex 1-A as is attached in Annex 1 to the Guaranty and Security Agreement.

ACKNOWLEDGED AND AGREED
as of the date first above written:

BIOPHARMA CREDIT PLC,
as Collateral Agent

By: Pharmakon Advisors, LP,
its Investment Manager

By: Pharmakon Management I, LLC,
its General Partner

By _____
Name: Pedro Gonzalez de Cosio
Title: Managing Member

ANNEX 3
TO
GUARANTY AND SECURITY AGREEMENT

FORM OF INTELLECTUAL PROPERTY SECURITY AGREEMENT

THIS [COPYRIGHT] [PATENT] [TRADEMARK] SECURITY AGREEMENT, dated as of _____, 20__, is made by _____ ("Grantor"), in favor of BIOPHARMA CREDIT PLC (together with its successors and permitted assigns, the "Collateral Agent") on behalf of Lenders and the other Secured Parties (as defined in the Loan Agreement referred to below).

W I T N E S S E T H:

WHEREAS, pursuant to the Loan Agreement, dated as of December 13, 2019 (as the same may be amended, amended and restated, supplemented or otherwise modified from time to time, the "Loan Agreement"), by and among SAREPTA THERAPEUTICS, INC. ("Borrower"), certain Guarantors, BIOPHARMA CREDIT PLC (as the "Collateral Agent" and a "Lender"), and BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP (as a "Lender"), each Lender has agreed to make extensions of credit to Borrower upon the terms and subject to the conditions set forth therein;

WHEREAS, Grantor [(other than Borrower)] has agreed, pursuant to a Guaranty and Security Agreement dated as of December 20, 2019 in favor of the Collateral Agent for the benefit of Lenders and the other Secured Parties (as such agreement may be amended, amended and restated, supplemented or otherwise modified from time to time, the "Guaranty and Security Agreement"), to guarantee the Obligations (as defined in the Loan Agreement) of Borrower; and

WHEREAS, Grantor is party to the Guaranty and Security Agreement pursuant to which Grantor is required to execute and deliver this [Copyright] [Patent] [Trademark] Security Agreement;

NOW, THEREFORE, in consideration of the mutual covenants, terms and conditions set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree, intending to be legally bound, as follows:

Section 1. Defined Terms. Capitalized terms used herein without definition are used as defined in the Guaranty and Security Agreement.

Section 2. Grant of Security Interest in [Copyright] [Trademark] [Patent] Collateral. Grantor, as collateral security for the prompt and complete payment and performance when due (whether at stated maturity, by acceleration or otherwise) of the Secured Obligations, hereby mortgages, pledges and hypothecates to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, and grants to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, a Lien on and security interest in, all of its right, title and interest in, to and under the following Collateral of Grantor, in each case, solely to the extent constituting Collateral (and excluding any Excluded Property) (the "[Copyright] [Patent] [Trademark] Collateral"):

a) [any and all of its Copyrights and all IP Licenses (including, without limitation, any IP Licenses under the Current Company IP Agreements to which Grantor is a party and the rights of Grantor thereunder, and all of Grantor's right, title and interest in, to and under any Internet Domain Names and Software) and IP Ancillary Rights providing for the grant by or to Grantor of any right under any Copyright, including, without limitation, those referred to on Schedule 1 hereto;

b) all renewals, reversions and extensions of the foregoing; and

c) all income, royalties, proceeds and liabilities at any time due or payable or asserted under and with respect to any of the foregoing, including, without limitation, all rights to sue and recover at law or in equity for any past, present and future infringement, misappropriation, dilution, violation or other impairment thereof.]

a) [all of its Patents and all IP Licenses (including, without limitation, any IP Licenses under the Current Company IP Agreements to which Grantor is a party and the rights of Grantor thereunder, and all of Grantor's right, title and interest in, to and under any Internet Domain Names and Software) and IP Ancillary Rights providing for the grant by or to Grantor of any right under any Patent, including, without limitation, those referred to on Schedule 1 hereto;

b) all reissues, reexaminations, continuations, continuations-in-part, divisionals, substitutes, renewals and extensions of the foregoing; and

c) all income, royalties, proceeds and liabilities at any time due or payable or asserted under and with respect to any of the foregoing, including, without limitation, all rights to sue and recover at law or in equity for any past, present and future infringement, misappropriation, dilution, violation or other impairment thereof.]

or

a) [all of its Trademarks and all IP Licenses (including, without limitation, any IP Licenses under the Current Company IP Agreements to which Grantor is a party and the rights of Grantor thereunder, and all of Grantor's right, title and interest in, to and under any Internet Domain Names and Software) and IP Ancillary Rights providing for the grant by or to Grantor of any right under any Trademark, including, without limitation, those referred to on Schedule 1 hereto, but excluding any "intent to use" Trademark applications for which a statement of use has not been filed (but only excluding such applications until such statement is filed);

b) all renewals and extensions of the foregoing;

c) all goodwill of the business connected with the use of, and symbolized by, each such Trademark; and

d) all income, royalties, proceeds and liabilities at any time due or payable or asserted under and with respect to any of the foregoing, including, without limitation, all rights to sue and recover at law or in equity for any past, present and future infringement, misappropriation, dilution, violation or other impairment thereof.]

Section 3. Guaranty and Security Agreement. The security interest granted pursuant to this [Copyright] [Patent] [Trademark] Security Agreement is granted in conjunction with the security interest granted to the Collateral Agent for the benefit of Lenders and the other Secured Parties, pursuant to the Guaranty and Security Agreement and Grantor hereby acknowledges and agrees that the obligations, rights and remedies of Grantor and of the Collateral Agent on behalf of Lenders and the other Secured Parties with respect to the security interest in the [Copyright] [Patent] [Trademark] Collateral made and granted hereby are more fully set forth in the Guaranty and Security Agreement, the terms and provisions of which are incorporated by reference herein as if fully set forth herein.

Section 4. Grantor Remains Liable. Grantor hereby agrees that, anything herein to the contrary notwithstanding, Grantor shall assume full and complete responsibility for the prosecution, defense, enforcement or any other reasonably necessary actions in connection with their [Copyrights] [Patents] [Trademarks] and IP Licenses subject to a security interest hereunder.

Section 5. Termination. This [Copyright] [Patent] [Trademark] Security Agreement shall terminate and the Lien on the security interest in the [Copyright] [Patent] [Trademark] Collateral shall be released upon the payment and performance of the Secured Obligations (other than inchoate indemnity obligations). Upon the termination of this [Copyright] [Patent] [Trademark] Security Agreement, the Collateral Agent shall execute all documents, make all filings, and take all other actions reasonably requested by the Grantor to evidence and record the release of the Lien on and security interests in the [Copyright] [Patent] [Trademark] Collateral granted herein.

Section 6. Counterparts. This [Copyright] [Patent] [Trademark] Security Agreement may be executed in any number of counterparts and by different parties in separate counterparts, each of which when so executed shall be deemed to be an original and all of which taken together shall constitute one and the same agreement. Signature pages may be detached from multiple separate counterparts and attached to a single counterpart. Delivery of an executed signature page of this [Copyright] [Patent] [Trademark] Security Agreement by facsimile or electronic transmission shall be as effective as delivery of a manually executed counterpart hereof.

Section 7. Governing Law. This [Copyright] [Patent] [Trademark] Security Agreement and the rights and obligations of the parties hereto shall be governed by, and construed and interpreted in accordance with, the law of the State of New York without regard to any principle of conflicts of law that could require the application of the law of any other jurisdiction.

IN WITNESS WHEREOF, Grantor has caused this [Copyright] [Patent] [Trademark] Security Agreement to be executed and delivered by its duly authorized officer as of the date first set forth above.

Very truly yours,

[GRANTOR]
as Grantor

By: _____
Name:
Title:

ACCEPTED AND AGREED
as of the date first above written:

BIOPHARMA CREDIT PLC,
as Collateral Agent

By: Pharmakon Advisors, LP,
its Investment Manager

By: Pharmakon Management I, LLC,
its General Partner

By _____
Name: Pedro Gonzalez de Cosio
Title: Managing Member

ANNEX 4
TO
GUARANTY AND SECURITY AGREEMENT
FORM OF UNCERTIFICATED STOCK CONTROL AGREEMENT

This UNCERTIFICATED STOCK CONTROL AGREEMENT (this "**Agreement**"), dated as of _____ __, 20__, is made by and among [APPLICABLE GRANTOR], a [JURISDICTION OF ORGANIZATION] [ENTITY TYPE] (the "**Grantor**"), BIOPHARMA CREDIT PLC, a public limited company organized under the laws of England and Wales, as collateral agent on behalf of the Secured Parties (the "**Collateral Agent**"), and [APPLICABLE INTEREST ISSUING COMPANY], a [JURISDICTION OF ORGANIZATION] [ENTITY TYPE] (the "**Issuer**"). All capitalized terms used but not otherwise defined herein shall have the meanings assigned to such terms in the Security Agreement (as defined below) or the Loan Agreement (as defined below), as applicable.

WHEREAS, SAREPTA THERAPEUTICS, INC., a Delaware corporation (as "**Borrower**"), certain Guarantors, the Collateral Agent and the Lenders have entered into that certain Loan Agreement, dated as of December 13, 2019 (as may be amended, restated, supplemented or otherwise modified from time to time, the "**Loan Agreement**");

WHEREAS, the Grantor is the registered holder of [DESCRIBE PLEDGED UNCERTIFICATED STOCK] issued by the Issuer (the "**Pledged Stock**");

WHEREAS, pursuant to the Guaranty and Security Agreement, dated as of December 20, 2019, by and among the Grantor, the Collateral Agent and the other parties thereto (as amended, amended and restated, supplemented or otherwise modified from time to time, the "**Security Agreement**"), the Grantor has granted a continuing Lien on and security interest (the "**Security Interest**") in, all of its right, title and interest in, to and under the Pledged Stock (other than Excluded Equity Interests), whether now existing or hereafter arising or acquired; and

WHEREAS, it is a condition precedent to the making of the Tranche A Loans and maintaining of the Term Loans by Lenders under the Loan Agreement that the parties hereto execute and deliver this Agreement in order to perfect a first priority Security Interest in the Pledged Stock.

NOW, THEREFORE, in consideration of the mutual covenants, terms and conditions set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree, intending to be legally bound, as follows:

1. The Issuer confirms that:

(a) The Pledged Stock is Equity Interests that are not represented by certificates;

(b) The Issuer is the issuer of the Pledged Stock and the Grantor is registered on the books and records of the Issuer as the registered holder of the Pledged Stock; and

(c) The Security Interest in the Pledged Stock is registered on the books and records of the Issuer.

2. The Grantor hereby irrevocably agrees that, for so long as this Agreement remains in effect, the Collateral Agent, for the benefit of Lenders and the other Secured Parties, shall have exclusive control of the Pledged Stock. In furtherance of such agreement, the Grantor hereby irrevocably authorizes and directs the Issuer, and the Issuer hereby agrees:

(d) Subject to the provisions of Section 3 hereof, to comply with any and all written instructions delivered to the Issuer which directs that the transfer of any or all of the Pledged Stock to the Collateral Agent be registered on the books and records of the Issuer in the name of the Collateral Agent as the holder thereof, for the benefit of Lenders and the other Secured Parties, without further consent by the Grantor or any other Person; and

(e) Subject to the provisions of Section 3 hereof, not to comply with any instructions relating to any or all of the Pledged Stock originated by any Person other than the Collateral Agent, on behalf of Lenders and the other Secured Parties, or a court of competent jurisdiction. In the event of any conflict between any instruction originated by the Collateral Agent and any instruction originated by any other Person, the Issuer shall comply only with the instruction originated by the Collateral Agent.

3. In addition to, and not in lieu of, the obligation of the Issuer to honor instructions as agreed in Section 2 hereof, the Issuer and the Collateral Agent hereby agree as follows:

(f) Subject to the rights of the Grantor described herein, the Issuer agrees that, from and after the date hereof, the Pledged Stock shall be under the exclusive dominion and control of the Collateral Agent;

(g) So long as the Issuer has not received a written notice from the Collateral Agent that it is exercising exclusive control over the Pledged Stock (a "**Notice of Exclusive Control**"), the Issuer may comply with instructions of the Grantor concerning the Pledged Stock, which Notice of Exclusive Control shall only be given by the Collateral Agent following the occurrence and during the continuance of an Event of Default. After the Issuer receives a Notice of Exclusive Control from the Collateral Agent, the Issuer will not accept any instructions concerning the Pledged Stock from any Person other than the Collateral Agent, unless otherwise ordered by a court of competent jurisdiction; and

(h) Until the Issuer receives a Notice of Exclusive Control, the Grantor shall be entitled to direct the Issuer with respect to voting the Pledged Stock.

4. This Agreement shall not subject the Issuer to any obligation or liability except as expressly set forth herein and under any Requirements of Law. In particular, the Issuer need not investigate whether the Collateral Agent is entitled under the Security Agreement or otherwise to give an instruction or Notice of Exclusive Control.

5. The Issuer hereby represents, warrants and covenants with the Collateral Agent that:

(i) This Agreement has been duly authorized, executed and delivered by the Issuer and constitutes a legal, valid and binding obligation of the Issuer enforceable in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium or other similar laws affecting creditors' rights generally and subject to equitable principles (regardless of whether enforcement is sought in equity or at law);

(j) The Issuer has not entered into, and until termination of this Agreement will not enter into, any agreement with any other Person relating to the Pledged Stock pursuant to which it has agreed, or will agree, to comply with instructions provided by such Person in a circumstance which would conflict with the instructions of the Collateral Agent. The Issuer has not entered into any other agreement with the Grantor purporting to limit or condition the obligation of the Issuer to comply with instructions as agreed in Section 3 hereof;

(k) Except for the claims and interests of the Collateral Agent, on behalf of Lenders and the other Secured Parties, and the Grantor in the Pledged Stock, the Issuer does not know of any claim to, or interest in, the Pledged Stock (except to the extent constituting Permitted Liens). If any Person asserts any Lien or adverse claim (including any writ, garnishment, judgment, attachment, execution or similar process) against the Pledged Stock (other than Permitted Liens), the Issuer will promptly notify the Collateral Agent and the Grantor thereof;

(l) In the event of any conflict between this Agreement (or any portion hereof) and any between the Issuer and the Grantor or among the Issuer, the Grantor and any third Person with respect to the Pledged Stock, whether now existing or hereafter entered into, the terms of this Agreement shall prevail; and

(m) The granting by the Grantor of the Security Interest in the Pledged Stock to the Collateral Agent for the benefit of Lenders and the other Secured Parties does not violate the Operating Documents or any other agreement governing the Issuer or the Pledged Stock.

6. This Agreement shall be binding upon, and shall inure to the benefit of, the parties hereto and their respective successors and assigns.

7. Each notice, request or other communication to a party hereto under this Agreement shall be in writing, will be sent to such party's address set forth under its name below or to such other address as such party may notify the other parties hereto and will be effective on receipt.

8. No amendment or modification of this Agreement or waiver of any right hereunder shall be binding on any party hereto unless it is in writing and is signed by all the parties hereto.

9. The rights and powers granted herein to the Collateral Agent (a) have been granted in order to perfect the Security Interest in the Pledged Stock, (b) are powers coupled with an interest and (c) will not be affected by any bankruptcy of the Grantor or any lapse in time. The obligations of the Issuer hereunder shall continue in effect until the Collateral Agent has notified the Issuer in writing that the Security Interest in the Pledged Stock has been terminated pursuant to the Security Agreement.

10. This Agreement shall be governed by and construed in accordance with the laws of the [ISSUER'S JURISDICTION OF ORGANIZATION].

11. If any term or provision of this Agreement is invalid, illegal or unenforceable in any jurisdiction, such invalidity, illegality or unenforceability shall not affect any other term or provision of this Agreement or invalidate or render unenforceable such term or provision in any other jurisdiction.

12. This Agreement may be executed in any number of counterparts and by different parties in separate counterparts, each of which when so executed shall be deemed to be an original and all of which taken together shall constitute one and the same agreement. Signature pages may be detached from multiple separate counterparts and attached to a single counterpart. Delivery of an executed signature page of this Agreement by facsimile transmission or by electronic transmission shall be as effective as delivery of a manually executed counterpart hereof.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first written above.

[GRANTOR]

By: _____
Name: _____
Title: _____

Address for Notices:

[ISSUER]

By: _____
Name: _____
Title: _____

Address for Notices:

Sarepta Therapeutics, Inc.
215 First Street, Suite 415
Cambridge, MA 02142
Attention: [**]
Telephone: [**]
Email: [**]

Sarepta Therapeutics, Inc.
215 First Street, Suite 415
Cambridge, MA 02142
Attention: [**]
Telephone: [**]
Email: [**]

Sarepta Therapeutics, Inc.
215 First Street, Suite 415
Cambridge, MA 02142
Attention: [**]
Telephone: [**]
Email: [**]

with a copy to (which shall not constitute notice) to:

Ropes & Gray LLP
Prudential Tower, 800 Boylston Street
Boston, MA 02199-3600
Attn: [**]
Telephone: [**]
Facsimile: [**]
Email: [**]

BIOPHARMA CREDIT PLC,
a public limited company

By: Pharmakon Advisors, LP,
its Investment Manager

By: Pharmakon Management I, LLC,
its General Partner

By _____
Name: Pedro Gonzalez de Cosio
Title: Managing Member

Address for Notices:

BIOPHARMA CREDIT PLC
c/o Beaufort House
51 New North Road
Exeter EX4 4EP
United Kingdom
Attention: Company Secretary
Telephone: [**]
Facsimile: [**]

with copies (which shall not constitute notice) to:

Pharmakon Advisors LP
110 East 59th Street, #3300
New York, NY 10022
Attn: Pedro Gonzalez de Cosio
Phone: [**]
Fax: [**]
Email: [**]

and

Akin Gump Strauss Hauer & Feld LLP
One Bryant Park
New York, NY 10036-6745
Attn: [**]
Phone: [**]
Fax: [**]
Email: [**]

EXHIBIT 10.54

GUARANTY AND SECURITY AGREEMENT

Dated as of December 20, 2019

by

SAREPTA THERAPEUTICS, INC.

(as *Borrower*),

THE GUARANTORS PARTY HERETO,

and

EACH OTHER GRANTOR
FROM TIME TO TIME PARTY HERETO

in favor of

BIOPHARMA CREDIT PLC

(as *Collateral Agent* on behalf of Lenders and the other Secured Parties)

GUARANTY AND SECURITY AGREEMENT, dated as of December 20, 2019 by SAREPTA THERAPEUTICS, INC., a Delaware corporation ("Borrower"), the Guarantors party to the Loan Agreement (as defined below) as of the date hereof, and each other Person that becomes a party hereto pursuant to Section 8.6 (together with Borrower and such Guarantors, "Grantors"), in favor of BIOPHARMA CREDIT PLC, a public limited company incorporated under the laws of England and Wales (as the "Collateral Agent") on behalf of Lenders and each other Secured Party.

W I T N E S S E T H:

WHEREAS, pursuant to the Loan Agreement dated as of December 13, 2019 (as the same may be amended, restated, amended and restated, supplemented or otherwise modified from time to time, the "Loan Agreement") by and among Borrower, the Collateral Agent and the other parties thereto, Lenders agrees to make extensions of credit to Borrower upon the terms and subject to the conditions set forth therein;

WHEREAS, each Grantor other than Borrower agrees to guaranty, jointly and severally, the Obligations (as defined in the Loan Agreement) of Borrower;

WHEREAS, each Grantor will derive substantial direct and indirect benefits from the making of the extensions of credit under the Loan Agreement; and

WHEREAS, it is a condition precedent to the obligation of Lenders to extend credit to Borrower under the Loan Agreement that the Grantors shall have executed and delivered this Agreement to the Collateral Agent and each Lender for the benefit of Lenders and the other Secured Parties.

NOW, THEREFORE, in consideration of the mutual premises herein contained and for valuable consideration the receipt and sufficiency of which is hereby acknowledged and to induce the Collateral Agent, Lenders and the Credit Parties to enter into the Loan Agreement and to induce each Lender to make extensions of credit to Borrower thereunder, each Grantor hereby agrees with the Collateral Agent, each intending to be legally bound, as follows:

ARTICLE I

DEFINED TERMS

Section 1.1. Definitions. Capitalized terms used herein without definition are used as defined in the Loan Agreement.

(a) The following terms have the meanings given to them in the Code and terms used herein without definition that are defined in the Code have the meanings given to them in the Code (such meanings to be equally applicable to both the singular and plural forms of the terms defined): "account", "account debtor", "as-extracted collateral", "certificated security", "chattel paper", "check", "commercial tort claim", "commodity account", "commodity contract", "documents", "deposit account", "electronic chattel paper", "encumbrance", "entitlement holder", "equipment", "farm products", "financial asset", "fixture", "general intangible", "goods", "health-care-insurance receivable", "instruments", "inventory", "investment property", "letter of credit", "letter-of-credit right", "money", "proceeds", "promissory note", "record", "securities account", "security", "security entitlement", "supporting obligation", "tangible chattel paper" and "uncertificated security".

(b) The following terms shall have the following meanings:

"Agreement" means this Guaranty and Security Agreement, as it may be amended, restated, supplemented or otherwise modified from time to time.

"Applicable IP Office" means the United States Patent and Trademark Office or the United States Copyright Office, as the context dictates.

"Collateral" has the meaning specified in Section 3.1.

"Excluded Property" means, collectively:

(i) any "intent to use" United States Trademark applications for which a statement of use or an amendment to allege use has not been filed (but only until such statement is filed) solely to the extent, if any, that, and only during the period, if any, in which, the grant of a security interest therein would impair the validity or enforceability of such intent to use Trademark applications under applicable federal law;

(ii) any permit, lease, license, contract, instrument or other agreement held by any Grantor with respect to which, the grant to the Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, of a security interest therein and Lien thereupon, and the pledge to the Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, thereof, to secure the Obligations (and any guaranty thereof) are validly prohibited by the terms thereof, or would create a right of termination in favor of any other party thereto (other than Borrower or a controlled Affiliate of Borrower) but only, in each case, to the extent, and for so long as, such prohibition or term is not terminated or rendered unenforceable or otherwise deemed ineffective by the Code (including Sections 9-406(d), 9-407(a), 9-408(a) and 9-409 of the Code) or by any applicable Requirements of Law;

(iii) any permit, lease, license, contract, instrument or other agreement held by any Grantor with respect to which, the grant to the Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, of a security interest in and Lien thereupon, and the pledge to the Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, thereof, to secure the Obligations (and any guaranty thereof) require the consent, approval or waiver of any Governmental Authority or other third party (other than Borrower or a controlled Affiliate of Borrower) and such consent, approval or waiver has not been obtained by such Grantor or Borrower following their respective commercially reasonable efforts to obtain the same;

(iv) any other asset or property subject or purported to be subject to a Lien under any Collateral Document held by any Grantor with respect to which, the grant to the Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, of a security interest in and Lien thereupon, and the pledge to the Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, thereof, to secure the Obligations (and any guaranty thereof) require the consent, approval or waiver of any Governmental Authority or other third party (other than Borrower or a controlled Affiliate of Borrower) and such consent, approval or waiver has not been obtained by such Grantor or Borrower following their respective commercially reasonable efforts to obtain the same;

(v) any property or asset subject or purported to be subject to a Lien under any Collateral Document held by any Grantor that is a non-Wholly-Owned Subsidiary with respect to which, the grant to the Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, of a security interest therein and Lien thereupon, and the pledge to the Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, thereof, to secure the Obligations (and any guaranty thereof) are validly prohibited by, or would give any third party (other than Borrower or an Affiliate of Borrower) the right to terminate its obligations under, the Operating Documents of, the joint venture agreement or shareholder agreement with respect to, or any other contract with such third party relating to such non-Wholly-Owned Subsidiary (other than customary non-assignment provisions which are ineffective under Article 9 of the Code or other Requirements of Law), but only, in each case, to the extent, and for so long as such Operating Documents, joint venture agreement, shareholder agreement or other contract is in effect;

(vi) any asset or property subject or purported to be subject to a Lien under any Collateral Document held by any Grantor with respect to which, the cost, difficulty, burden or consequences (including adverse Tax consequences) of granting the Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, a security interest therein and Lien thereupon, and pledging to the Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, thereof, to secure the Obligations (and any guaranty thereof) are excessive relative to the value to be afforded to Secured Parties thereby;

(vii) any rights under any Federal or state governmental license, permit, franchise or authorization to the extent that the granting of a security interest therein is specifically prohibited or restricted by any Requirements of Law;

(viii) any asset or property subject to a Permitted Lien to the extent the documents governing such Permitted Lien or the Permitted Indebtedness secured thereby validly prohibit other Liens on such asset or property, or would create a right of termination in favor of any other party thereto (other than Borrower or a controlled Affiliate of Borrower) but only, in each case, to the extent, and for so long as, such prohibition or term is not terminated or rendered unenforceable or otherwise deemed ineffective by the Code (including Sections 9-406(d), 9-407(a), 9-408(a) and 9-409 of the Code) or by any applicable Requirements of Law;

(ix) leasehold interests in real property;

(x) fee interests in real property;

(xi) Vehicles;

(xii) any letter of credit with an amount less than $500,000 and all letter-of-credit rights with respect thereto;

(xiii) any Intellectual Property unrelated in any way to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of any Product in the Territory, including any similar or equivalent rights to those set forth in any of clauses (a) through (f) of the definition of "Intellectual Property" and, for the avoidance of doubt, any non-U.S. Intellectual Property;

(xiv) Excluded Equity Interests; and

(xv) Excluded Accounts;

provided, however, that "Excluded Property" shall not include any proceeds, products, substitutions or replacements of Excluded Property (unless such proceeds, products, substitutions or replacements would otherwise constitute Excluded Property).

"Fraudulent Transfer Laws" has the meaning set forth in Section 2.2.

"Guaranteed Obligations" has the meaning set forth in Section 2.1.

"Guarantor" means each Grantor other than Borrower.

"Guaranty" means the guaranty of the Guaranteed Obligations made by Guarantors as set forth in this Agreement.

"IP License" means all express and implied grants or rights to make, have made, use, sell, reproduce, distribute, modify, or otherwise exploit any Intellectual Property, as well as all covenants not to sue and co-existence agreements (and all related IP Ancillary Rights), whether written or oral, relating to any Intellectual Property.

"Maximum Guaranteed Amount" has the meaning set forth in Section 2.2.

"NDA" means a new drug application filed with the FDA pursuant to Section 505(b) of the U.S. Federal Food, Drug, and Cosmetic Act, along with all supplements and amendments thereto.

"Pledged Certificated Stock" means all of the Equity Interests (other than Excluded Equity Interests) in any Subsidiary evidenced by a certificate, instrument or other similar document (as defined in the Code), in each case owned by any Grantor, including a Grantor's right, title and interest resulting from its ownership of any such Equity Interests as a limited or general partner in any partnership that has issued Pledged Certificated Stock or as a member of any limited liability company that has issued Pledged Certificated Stock, and a Grantor's right, title and interest resulting from its ownership of any such Equity Interests in, to and under any Operating Document or shareholder agreement of any corporation, partnership or limited liability company to which it is a party, and any distribution of property made on, in respect of or in exchange for the foregoing from time to time, including all certificated Equity Interests listed on Schedule 1 of the Security Disclosure Letter. "Pledged Certificated Stock" includes, for the avoidance of doubt, any Pledged Uncertificated Stock that subsequently becomes certificated.

"Pledged Collateral" means, collectively, the Pledged Stock and the Pledged Debt Instruments.

"Pledged Debt Instruments" means all right, title and interest of any Grantor in instruments evidencing any Indebtedness owed to such Grantor, and any distribution of property made on, in respect of or in exchange for the foregoing from time to time, including all Indebtedness described on Schedule 3 of the Security Disclosure Letter, issued by the obligors named therein. "Pledged Debt Instruments" excludes any Excluded Property.

"Pledged Investment Property" means any investment property of any Grantor, and any distribution of property made on, in respect of or in exchange for the foregoing from time to time, other than any Pledged Stock or Pledged Debt Instruments. "Pledged Investment Property" excludes any Excluded Property.

"Pledged Stock" means all Pledged Certificated Stock and all Pledged Uncertificated Stock.

"Pledged Uncertificated Stock" means all of the Equity Interests (other than Excluded Equity Interests) in any Subsidiary that is not Pledged Certificated Stock, in each case owned by any Grantor, including Grantor's right, title and interest resulting from its ownership of any such Equity Interests as a limited or general partner in any partnership not constituting Pledged Certificated Stock or as a member of any limited liability company not constituting Pledged Certificated Stock, a Grantor's right, title and interest resulting from its ownership of any such Equity Interests in, to and under any Operating Document or shareholder agreement of any partnership or limited liability company to which it is a party, and any distribution of property made on, in respect of or in exchange for the foregoing from time to time, including in each case those interests set forth on Schedule 1 of the Security Disclosure Letter, to the extent such interests are not certificated.

"Secured Obligations" has the meaning set forth in Section 3.2.

"Security Disclosure Letter" means the security agreement disclosure letter, dated as of the date hereof, delivered by the Grantors to the Collateral Agent and each Lender.

"Vehicles" means rolling stock, motor vehicles, vessels, aircraft and other assets subject to certificates of title.

Section 1.2. Certain Other Terms.

(a) For the purposes of and as used in this Agreement: (i) references to any Person include its successors and assigns and, in the case of any Governmental Authority, any Person succeeding to its functions and capacities; (ii) each authorization herein shall be deemed irrevocable and coupled with an interest; and (iii) where the context requires, provisions relating to any Collateral when used in relation to a Grantor shall refer to such Grantor's Collateral or any relevant part thereof.

(b) Other Interpretive Provisions.

(i) Defined Terms. Unless otherwise specified herein or therein, all terms defined in this Agreement shall have the defined meanings when used in any certificate or other document made or delivered pursuant hereto.

(ii) This Agreement. The words “hereof”, “herein”, “hereunder” and words of similar import when used in this Agreement shall refer to this Agreement as a whole and not to any particular provision of this Agreement.

(iii) Certain Common Terms. The words “include”, “included” and “including” are not limiting and mean “including without limitation.” The word “or” has the inclusive meaning represented by the phrase “and/or”. The word “shall” is mandatory. The word “may” is permissive. The singular includes the plural and the plural includes the singular.

(iv) Performance; Time. Whenever any performance obligation hereunder (other than a payment obligation) shall be stated to be due or required to be satisfied on a day other than a Business Day, such performance shall be made or satisfied on the next succeeding Business Day. In the computation of periods of time from a specified date to a later specified date, the word “from” means “from and including”; the words “to” and “until” each mean “to but excluding”, and the word “through” means “to and including.” If any provision of this Agreement refers to any action taken or to be taken by any Person, or which such Person is prohibited from taking, such provision shall be interpreted to encompass any and all means, direct or indirect, of taking, or not taking, such action.

(v) Contracts. Except as the context otherwise requires (including to the extent otherwise expressly provided herein), references to any contract, agreement, instrument or other document, including this Agreement and the other Loan Documents, shall be deemed to include any and all amendments, supplements or modifications thereto or restatements or substitutions thereof, in each case which are in effect from time to time, but only to the extent such amendments, supplements, modifications, restatements or substitutions are not prohibited by the terms of any Loan Document.

(vi) Laws. Except as the context otherwise requires (including to the extent otherwise expressly provided herein), references to any law, statute, treaty, order, policy, rule or regulation include any amendments, supplements and successors thereto, and references to any law, statute, treaty, order, policy, rule or regulation are to be construed as including all statutory and regulatory provisions related thereto or consolidating, amending, replacing, supplementing or interpreting such law, statute, treaty, order, policy, rule or regulation.

(vii) Excluded Property. Notwithstanding anything to the contrary herein, the representations, warranties and covenants set forth herein in relation to the assets of the Grantors shall not apply to any Excluded Property.

ARTICLE II

GUARANTY

Section 2.1. Guaranty. To induce Lenders to make the Term Loans to Borrower in accordance with the terms and conditions of the Loan Agreement, each Guarantor, jointly and severally with each other Guarantor, absolutely, unconditionally and irrevocably guarantees, as primary obligor and not merely as surety, the full and punctual payment when due, whether at stated maturity or earlier, by reason of acceleration, mandatory prepayment or otherwise in accordance with any Loan Document, of all the Obligations of Borrower existing on the date hereof or hereinafter incurred or created (the "Guaranteed Obligations"). This Guaranty by each Guarantor hereunder constitutes a guaranty of payment and not of collection. Each Guarantor hereby acknowledges and agrees that the Guaranteed Obligations, at any time and from time to time, may exceed the Maximum Guaranteed Amount of such Guarantor and may exceed the aggregate of the Maximum Guaranteed Amounts of all Guarantors, in each case without discharging, limiting or otherwise affecting the obligations of any Guarantor hereunder or the rights, powers and remedies of any Secured Party hereunder or under any other Loan Document.

Section 2.2. Limitation of Guaranty. Any term or provision of this Guaranty or any other Loan Document to the contrary notwithstanding, the maximum aggregate amount for which any Guarantor shall be liable hereunder (the "Maximum Guaranteed Amount") shall not exceed the maximum amount for which such Guarantor can be liable without rendering this Guaranty or any other Loan Document, as it relates to such Guarantor, subject to avoidance under applicable Requirements of Law relating to fraudulent conveyance or fraudulent transfer (including the Uniform Fraudulent Conveyance Act, the Uniform Fraudulent Transfer Act and Section 548 of title 11 of the United States Code or any applicable provisions of comparable Requirements of Law) (collectively, "Fraudulent Transfer Laws"). Any analysis of the provisions of this Guaranty for purposes of Fraudulent Transfer Laws shall take into account the right of contribution established in Section 2.7 below and, for purposes of such analysis, give effect to any discharge of intercompany debt as a result of any payment made under the Guaranty.

Section 2.3. Authorization; Other Agreements. The Collateral Agent, on behalf of Lenders and the other Secured Parties is hereby authorized, without notice, to or demand upon any Guarantor and without discharging or otherwise affecting the obligations of any Guarantor hereunder and without incurring any liability hereunder, from time to time, to do each of the following but subject in all cases to the terms and conditions of the other Loan Documents:

(a) (i) modify, amend, supplement or otherwise change, (ii) accelerate or otherwise change the time of payment or (iii) waive or otherwise consent to noncompliance with, any Guaranteed Obligation or any Loan Document;

(b) apply to the Guaranteed Obligations any sums by whomever paid or however realized to any Guaranteed Obligation in such order as provided in the Loan Documents;

(c) refund at any time any payment received by any Secured Party in respect of any Guaranteed Obligation;

(d) (i) sell, exchange, enforce, waive, substitute, liquidate, terminate, release, abandon, fail to perfect, subordinate, accept, substitute, surrender, exchange, affect, impair or otherwise alter or release any Collateral for any Guaranteed Obligation or any other guaranty therefor in any manner, (ii) receive, take and hold additional Collateral to secure any Guaranteed Obligation, (iii) add, release or substitute any one or more other Guarantors, makers or endorsers of any Guaranteed Obligation or any part thereof and (iv) otherwise deal in any manner with Borrower or any other Guarantor, maker or endorser of any Guaranteed Obligation or any part thereof; and

(e) settle, release, compromise, collect or otherwise liquidate the Guaranteed Obligations.

Section 2.4. Guaranty Absolute and Unconditional. Each Guarantor hereby waives and agrees not to assert any defense (other than the defense of indefeasible payment in full of the Guaranteed Obligations (other than inchoate indemnity obligations)), whether arising in connection with or in respect of any of the following clauses (a) through (f) or otherwise, and hereby agrees that its obligations under this Guaranty are irrevocable, absolute and unconditional and shall not be discharged as a result of or otherwise affected by any of the following clauses (a) through (f) (which may not be pleaded and evidence of which may not be introduced in any proceeding with respect to this Guaranty, in each case except as otherwise agreed in writing by the Collateral Agent):

(a) the invalidity or unenforceability of any obligation of Borrower or any other Guarantor under any Loan Document or any other agreement or instrument relating thereto (including any amendment, consent or waiver thereto), or any security for, or other guaranty of, any Guaranteed Obligation or any part thereof, or the lack of perfection or continuing perfection or failure of priority of any security for the Guaranteed Obligations or any part thereof;

(b) the absence of (i) any attempt to collect any Guaranteed Obligation or any part thereof from Borrower or any other Guarantor or other action to enforce the same or (ii) any action to enforce any Loan Document or any Lien thereunder;

(c) the failure by any Person to take any steps to perfect and maintain any Lien on, or to preserve any rights with respect to, any Collateral;

(d) any workout, insolvency, bankruptcy proceeding, reorganization, arrangement, liquidation or dissolution by or against Borrower, any other Guarantor or any of Borrower's other Subsidiaries or any procedure, agreement, order, stipulation, election, action or omission thereunder, including any discharge or disallowance of, or bar or stay against collecting, any Guaranteed Obligation (or any interest thereon) in or as a result of any such proceeding;

(e) any foreclosure, whether or not through judicial sale, and any other sale or other disposition of any Collateral or any election following the occurrence of an Event of Default and during the continuance thereof by the Collateral Agent, on behalf of Lenders and any other Secured Party, to proceed separately against any Collateral in accordance with the Collateral Agent's rights and the rights of any Lender or other Secured Party under any applicable Requirements of Law; or

(f) any other defense, setoff, counterclaim or any other circumstance that might otherwise constitute a legal or equitable discharge of Borrower, any other Guarantor or any other Subsidiary of Borrower, in each case other than the defense of indefeasible payment in full of the Guaranteed Obligations (other than inchoate indemnity obligations).

Section 2.5. Waivers. To the fullest extent permitted by Requirements of Law, each Guarantor hereby unconditionally and irrevocably waives and agrees not to assert any claim, defense (other than the defense of payment in full of the Guaranteed Obligations (other than inchoate indemnity obligations)), setoff or counterclaim based on diligence, promptness, presentment, requirements for any demand or notice hereunder, including any of the following: (a) any demand for payment or performance and protest and notice of protest; (b) any notice of acceptance; (c) any presentment, demand, protest or further notice or other requirements of any kind with respect to any Guaranteed Obligation (including any accrued but unpaid interest thereon) becoming immediately due and payable; and (d) any other notice in respect of any Guaranteed Obligation or any part thereof, and any defense arising by reason of any disability or other defense of Borrower or any other Guarantor. Until the indefeasible payment in full of the Guaranteed Obligations (other than inchoate indemnity obligations), each Guarantor further unconditionally and irrevocably agrees not to (x) enforce or otherwise exercise any right of subrogation or any right of reimbursement or contribution or similar right against Borrower or any other Guarantor by reason of any Loan Document or any payment made thereunder or (y) assert any claim, defense, setoff or counterclaim it may have against any other Credit Party or set off any of its obligations to such other Credit Party against obligations of such Credit Party to such Guarantor. No obligation of any Guarantor hereunder shall be discharged other than by complete performance.

Section 2.6. Reliance. Each Guarantor hereby assumes responsibility for keeping itself informed of the financial condition of Borrower, each other Guarantor and any other guarantor, maker or endorser of any Guaranteed Obligation or any part thereof, and of all other circumstances bearing upon the risk of nonpayment of any Guaranteed Obligation or any part thereof that reasonable and diligent inquiry would reveal, and each Guarantor hereby agrees that neither the Collateral Agent nor any Lender or other Secured Party shall have any duty to advise any Guarantor of information known to it regarding such condition or any such circumstances. In the event the Collateral Agent, in its sole discretion, undertakes at any time or from time to time to provide any such information to any Guarantor, such Person shall be under no obligation to (a) undertake any investigation not a part of its regular business routine, (b) disclose any information that any Lender or other Secured Party, pursuant to accepted or reasonable commercial finance or banking practices, wishes to maintain confidential or (c) make any future disclosures of such information or any other information to any Guarantor.

Section 2.7. Contribution. To the extent that any Guarantor shall be required hereunder to pay any portion of any Guaranteed Obligation exceeding the greater of (a) the amount of the value actually received by such Guarantor and its Subsidiaries from the Term Loans and other Obligations and (b) the amount such Guarantor would otherwise have paid if such Guarantor had paid the aggregate amount of the Guaranteed Obligations (excluding the amount thereof repaid by Borrower) in the same proportion as such Guarantor's net worth on the date enforcement is sought hereunder bears to the aggregate net worth of all Guarantors on such date, then such Guarantor shall be reimbursed by such other Guarantors for the amount of such excess, *pro rata*, based on the respective net worth of such other Guarantors on such date.

ARTICLE III

GRANT OF SECURITY INTEREST

Section 3.1. Collateral. For the purposes of this Agreement, the following tangible and intangible assets and property now owned or at any time hereafter acquired, developed or created by a Grantor or in which a Grantor now has or at any time in the future may acquire any right, title or interest, in each case, wherever located, is collectively referred to as the "Collateral":

(a) all accounts;

(b) all as-extracted collateral;

(c) all chattel paper, including electronic chattel paper or tangible chattel paper;

(d) all checks;

(e) all deposit accounts;

(f) all documents;

(g) all equipment;

(h) all fixtures;

(i) all general intangibles (including all Current Company IP Agreements);

(j) all goods;

(k) all instruments (including all promissory notes);

(l) any and all U.S. Intellectual Property and IP Licenses (including IP Licenses under the Current Company IP Agreements to which a Grantor is a party and the rights of such Grantor thereunder, and all of a Grantor's right, title and interest in, to and under any Internet Domain Names and Software) relating to the research, development, manufacture, production, use, commercialization, marketing, importing, storage, transport, offer for sale, distribution or sale of any Product in the Territory, including any similar or equivalent rights to those set forth in any of clauses (a) through (f) of the definition of "Intellectual Property";

(m) all right title and interest in, to and under any NDA relating to the commercialization, marketing, offer for sale, distribution or sale of any Product in the Territory;

(n) all inventory;

(o) all investment property (including Pledged Collateral, Pledged Investment Property, Equity Interests, securities, securities accounts and security entitlements with respect thereto and financial assets carried therein, and all commodity accounts and commodity contracts);

(p) all money;

(q) all letters of credit, letter-of-credit rights and supporting obligations;

(r) the commercial tort claims with a predicted value of $500,000 or more (as reasonably determined by a Responsible Officer of Borrower in good faith and based upon reasonable assumptions) described on Schedule 4 of the Security Disclosure Letter;

(s) all books, records, ledger cards, files, correspondence, customer lists, blueprints, technical specifications, manuals, computer software, computer printouts, tapes, disks and other electronic storage media and related data processing software and similar items that at any time pertain to or evidence or contain information specifically relating to any of the other property described in the foregoing clauses (a) - (p) of this Section 3.1;

(t) all property of such Grantor held by the Collateral Agent for the benefit of Lenders and any other Secured Party, including all property of every description, in the custody of or in transit to the Collateral Agent for the benefit of Lenders and any other Secured Party for any purpose, including safekeeping, collection or pledge, for the account of such Grantor or as to which such Grantor may have any right or power, including cash;

(u) all proceeds, products, accessions, rents and profits of or in respect of any of the foregoing;

(v) to the extent not otherwise included, all personal property of such Grantor, whether tangible or intangible and wherever located, and all proceeds, products, accessions, rents, issues and profits of any and all of the foregoing and all collateral security, supporting obligations and guarantees given by any Person with respect to any of the foregoing; and

(w) to the extent not otherwise included, all other properties or assets of whatever kind and nature subject or purported to be subject from time to time to a Lien under any Collateral Document;

excluding, however, all Excluded Property.

Section 3.2. Grant of Security Interest in Collateral.

(a) Without limiting any other security interest granted to the Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, each Grantor, as collateral security for the prompt and complete payment and performance when due (whether at stated maturity, by acceleration or otherwise) of the Obligations of such Grantor (the "Secured Obligations"), hereby pledges, hypothecates and grants to the Collateral Agent, in favor and for the benefit of Lenders and the other Secured Parties, to secure the payment and performance in full of all of the Obligations for the benefit of Lenders and the other Secured Parties, a first priority Lien (subject only to Permitted Liens) on and continuing security interest in, all of its right, title and interest in, to and under the Collateral of such Grantor, wherever located, whether now owned or hereafter acquired or arising; provided, however, notwithstanding the foregoing, no Lien or security interest is hereby granted on, and "Collateral" shall not include, any Excluded Property; provided, further, that if and when any property or asset shall cease to be Excluded Property, a first priority Lien (subject only to Permitted Liens) on and security interest in such property or asset shall be deemed granted therein and, therefore, "Collateral" shall then include any such property or asset.

(b) Notwithstanding anything herein to the contrary, no Grantor or Subsidiary of any Grantor shall be required to take any action under laws outside the United States, or enter into agreements governed or purported to be governed by laws outside of the United States, to attach, maintain, perfect, protect or enforce any Lien of the Collateral Agent in favor and for the benefit of Lenders and the other Secured Parties on Collateral.

ARTICLE IV

REPRESENTATIONS AND WARRANTIES

To induce the Collateral Agent and Lenders to enter into the Loan Documents, each Grantor, jointly and severally with each other Grantor, represents and warrants each of the following to the Collateral Agent, each Lender and the other Secured Parties:

Section 4.1. Title; No Other Liens. Except for the Lien granted to the Collateral Agent for the benefit of Lenders and the other Secured Parties pursuant to this Agreement and any other Permitted Liens under any Loan Document (including Section 4.2 hereof), such Grantor owns or otherwise has the rights it purports to have in each item of the Collateral, free and clear of any and all Liens or claims of others. Such Grantor (a) is the record and beneficial owner of the Collateral pledged by it hereunder constituting instruments or certificates and (b) except for Permitted Subsidiary Distribution Restrictions, has rights in or the power to transfer each other item of Collateral in which a Lien is granted by it hereunder, free and clear of any other Lien other than any Permitted Liens.

Section 4.2. Perfection and Priority. Other than in respect of money and other Collateral subject to Section 9-311(a)(1) of the Code, the security interest granted to the Collateral Agent pursuant to this Agreement constitutes a valid and continuing first priority perfected security interest (subject, in the case of priority only, to Permitted Liens that are expressly permitted (if at all) by the terms of the Loan Agreement or this Agreement to, or that by operation of law, have superior priority to the Lien and security interest granted to the Collateral Agent for the benefit of Lenders and the other Secured Parties) in favor of and for the benefit of Lenders and the other Secured Parties in all Collateral, subject, for the following Collateral, to the occurrence of the following: (a) in the case of all Collateral in which a security interest may be perfected by filing a financing statement under the Code, the completion of the filings and other actions specified on Schedule 2 of the Security Disclosure Letter (which, in the case of all filings and other documents referred to on such schedule, have been duly authorized by the applicable Guarantor); (b) with respect to any account over which a Control Agreement is required pursuant to Section 5.5 of the Loan Agreement, the execution of Control Agreements; in the case of all United States Trademarks, Patents and Copyrights for which Code filings are insufficient to effectuate perfection, all appropriate filings having been made with the Applicable IP Office, as applicable; (d) in the case of all Pledged Certificated Stock, Pledged Debt Instruments and Pledged Investment Property, the delivery to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of such Pledged Certificated Stock, Pledged Debt Instruments and Pledged Investment Property consisting of instruments and certificates, in each case, properly endorsed for transfer to the Collateral Agent or in blank; (e) in the case of all Pledged Uncertificated Stock, the delivery to the Collateral

Agent, for the benefit of the Lenders and the other Secured Parties, of an executed uncertificated stock control agreement among the issuer, the registered owner and the Collateral Agent in the form attached as Annex 4 hereto; and (f) in the case of all other instruments that are not Pledged Stock, if any, the delivery thereof to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, of such instruments. Such Lien on and security interest in Pledged Stock shall be prior to all other Liens on such Collateral, subject to Permitted Liens having priority over the Collateral Agent's Lien by operation of law or as and to the extent expressly permitted (if at all) by any Loan Document. Except to the extent expressly not required pursuant to the terms of the Loan Agreement or this Agreement, all actions by each Grantor necessary or desirable to protect and perfect the first priority Lien on and security interest in the Collateral granted hereunder have been duly taken (subject to Section 3.2(b)).

Section 4.3. Pledged Stock.

(a) As of the Tranche A Closing Date, the Pledged Stock issued by any Subsidiary of any Grantor pledged by such Grantor hereunder (i) consist of the number and types of Equity Interests listed on Schedule 1 of the Security Disclosure Letter and constitutes that percentage of the issued and outstanding equity of all classes in each issuer thereof as set forth on Schedule 1 of the Security Disclosure Letter, (ii) has been duly authorized, validly issued and is fully paid and nonassessable (other than Pledged Stock in limited liability companies and partnerships), and (ii) constitutes the legal, valid and binding obligation of the obligor with respect thereto, enforceable in accordance with its terms. As of the date any Joinder Agreement or Pledge Amendment is delivered pursuant to Section 8.6, the Pledged Stock pledged by each applicable Grantor thereunder (x) is listed on the applicable schedule attached to such Joinder Agreement or Pledge Amendment, as applicable, and constitutes that percentage of the issued and outstanding equity of all classes of each issuer thereof as set forth on such schedule, (y) has been duly authorized, validly issued and is fully paid and non-assessable (other than Pledged Stock in limited liability companies and partnerships) and (z) constitutes the legal, valid and binding obligation of the obligor with respect thereto, enforceable in accordance with its terms.

(b) As of, or substantially concurrently with, the Tranche A Closing Date, (i) all Pledged Certificated Stock has been delivered to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, in accordance with Section 5.2(a), and (ii) with respect to all Pledged Uncertificated Stock of Persons organized under the laws of the United States, uncertificated stock control agreements in the form attached as Annex 4 hereto have been delivered to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, in accordance with Section 5.2(a).

(c) Upon (i) the occurrence and during the continuance of an Event of Default and (ii) concurrent, written notice by the Collateral Agent to the relevant Grantor, the Collateral Agent for the benefit of Lenders and the other Secured Parties shall be entitled to exercise all of the rights of the Grantor granting the security interest in any Pledged Stock, and a transferee or assignee of such Pledged Stock shall become a holder of such Pledged Stock to the same extent as such Grantor and, upon the transfer of the entire interest of such Grantor, such Grantor shall, by operation of law, cease to be a holder of such Pledged Stock.

ARTICLE V

COVENANTS

Each Grantor agrees with the Collateral Agent to the following, until the indefeasible payment in full of the Obligations (other than inchoate indemnity obligations) and unless the Collateral Agent, on behalf of Lenders and the other Secured Parties, otherwise consents in writing:

Section 5.1. Maintenance of Perfected Security Interest; Further Documentation and Consents.

(a) Subject to the occurrence of the actions described in Section 4.2, which each Grantor shall promptly undertake, and except to the extent perfection is either (i) mutually agreed between Borrower and the Collateral Agent not to be required under this Agreement or the other Loan Documents or (ii) mutually agreed between Borrower and the Collateral Agent to be effected by filings of financing statements or amendments thereto to be made by the Collateral Agent or any Lender or its Related Party pursuant to Section 7.2, such Grantor shall maintain the security interest created by this Agreement as a perfected security interest having at least the priority described in Section 4.2 and shall take reasonable steps to warrant and defend the Collateral covered by such security interest and such priority against the claims and demands of all Persons (other than Secured Parties).

(b) Such Grantor shall furnish to the Collateral Agent at any time and from time to time statements and schedules further identifying and describing the Collateral and such other documents in connection with the Collateral as the Collateral Agent may reasonably request in writing, in all cases in reasonable detail and in form and substance reasonably satisfactory to the Collateral Agent.

(c) At any time and from time to time, upon the written request of the Collateral Agent, such Grantor shall, for the purpose of obtaining or preserving the full benefits of this Agreement and the other Collateral Documents and of the rights and powers herein and therein granted, (i) promptly and duly execute and deliver, and have recorded, such further documents, including an authorization to file (or, as applicable, the filing) of any financing statement or amendment under the Code (or other filings under similar Requirements of Law) in effect in any jurisdiction with respect to the security interest created hereby and (ii) take such further action as the Collateral Agent may reasonably request in writing that is consistent with the requirements hereof and of the other Loan Documents, including executing and delivering any Control Agreements required by Section 5.5 of the Loan Agreement with respect to the Collateral Accounts.

Section 5.2. Pledged Collateral.

(a) Delivery of Pledged Collateral. Such Grantor shall, promptly after acquiring any Pledged Collateral not owned on the Tranche A Closing Date: (i) deliver to the Collateral Agent, in suitable form for transfer and in form and substance reasonably satisfactory to the Collateral Agent, (A) all such Pledged Stock that is Pledged Certificated Stock, (B) all Pledged Debt Instruments in an amount greater than, individually, $75,000 and (C) all certificates and instruments evidencing Pledged Investment Property in an amount greater than, individually, $75,000, (ii) subject all Collateral Accounts required to be subject to a Control Agreement pursuant to the Loan Agreement to a Control Agreement; and (iii) cause the issuer of any such Pledged Stock that is Pledged Uncertificated Stock of Persons organized under the laws of the United States to execute an uncertificated stock control agreement in the form attached hereto as Annex 4, pursuant to which, *inter alia*, such issuer agrees to comply with the Collateral Agent's instructions with respect to such Pledged Uncertificated Stock without further consent by such Grantor, and, for the avoidance of doubt, if any such Pledged Uncertificated Stock becomes certificated, promptly (but in any event within thirty (30) days thereof) deliver to the Collateral Agent, in suitable form for transfer and in form and substance reasonably satisfactory to the Collateral Agent, all such certificates, instruments or other similar documents (as defined in the Code).

(b) Event of Default. During the continuance of any Event of Default and in connection with the exercise of rights or remedies hereunder or under any other Loan Document, the Collateral Agent shall have the right, at any time in its discretion, and upon concurrent, written notice by the Collateral Agent to the relevant Grantor, to (i) transfer to or to register in its name or in the name of its nominees any Pledged Stock and (ii) exchange any certificate or instrument representing or evidencing any Pledged Stock for certificates or instruments of smaller or larger denominations.

(c) Cash Distributions with respect to Pledged Collateral and Pledged Investment Property. Except as provided in Article VI and subject to any limitations set forth in the Loan Agreement, such Grantor shall be entitled to receive all cash distributions paid in respect of the Pledged Collateral and the Pledged Investment Property.

(d) Voting Rights. Except as provided in Article VI, such Grantor shall be entitled to exercise all voting, consent and corporate, partnership, limited liability company and similar rights with respect to the Pledged Collateral and Pledged Investment Property; provided, however, that no vote shall be cast, consent, waiver or ratification given or right exercised (or failed to be exercised) or other action taken (or failed to be taken) by such Grantor in any manner that would reasonably be expected to (i) violate or be inconsistent with any of the terms of this Agreement or any other Loan Document or (ii) have the effect of materially impairing such Collateral or the position or interests of the Secured Parties.

ARTICLE VI

REMEDIAL PROVISIONS

Section 6.1. Code and Other Remedies.

(a) Code Remedies. During the continuance of an Event of Default, the Collateral Agent, on behalf of Lenders and the other Secured Parties, may exercise, in addition to all other rights and remedies granted to it in this Agreement, any IP Agreement, any other Loan Document or in any other instrument or agreement securing, evidencing or relating to any Secured Obligation, all rights, powers and remedies of a secured party under the Code or any other Requirements of Law or in equity.

(b) Disposition of Collateral. During the continuance of an Event of Default, without limiting the generality of the foregoing, the Collateral Agent may (personally or through its agents or attorneys), without demand of performance or other demand, presentment, protest, advertisement or notice of any kind (except any notice required by Requirements of Law referred to below) to or upon any Grantor or any other Person (all and each of which demands, defenses, advertisements and notices are hereby waived): (i) enter upon the premises where any Collateral is located, without any obligation to pay rent, through self-help, without judicial process, without first obtaining a final judgment or giving Grantor or any other Person notice or opportunity for a hearing on the Collateral Agent's or any Lender's claim or action; (ii) collect, receive, appropriate and realize upon any Collateral; (iii) store, process, repair or recondition the Collateral or otherwise prepare any Collateral for disposition in any manner to the extent the Collateral Agent deems appropriate; and (iv) sell, assign, license out, convey, transfer, grant option or options to purchase or license and deliver any Collateral (or enter into contractual obligations to do any of the foregoing), in one or more parcels at public or private sale or sales, at any exchange, broker's board or office of the Collateral Agent or any Lender or other Secured Party or elsewhere upon such terms and conditions as it may deem advisable and at such prices as it may deem best, for cash or on credit or for future delivery without assumption of any credit risk. The Collateral Agent, on behalf of Lenders and the other Secured Parties, shall have the right, upon any such public sale or sales and, to the extent permitted by the Code and other Requirements of Law, upon any such private sale or sales, to purchase or license the whole or any part of the Collateral so sold or licensed, free of any right or equity of redemption of any Grantor, which right or equity is hereby waived and released. The Collateral Agent, as representative of all Lenders and other Secured Parties, shall be entitled, for the purpose of bidding and making settlement or payment of the purchase price for all or any portion of the Collateral sold at any such sale made in accordance with the Code, to use and apply any of the Secured Obligations as a credit on account of the purchase price for any Collateral payable by the Collateral Agent on behalf of Lenders and the other Secured Parties, at such sale. If the Collateral Agent on behalf of any Lender sells any of the Collateral upon

credit, Grantor will be credited only with payments actually made by purchaser and received by such Lender and applied to indebtedness of the purchaser. In the event the purchaser fails to pay for the Collateral, the Collateral Agent may resell the Collateral and Grantor shall be credited with proceeds of the sale. Neither the Collateral Agent nor any Lender shall have an obligation to marshal any of the Collateral.

(c) Management of the Collateral. Each Grantor further agrees, that, during the continuance of any Event of Default, (i) at the Collateral Agent's request, it shall assemble the Collateral and make it available to the Collateral Agent at places that the Collateral Agent shall reasonably select, whether at such Grantor's premises or elsewhere, (ii) without limiting the foregoing, the Collateral Agent also has the right to require that such Grantor store and keep any Collateral pending further action by the Collateral Agent and, while any such Collateral is so stored or kept, provide such guards and maintenance services as shall be necessary to protect the same and to preserve and maintain such Collateral in good condition, normal wear and tear excepted, (iii) until the Collateral Agent is able to sell, assign, license out, convey or transfer any Collateral, the Collateral Agent shall have the right to hold or use such Collateral to the extent that it deems appropriate for the purpose of preserving the Collateral or its value or for any other purpose deemed appropriate by the Collateral Agent and (iv) the Collateral Agent may, if it so elects, seek the appointment of a receiver or keeper to take possession of any Collateral and to enforce any of the Collateral Agent's or any Lender's remedies, with respect to such appointment without prior notice or hearing as to such appointment. The Collateral Agent shall not have any obligation to any Grantor to maintain or preserve the rights of any Grantor as against other Persons with respect to any Collateral while such Collateral is in the possession of the Collateral Agent.

(d) Application of Proceeds. The Collateral Agent shall apply the cash proceeds received by it in respect of any sale of, any collection from, or other realization upon all or any part of the Collateral, after deducting all reasonable costs and expenses of every kind incurred in connection therewith or incidental to the care or safekeeping of any Collateral or in any way relating to the Collateral or the rights of Lenders and the other Secured Parties, including reasonable and documented out-of-pocket attorneys' fees and disbursements, to the payment in whole or in part of the Secured Obligations, as set forth in the Loan Agreement, and only after such application and after the payment by the Collateral Agent or Lenders of any other amount required by any Requirements of Law, need the Collateral Agent or any Lender account for the surplus, if any, to any Grantor.

(e) Direct Obligation. Neither the Collateral Agent nor any Lender or other Secured Party shall be required to make any demand upon, or pursue or exhaust any right or remedy against, any Grantor or any other Person with respect to the payment of the Obligations or to pursue or exhaust any right or remedy with respect to any Collateral therefor or any direct or indirect guaranty thereof. All of the rights and remedies of the Collateral Agent and Lenders and any other Secured Party shall be cumulative, may be exercised individually or concurrently and not exclusive of any other rights or remedies provided by any Requirements of Law. To the extent it may lawfully do so, each Grantor absolutely and irrevocably waives and relinquishes the benefit and advantage of, and covenants not to assert against the Collateral Agent, Lenders or any other Secured Party, any valuation, stay, appraisement, extension, redemption or similar laws and any and all rights or defenses it may have as a surety, now or hereafter existing, arising out of the exercise by any of them of any rights or remedies hereunder. If any notice of a proposed sale or other disposition of any Collateral shall be required by Requirements of Law, such notice shall be deemed reasonable and proper if given at least ten (10) days before such sale or other disposition.

(f) Commercially Reasonable. To the extent that applicable Requirements of Law impose duties on the Collateral Agent or any Lender or other Secured Party to exercise remedies in a commercially reasonable manner, each Grantor acknowledges and agrees that it is not commercially unreasonable for the Collateral Agent or any Lender to do any of the following:

(i) fail to incur significant costs, expenses or other liabilities reasonably deemed as such by the Collateral Agent or such Lender to prepare any Collateral for disposition or otherwise to complete raw material or work in process into finished goods or other finished products for disposition;

(ii) fail to obtain permits, licenses or other consents for access to any Collateral to sell or license or for the collection or sale or licensing of any Collateral, or, if not required by other Requirements of Law, fail to obtain permits, licenses or other consents for the collection or disposition of any Collateral;

(iii) fail to exercise remedies against account debtors or other Persons obligated on any Collateral or to remove Liens on any Collateral or to remove any adverse claims against any Collateral;

(iv) advertise dispositions of any Collateral through publications or media of general circulation, whether or not such Collateral is of a specialized nature, or to contact other Persons, whether or not in the same business as any Grantor, for expressions of interest in acquiring any such Collateral;

(v) exercise collection remedies against account debtors and other Persons obligated on any Collateral, directly or through the use of collection agencies or other collection specialists, hire one or more professional auctioneers to assist in the disposition of any Collateral, whether or not such Collateral is of a specialized nature, or, to the extent deemed appropriate by the Collateral Agent or such Lender, obtain the services of other brokers, investment bankers, consultants and other professionals to assist the Collateral Agent or such Lender in the collection or disposition of any Collateral, or utilize Internet sites that provide for the auction of assets of the types included in the Collateral or that have the reasonable capacity of doing so, or that match buyers and sellers of assets to dispose of any Collateral;

(vi) dispose of assets in wholesale rather than retail markets;

(vii) disclaim warranties, such as title, merchantability, possession, non-infringement or quiet enjoyment; or

(viii) purchase insurance or credit enhancements to insure the Collateral Agent or any Lender or other Secured Party against risks of loss, collection or disposition of any Collateral or to provide to the Collateral Agent and Lenders a guaranteed return from the collection or disposition of any Collateral.

Each Grantor acknowledges that the purpose of this Section 6.1 is to provide a non-exhaustive list of actions or omissions that are commercially reasonable when exercising remedies against any Collateral and that other actions or omissions by the Collateral Agent, Lenders or any other Secured Party shall not be deemed commercially unreasonable solely on account of not being indicated in this Section 6.1. Without limitation upon the foregoing, nothing contained in this Section 6.1 shall be construed to grant any rights to any Grantor or to impose any duties on the Collateral Agent or any Lender or other Secured Party that would not have been granted or imposed by this Agreement or by applicable Requirements of Law in the absence of this Section 6.1.

(g) IP Licenses. To the extent permitted, and only for the purpose of enabling the Collateral Agent to exercise rights and remedies under this Section 6.1 during the continuance of an Event of Default (including in order to take possession of, collect, receive, assemble, process, appropriate, remove, realize upon, sell, assign, license out, convey, transfer or grant options to purchase any Collateral) at such time as the Collateral Agent on behalf of Lenders and the other Secured Parties shall be lawfully entitled to exercise such rights and remedies, each Grantor hereby grants to the Collateral Agent (i) an irrevocable, nonexclusive, assignable, license in the Territory (exercisable without payment of royalty or other compensation to such Grantor), including the right to sublicense, use and practice any and all Intellectual Property now owned or held or hereafter acquired or held by such Grantor and access to all media in which any of the licensed items may be recorded or stored and to all Software and programs used for the compilation or printout thereof; provided, however, (A) that such licenses to be granted hereunder with respect to Trademarks shall be subject to the maintenance of quality standards with respect to the goods and services on which such Trademarks are used sufficient to preserve the validity of such Trademarks; (B) that such licenses granted with regard to trade secrets shall be subject to the requirement that the secret status of trade secrets be maintained and reasonable steps are taken to ensure that they are maintained; and (C) that the Collateral Agent shall have no greater rights than those of any such Grantor under such license or sublicense and (ii) an irrevocable license (without payment of rent or other compensation to such Grantor) to use, operate and occupy all real property owned by such Grantor.

Section 6.2. Accounts and Payments in Respect of General Intangibles.

(a) In addition to, and not in substitution for, any similar requirement in the Loan Agreement, if required by the Collateral Agent at any time during the continuance of an Event of Default, any payment of accounts or payment in respect of general intangibles relating to the Collateral, when collected by any Grantor, shall be promptly (and, in any event, within two (2) Business Days of such collection) deposited by such Grantor in the exact form received, duly indorsed by such Grantor to the Collateral Agent for the benefit of Lenders and the other Secured Parties, in a Collateral Account, subject to withdrawal by the Collateral Agent as provided in Section 6.4. Until so turned over, such payment shall be held by such Grantor in trust for the Collateral Agent for the benefit of Lenders and the other Secured Parties, segregated from other funds of such Grantor. Each such deposit of proceeds of accounts and payments in respect of general intangibles relating to the Collateral shall, upon the Collateral Agent's request, be accompanied by a report identifying in reasonable detail the nature and source of the payments included in the deposit.

(b) At any time during the continuance of an Event of Default:

(i) each Grantor shall, upon the Collateral Agent's request, assemble and hold for the benefit of Lenders and the other Secured Parties all original and other documents evidencing, and relating to, the contractual obligations and transactions that gave rise to any account or any payment in respect of general intangibles included in or otherwise relating to the Collateral, including all IP Licenses, original orders, invoices and shipping receipts and notify account debtors that the accounts or general intangibles have been collaterally assigned to the Collateral Agent for the benefit of Lenders and the other Secured Parties and that payments in respect thereof shall be made directly to the Collateral Agent for the benefit of Lenders and the other Secured Parties or to any Lender on behalf of itself and the other Secured Parties, as the Collateral Agent shall direct; and

(ii) each Grantor shall take all actions, deliver all documents and provide all information necessary or reasonably requested by the Collateral Agent to ensure any Internet Domain Name included in or otherwise relating to the Collateral is registered.

(c) Anything herein to the contrary notwithstanding, each Grantor shall remain liable under each account and each payment in respect of general intangibles included in the Collateral to observe and perform all the conditions and obligations to be observed and performed by it thereunder, all in accordance with the terms of any agreement giving rise thereto. Neither the Collateral Agent nor any Lender or other Secured Party shall have any obligation or liability under any agreement giving rise to an account or a payment in respect of a general intangible included in the Collateral by reason of or arising out of any Loan Document or the receipt by the Collateral Agent or any Lender or other Secured Party of any payment relating thereto, nor shall the Collateral Agent nor any Lender or other Secured Party be obligated in any manner to perform any obligation of any Grantor under or pursuant to any agreement giving rise to an account or a payment in respect of a general intangible included in the Collateral, to make any payment, to make any inquiry as to the nature or the sufficiency of any payment received by it or as to the sufficiency of any performance by any party thereunder, to present or file any claim, to take any action to enforce any performance or to collect the payment of any amounts that may have been assigned to it or to which it may be entitled at any time or times.

Section 6.3. Pledged Collateral.

(a) Voting Rights. During the continuance of an Event of Default, upon concurrent, written notice by the Collateral Agent to the relevant Grantor or Grantors, all rights of each Grantor to exercise or refrain from exercising the voting and other consensual rights which it would otherwise be entitled to exercise pursuant hereto shall cease and all such rights shall thereupon become vested in the Collateral Agent or a nominee on behalf of Lenders or the other Secured Parties, who shall thereupon have the sole right to exercise such voting and other consensual rights, including (i) the right to exercise any voting, consent, corporate and other right pertaining to the Pledged Collateral at any meeting of shareholders, partners or members, as the case may be, of the relevant issuer or issuers of Pledged Collateral or otherwise, and (ii) any right of conversion, exchange and subscription and any other right, privilege or option pertaining to the Pledged Collateral as if it were the absolute owner thereof (including the right to exchange at its discretion any Pledged Collateral upon the merger, amalgamation, consolidation, reorganization, recapitalization or other fundamental change in the corporate or equivalent structure of any issuer of

Pledged Collateral, the right to deposit and deliver any Pledged Collateral with any committee, depositary, transfer agent, registrar or other designated agency upon such terms and conditions as the Collateral Agent (or such nominee) on behalf of Lenders or the other Secured Parties may determine), all without liability except to account for property actually received by it; provided, however, that the Collateral Agent (or such nominee) shall have no duty to any Grantor to exercise any such right, privilege or option and shall not be responsible for any failure to do so or delay in so doing.

(b) Proxies. During the continuance of an Event of Default, in order to permit the Collateral Agent on behalf of Lenders and the other Secured Parties to exercise the voting and other consensual rights that it may be entitled to exercise pursuant hereto and to receive all dividends and other distributions that it may be entitled to receive hereunder, (i) each Grantor shall promptly execute and deliver (or cause to be executed and delivered) to the Collateral Agent all such proxies, dividend payment orders and other instruments as the Collateral Agent may from time to time reasonably request and (ii) without limiting the effect of clause (i) above, such Grantor hereby grants to the Collateral Agent for the benefit of Lenders and the other Secured Parties an irrevocable proxy to vote all or any part of the Pledged Collateral and to exercise all other rights, powers, privileges and remedies to which a holder of the Pledged Collateral would be entitled (including giving or withholding written consents of shareholders, partners or members, as the case may be, calling special meetings of shareholders, partners or members, as the case may be, and voting at such meetings), which proxy shall be effective, automatically and without the necessity of any action (including any transfer of any Pledged Collateral on the record books of the issuer thereof) by any other Person (including the issuer of such Pledged Collateral or any officer or agent thereof) during the continuance of an Event of Default and which proxy shall only terminate upon (A) the cure of any and all Events of Default or (B) the indefeasible payment in full of the Secured Obligations (other than contingent indemnification obligations to the extent no claim giving rise thereto has been asserted).

(c) Authorization of Issuers. Each Grantor hereby expressly and irrevocably authorizes and instructs, without any further instructions from such Grantor, each issuer of any Pledged Collateral pledged hereunder by such Grantor to, and each Grantor that is an issuer of Pledged Collateral so pledged hereunder hereby agrees to (i) comply with any instruction received by it from the Collateral Agent in writing that states that an Event of Default is continuing and is otherwise in accordance with the terms of this Agreement and each Grantor agrees that such issuer shall be fully protected from liabilities to such Grantor in so complying, and (ii) during the continuance of such Event of Default, unless otherwise permitted hereby or by the Loan Agreement, pay any dividend or make any other payment with respect to the Pledged Collateral directly to the Collateral Agent for the benefit of Lenders and the other Secured Parties or to any Lender on behalf of itself and the other Secured Parties, as the Collateral Agent shall direct.

Section 6.4. Proceeds to be Turned over to and Held by Collateral Agent. Unless otherwise expressly provided in the Loan Agreement or this Agreement, during the continuance of an Event of Default and, upon written notice by the Collateral Agent to the relevant Grantor or Grantors, all proceeds of any Collateral received by any Grantor hereunder in cash or Cash Equivalents shall be held by such Grantor in trust for Lenders and the other Secured Parties, segregated from other funds of such Grantor, and shall, promptly upon receipt by any Grantor, be turned over to the Collateral Agent for the benefit of Lenders and the other Secured Parties in the exact form received (with any necessary endorsement). All such proceeds of Collateral and any other proceeds of any Collateral received by the Collateral Agent in cash or Cash Equivalents shall be held by the Collateral Agent for the benefit of itself and the other Secured Parties in a Collateral Account. All proceeds being held by the Collateral Agent in a Collateral Account (or by such Grantor in trust for Lenders and the other Secured Parties) shall continue to be held as collateral security for the Secured Obligations and shall not constitute payment thereof until applied as provided in the Loan Agreement.

Section 6.5. Sale of Pledged Collateral.

(a) Each Grantor recognizes that the Collateral Agent may be unable to effect a public sale of any Pledged Collateral by reason of certain prohibitions contained in the Securities Act and applicable state or foreign securities laws or otherwise or may determine that a public sale is impracticable, not desirable or not commercially reasonable and, accordingly, may resort to one or more private sales thereof to a restricted group of purchasers that shall be obliged to agree, among other things, to acquire such securities for their own account for investment and not with a view to the distribution or resale thereof. Each Grantor acknowledges and agrees that any such private sale may result in prices and other terms less favorable than if such sale were a public sale and, notwithstanding such circumstances, agrees that any such private sale shall be deemed to have been made in a commercially reasonable manner. The Collateral Agent shall be under no obligation to delay a sale of any Pledged Collateral for the period of time necessary to permit the issuer thereof to register such securities for public sale under the Securities Act or under applicable state securities laws even if such issuer would agree to do so.

(b) Each Grantor agrees to use commercially reasonable efforts to do or cause to be done all such other acts as may be reasonably necessary to make such sale or sales of any portion of the Pledged Collateral pursuant to Section 6.1 and this Section 6.5 valid and binding and in compliance with all applicable Requirements of Law. Each Grantor further agrees that a breach of any covenant contained herein will cause irreparable injury to the Collateral Agent, Lenders and the other Secured Parties, that the Collateral Agent, Lenders and the other Secured Parties have no adequate remedy at law in respect of such breach and, as a consequence, that each and every covenant contained herein shall be specifically enforceable against such Grantor, and such Grantor hereby waives and agrees not to assert any defense against an action for specific performance of such covenants except for a defense that no Event of Default has occurred and is continuing under the Loan Agreement or a defense of indefeasible payment in full of the Guaranteed Obligations (other than inchoate indemnity obligations). Each Grantor waives any and all rights of contribution or subrogation upon the sale or disposition of all or any portion of the Pledged Collateral by the Collateral Agent on behalf of Lenders and the other Secured Parties.

Section 6.6. Deficiency. Each Grantor shall remain liable for any deficiency if the proceeds of any sale or other disposition of any Collateral are insufficient to pay the Secured Obligations and the reasonable and documented fees and disbursements of any attorney employed by the Collateral Agent or any Lender to collect such deficiency.

Section 6.7. Collateral Accounts. If any Event of Default shall have occurred and be continuing, the Collateral Agent may apply the balance from any Collateral Account of a Grantor or instruct the bank at which any Collateral Account is maintained to pay the balance of any Collateral Account to the Collateral Agent for the benefit of Lenders and the other Secured Parties or to any Lender on behalf of itself and the other Secured Parties, as the Collateral Agent shall direct, to be applied to the Secured Obligations in accordance with the terms hereof.

Section 6.8. Directions, Notices or Instructions. Neither the Collateral Agent nor any Lender or any Related Party thereof or any other Secured Party shall take any action under or issue any directions, notice or instructions pursuant to any Control Agreement or similar agreement unless an Event of Default has occurred and is continuing.

ARTICLE VII

ADDITIONAL RIGHTS OF COLLATERAL AGENT

Section 7.1. Collateral Agent's Appointment as Attorney-in-Fact.

(a) Each Grantor hereby irrevocably constitutes and appoints the Collateral Agent and any Related Party thereof, with full power of substitution, as its true and lawful attorney-in-fact with full irrevocable power and authority in the place and stead of such Grantor and in the name of such Grantor or in its own name, for the purpose of carrying out the terms of the Loan Documents, to take any appropriate action and to execute any document or instrument that may be necessary or desirable to accomplish the purposes of the Loan Documents, in each case during the continuance of an Event of Default, and, without limiting the generality of the foregoing, each Grantor hereby gives the Collateral Agent and its Related Party the power and right, on behalf of such Grantor, without notice to or assent by such Grantor, to do any of the following when an Event of Default shall be continuing:

(i) in the name of such Grantor, in its own name or otherwise, take possession of and indorse and collect any check, draft, note, acceptance or other instrument for the payment of moneys due under any account or general intangible or with respect to any other Collateral and file any claim or take any other action or proceeding in any court of law or equity or otherwise deemed appropriate by the Collateral Agent for the purpose of collecting any such moneys due under any account or general intangible or with respect to any other Collateral whenever payable;

(ii) in the case of any Intellectual Property (including any IP Ancillary Rights) or any IP Licenses included in the Collateral, execute, deliver and have recorded any document that the Collateral Agent may request to evidence, effect, publicize or record the Collateral Agent's security interest, in favor of and for the benefit of Lenders and the other Secured Parties, in such Intellectual Property or IP Licenses and the goodwill and general intangibles of such Grantor relating thereto or represented thereby and the Collateral Agent's (on behalf of Lenders and the other Secured Parties) rights and remedies with respect thereto;

(iii) pay or discharge taxes and Liens levied or placed on or threatened against any Collateral, effect any repair or obtain or pay any insurance called for by the terms of the Loan Agreement (including all or any part of the premiums therefor and the costs thereof);

(iv) execute, in connection with any sale provided for in Section 6.1 or 6.5, any document to effect or otherwise necessary or appropriate in relation to evidence the sale of any Collateral; or

(v) (A) direct any party liable for any payment under any Collateral to make payment of any moneys due or to become due thereunder directly to the Collateral Agent or as the Collateral Agent shall direct, (B) ask or demand for, and collect and receive payment of and receipt for, any moneys, claims and other amounts due or to become due at any time in respect of or arising out of any Collateral, (C) commence and prosecute any suit, action or proceeding at law or in equity in any court of competent jurisdiction to collect any Collateral and to enforce any other right in respect of any Collateral, (D) defend any actions, suits, proceedings, audits, claims, demands, orders or disputes brought against such Grantor with respect to any Collateral, (E) settle, compromise or adjust any such actions, suits, proceedings, audits, claims, demands, orders or disputes and, in connection therewith, give such discharges or releases as the Collateral Agent may deem appropriate, (F) assign or license any Intellectual Property included in the Collateral on such terms and conditions and in such manner as the Collateral Agent shall in its sole discretion determine, including the execution and filing of any document necessary to effectuate or record such assignment or license and (G) generally, sell, assign, license, convey, transfer or grant a Lien on, make any contractual obligation with respect to and otherwise deal with, any Collateral as fully and completely as though the Collateral Agent on behalf of Lenders and the other Secured Parties were the absolute owner thereof for all purposes and do, at the Collateral Agent's option, at any time or from time to time, all acts and things that the Collateral Agent deems necessary to protect, preserve or realize upon any Collateral and the Collateral Agent's, in favor of and for the benefit of Lenders and the other Secured Parties, security interests therein and to effect the intent of the Loan Documents, all as fully and effectively as such Grantor might do.

(vi) If any Grantor fails to perform or comply with any contractual obligation contained herein, the Collateral Agent, at its option, but without any obligation so to do, may perform or comply, or otherwise cause performance or compliance, with such contractual obligation.

(b) Without limiting the generality of Section 2.4 of the Loan Agreement, the Lender Expenses and any other reasonable and documented out-of-pocket expenses of the Collateral Agent and any Lender and other Secured Party incurred in connection with the taking of any actions pursuant to or as otherwise contemplated by this Section 7.1, together with, solely in the event any Grantor fails to pay any of the Obligations when due or upon the commencement and during the continuance of an Insolvency Proceeding of the Borrower or, at the election of the Required Lenders, upon the occurrence and during the continuance of any other Event of Default, interest thereon at the Default Rate, from the date of payment by such Person to the date reimbursed by the relevant Grantor, shall be payable by such Grantor to such Person in accordance with Section 2.4 of the Loan Agreement.

(c) Each Grantor hereby ratifies all that said attorneys shall lawfully do or cause to be done by virtue of this Section 7.1. All powers, authorizations and agencies contained in this Agreement are coupled with an interest and are irrevocable until the indefeasible payment in full of the Secured Obligations (other than inchoate indemnity obligations), this Agreement is terminated and the security interests created hereby are released.

Section 7.2. Authorization to File Financing Statements. Each Grantor authorizes the Collateral Agent and its Related Party, at any time and from time to time, without notice to any Grantor, to file or record financing statements, amendments thereto, and other filing or recording documents or instruments with respect to any Collateral in such form, in such jurisdictions and in such offices as the Collateral Agent reasonably determines appropriate to perfect or protect the security interests of the Collateral Agent, in favor of and for the benefit of Lenders and the other Secured Parties, under this Agreement or any other Loan Document (and the Collateral Agent's and each Lender's and each other Secured Party's rights in respect thereof), and such financing statements and amendments may describe the Collateral covered thereby as "all assets of the debtor" or words of similar effect and may include a notice that any disposition of the Collateral, by any Grantor or other Person, shall be deemed to violate the rights of the Collateral Agent and Lenders and other Secured Parties under the Code to the extent not permitted under this Agreement or any other Loan Document. A photographic or other reproduction of this Agreement shall be sufficient as a financing statement or other filing or recording document or instrument for filing or recording in any jurisdiction. Such Grantor also hereby ratifies its authorization for the Collateral Agent to have filed any initial financing statement or amendment thereto under the Code (or other similar laws) in effect in any jurisdiction if filed prior to the date hereof.

Section 7.3. Authority of Collateral Agent. Each Grantor acknowledges that, as between the Collateral Agent and the Grantors, the Collateral Agent shall be conclusively presumed to be acting as agent for each Lender and all of the other Secured Parties with full and valid authority so to act or refrain from acting, and no Grantor shall be under any obligation or entitlement to make any inquiry respecting such authority.

Section 7.4. Duty; Obligations and Liabilities.

(a) Duty of Collateral Agent. The Collateral Agent's sole duty with respect to the custody, safekeeping and physical preservation of the Collateral in its possession shall be to deal with it in the same manner as it deals with similar property for its own account. The powers conferred on the Collateral Agent hereunder are solely to protect each Lender's and the other Secured Parties' interest in the Collateral and shall not impose any duty upon the Collateral Agent to exercise any such powers. The Collateral Agent shall be accountable only for amounts that it receives as a result of the exercise of such powers, and neither it nor any of its Related Parties shall be responsible to any Grantor for any act or failure to act hereunder, except for its or their own gross negligence, bad faith or willful misconduct as finally determined by a court of competent jurisdiction. In addition, the Collateral Agent shall not be liable or responsible for any loss or damage to any Collateral, or for any diminution in the value thereof, by reason of the act or omission of any warehousemen, carrier, forwarding agency, consignee or other bailee if such Person has been selected by the Collateral Agent in good faith.

(b) Obligations and Liabilities with respect to Collateral. Neither the Collateral Agent nor Lenders or any other Secured Parties nor any of their respective Related Parties shall be liable for failure to demand, collect or realize upon any Collateral or for any delay in doing so or shall be under any obligation to sell or otherwise dispose of any Collateral upon the request of any Grantor or any other Person or to take any other action whatsoever with regard to any Collateral.

ARTICLE VIII

MISCELLANEOUS

Section 8.1. Reinstatement. Each Grantor agrees that, if any payment made by any Credit Party or other Person and applied to the Secured Obligations is at any time annulled, avoided, set aside, rescinded, invalidated, declared to be fraudulent or preferential or otherwise required to be refunded or repaid, or the proceeds of any Collateral are required to be returned by any Secured Party to such Credit Party, its estate, trustee, receiver or any other party, including any Grantor, under any bankruptcy law, state or federal law, common law or equitable cause, then, to the extent of such payment or repayment, any Lien or other Collateral securing such liability shall be and remain in full force and effect, as fully as if such payment had never been made. If, prior to any of the foregoing, (a) any Lien or other Collateral securing such Grantor's liability hereunder shall have been released or terminated by virtue of the foregoing or (b) any provision of the Guaranty hereunder shall have been terminated, cancelled or surrendered, such Lien, other Collateral or provision shall be reinstated in full force and effect and such prior release, termination, cancellation or surrender shall not diminish, release, discharge, impair or otherwise affect the obligations of such Grantor in respect of any Lien or other Collateral securing such obligation or the amount of such payment.

Section 8.2. Release of Collateral and Guarantee Obligations.

(a) When all Obligations (other than unasserted inchoate indemnity obligations) have been indefeasibly paid in full, the Collateral shall be released from the Lien created hereby and this Agreement and all obligations (other than those expressly stated to survive such termination) of each Lender and any other Secured Party and each Guarantor and Grantor hereunder shall terminate, all without delivery of any instrument or performance of any act by any party (except as required hereunder), and all rights of the Collateral Agent, Lenders and any other Secured Parties to the Collateral shall revert to the Grantors.

(b) In connection with any termination or release pursuant to this Section 8.2, the Collateral Agent shall, and to the extent required, each Secured Party hereby authorizes the Collateral Agent to, promptly execute and deliver to any Grantor all instruments, documents and agreements which such Grantor shall reasonably request in writing to evidence and confirm such termination or release (including termination statements under the Code and customary payoff letters), and will duly assign, transfer and deliver to such Grantor (or its designee), such of the Collateral that may be in the possession of the Collateral Agent, all without further consent or joinder of the Collateral Agent or any Lender or other Secured Party.

(c) Any termination or release pursuant to clauses (a) and (b) of this Section 8.2 is subject to reinstatement as provided in Section 8.1.

(d) Upon any disposition of property permitted by the Loan Agreement, the Liens granted herein shall be deemed to be automatically released and such property shall automatically revert to the applicable Grantor with no further action on the part of any Person.

(e) Upon (i) any sale or disposition of property of a Grantor to a Person other than a Grantor permitted by the Loan Agreement or (ii) the consummation of any other transaction permitted by the Loan Agreement as a result of which such Grantor becomes an Excluded Subsidiary or such Grantor is released from its Guaranty, the Liens granted herein shall be deemed to be automatically released and such property shall automatically revert to the applicable Grantor (or such other applicable Person) with no further action on the part of any Person.

(f) Upon any Collateral being or becoming Excluded Property, the security interests created pursuant to this Agreement on such Collateral shall be automatically released.

(g) Upon the release of the Liens on any Collateral or of a Grantor from all of its obligations as a Credit Party under the Loan Agreement and as a Grantor hereunder, any representation, warranty or covenant contained in any Loan Document relating to any such Collateral or such Grantor, as applicable, shall no longer be deemed to be made.

(h) Without limiting the generality of Section 2.4 of the Loan Agreement, the Lender Expenses and any other reasonable and documented out-of-pocket expenses of the Collateral Agent and any Lender and other Secured Party incurred in connection with the taking of any actions pursuant to or as otherwise contemplated by this Section 8.2 in accordance with Section 2.4 of the Loan Agreement.

Section 8.3. Independent Obligations. The obligations of each Grantor hereunder are independent of and separate from the Secured Obligations and the Guaranteed Obligations. Upon any Event of Default and during the continuance thereof, the Collateral Agent for the benefit of Lenders and the other Secured Parties may, at its sole election, proceed directly and at once, without notice, against any Grantor and any Collateral to collect and recover the full amount of any Secured Obligation or Guaranteed Obligation then due, without first proceeding against any other Grantor, any other Credit Party or any other Collateral and without first joining any other Grantor or any other Credit Party in any proceeding.

Section 8.4. No Waiver by Course of Conduct. Neither the Collateral Agent nor any Secured Party shall by any act (except by a written instrument pursuant to Section 8.5), delay, indulgence, omission or otherwise be deemed to have waived any right or remedy hereunder or to have acquiesced in any Default or Event of Default. No failure to exercise, nor any delay in exercising, on the part of the Collateral Agent or any Secured Party, any right, power or privilege hereunder shall operate as a waiver thereof. No single or partial exercise of any right, power or privilege hereunder shall preclude any other or further exercise thereof or the exercise of any other right, power or privilege. A waiver by the Collateral Agent or any Secured Party of any right or remedy hereunder on any one occasion shall not be construed as a bar to any right or remedy that the Collateral Agent or any Secured Party would otherwise have on any future occasion.

Section 8.5. Amendments in Writing. None of the terms or provisions of this Agreement may be waived, amended, supplemented or otherwise modified except in accordance with Section 11.5 of the Loan Agreement; provided, however, that annexes to this Agreement may be supplemented (but no existing provisions may be modified and no Collateral may be released) through Pledge Amendments and Joinder Agreements, in substantially the form of Annex 1 and Annex 2 attached hereto, respectively, in each case, duly executed by the Collateral Agent and each Grantor directly affected thereby.

Section 8.6. Additional Grantors and Guarantors; Additional Pledged Collateral.

(a) Joinder Agreements. If, at the option of Borrower or as required pursuant to Section 5.12 or Section 5.13 of the Loan Agreement, Borrower shall cause any Subsidiary (other than an Excluded Subsidiary) that is not a Grantor or Guarantor to become a Grantor and Guarantor hereunder, such Subsidiary shall execute and deliver to the Collateral Agent a Joinder Agreement substantially in the form of Annex 2 attached hereto and shall thereafter for all purposes be a party hereto and have the same rights, benefits and obligations as a Grantor party hereto on the Tranche A Closing Date.

(b) Pledge Amendments. To the extent any Pledged Collateral has not been delivered as of the Tranche A Closing Date, such Grantor shall, promptly after such Pledged Collateral is acquired, deliver a pledge amendment duly executed by the Grantor in substantially the form of Annex 1 attached hereto (each, a "Pledge Amendment"). Such Grantor authorizes the Collateral Agent to attach each Pledge Amendment to this Agreement.

Section 8.7. Notices. All notices, requests and demands to or upon the Collateral Agent or any Grantor hereunder shall be effected in the manner provided for in Section 9 of the Loan Agreement; provided, however, that any such notice, request or demand to or upon any Grantor shall be addressed to Borrower's notice address set forth in Section 9 of the Loan Agreement.

Section 8.8. Successors and Assigns. This Agreement shall be binding upon the successors and assigns of each Grantor and shall inure to the benefit of the Collateral Agent and each Secured Party and their respective successors and assigns; provided, however, that no Grantor may assign, transfer or delegate any of its rights or obligations under this Agreement without the prior written consent of the Collateral Agent.

Section 8.9. Counterparts. This Agreement may be executed in any number of counterparts and by different parties in separate counterparts, each of which when so executed shall be deemed to be an original and all of which taken together shall constitute one and the same agreement. Signature pages may be detached from multiple separate counterparts and attached to a single counterpart. Delivery of an executed signature page of this Agreement by facsimile transmission or by electronic transmission shall be as effective as delivery of a manually executed counterpart hereof.

Section 8.10. Severability. Any provision of this Agreement being held illegal, invalid or unenforceable in any jurisdiction shall not affect any part of such provision not held illegal, invalid or unenforceable, any other provision of this Agreement or any part of such provision in any other jurisdiction.

Section 8.11. SECTION 10 OF THE LOAN AGREEMENT IS HEREBY INCORPORATED BY REFERENCE, *MUTATIS MUTANDIS*.

[Signature Pages Follow]

IN WITNESS WHEREOF, each of the undersigned has caused this Guaranty and Security Agreement to be duly executed and delivered as of the date first above written.

SAREPTA THERAPEUTICS, INC.,
as Borrower and Grantor

By /s/ Sandesh Mahatme

Name: Sandesh Mahatme

Title: Executive Vice President, Chief Financial Officer, and Chief Business Officer

ACCEPTED AND AGREED
as of the date first above written:

BIOPHARMA CREDIT PLC,
as Collateral Agent

By: Pharmakon Advisors, LP,
its Investment Manager

By: Pharmakon Management I, LLC,
its General Partner

By /s/ Pedro Gonzalez de Cosio
Name: Pedro Gonzalez de Cosio
Title: Managing Member

ANNEX 1
TO GUARANTY AND SECURITY AGREEMENT

FORM OF PLEDGE AMENDMENT

This Pledge Amendment, dated as of _____, 20__, is delivered pursuant to Section 8.6 of the Guaranty and Security Agreement, dated as of December 20, 2019, by SAREPTA THERAPEUTICS, INC., as Borrower, the undersigned Grantor and the other Persons from time to time party thereto as Grantors in favor of BIOPHARMA CREDIT PLC, as Collateral Agent on behalf of Lenders and each of the other Secured Parties (as such agreement may be amended, restated, supplemented or otherwise modified from time to time, the "Guaranty and Security Agreement"). Capitalized terms used herein without definition are used as defined in the Guaranty and Security Agreement.

The undersigned hereby agrees that this Pledge Amendment may be attached to the Guaranty and Security Agreement and that the Pledged Collateral listed on Annex 1-A to this Pledge Amendment shall be and become part of the Collateral referred to in the Guaranty and Security Agreement and shall secure all Secured Obligations of the undersigned.

[GRANTOR]

By: _____
Name:
Title:

PLEDGED STOCK

ISSUER	CLASS	CERTIFICATE NO(S).	PAR VALUE	NUMBER OF SHARES, UNITS OR INTERESTS

PLEDGED DEBT INSTRUMENTS

COMMERCIAL TORT CLAIMS

ACKNOWLEDGED AND AGREED
as of the date first above written:

BIOPHARMA CREDIT PLC,
as Collateral Agent

By: Pharmakon Advisors, LP,
its Investment Manager

By: Pharmakon Management I, LLC,
its General Partner

By _____
Name: Pedro Gonzalez de Cosio
Title: Managing Member

ANNEX 2
TO
GUARANTY AND SECURITY AGREEMENT

FORM OF JOINDER AGREEMENT

This JOINDER AGREEMENT, dated as of _____ __, 20__, is delivered pursuant to Section 8.6 of the Guaranty and Security Agreement, dated as of December 20, 2019, by and among SAREPTA THERAPEUTICS, INC. ("Borrower") and the other Persons from time to time party thereto as Grantors, in favor of BIOPHARMA CREDIT PLC (together with its successors and permitted assigns, the "Collateral Agent") on behalf of Lenders and each of the other Secured Parties, (as such agreement may be amended, restated, supplemented or otherwise modified from time to time, the "Guaranty and Security Agreement"). Capitalized terms used herein without definition are used as defined in the Guaranty and Security Agreement.

By executing and delivering this Joinder Agreement, the undersigned, as provided in Section 8.6 of the Guaranty and Security Agreement, (a) hereby becomes a party to the Guaranty and Security Agreement as a "Grantor" and "Guarantor" thereunder with the same force and effect as if originally named as a Grantor and Guarantor therein and, without limiting the generality of the foregoing, hereby assumes all obligations and liabilities of a Grantor and a Guarantor thereunder and (b) as collateral security for the prompt and complete payment and performance when due (whether at stated maturity, by acceleration or otherwise) of the Secured Obligations of the undersigned, hereby pledges and hypothecates to the Collateral Agent for the benefit of Lenders and the other Secured Parties, and grants to the Collateral Agent for the benefit of Lenders and the other Secured Parties, a lien on and security interest in, all of its right, title and interest in, to and under the Collateral of the undersigned. The undersigned hereby agrees to be bound as a Grantor and a Guarantor for the purposes of the Guaranty and Security Agreement.

In connection with this Joinder Agreement, the undersigned has delivered to the Collateral Agent a completed Perfection Certificate duly executed by the undersigned. The information set forth in Annex 1-A[1] is hereby added to the information set forth in Schedules 1, 2 and 4 to the Security Disclosure Letter. By acknowledging and agreeing to this Joinder Agreement, the undersigned hereby agrees that this Joinder Agreement may be attached to the Guaranty and Security Agreement, the Perfection Certificate delivered herewith by the undersigned shall constitute a "Perfection Certificate" referred to in Section 4.6 of the Loan Agreement and that the Pledged Collateral listed on Annex 1-A to this Joinder Agreement shall be and become part of the Collateral referred to in the Guaranty and Security Agreement and shall secure all Secured Obligations of the undersigned.

The undersigned hereby represents and warrants that each of the representations and warranties contained in Article IV of the Guaranty and Security Agreement applicable to it is true and correct on and as the date hereof as if made on and as of such date.

In witness whereof, the undersigned has caused this Joinder Agreement to be duly executed and delivered as of the date first above written.

[Additional Grantor]

By: _____
Name:
Title:

[1] Use same Annex 1-A as is attached in Annex 1 to the Guaranty and Security Agreement.

ACKNOWLEDGED AND AGREED
as of the date first above written:

BIOPHARMA CREDIT PLC,
as Collateral Agent

By: Pharmakon Advisors, LP,
its Investment Manager

By: Pharmakon Management I, LLC,
its General Partner

By _____
Name: Pedro Gonzalez de Cosio
Title: Managing Member

ANNEX 3
TO
GUARANTY AND SECURITY AGREEMENT

FORM OF INTELLECTUAL PROPERTY SECURITY AGREEMENT

THIS [COPYRIGHT] [PATENT] [TRADEMARK] SECURITY AGREEMENT, dated as of _____, 20__, is made by _____ ("Grantor"), in favor of BIOPHARMA CREDIT PLC (together with its successors and permitted assigns, the "Collateral Agent") on behalf of Lenders and the other Secured Parties (as defined in the Loan Agreement referred to below).

W I T N E S S E T H:

WHEREAS, pursuant to the Loan Agreement, dated as of December 13, 2019 (as the same may be amended, amended and restated, supplemented or otherwise modified from time to time, the "Loan Agreement"), by and among SAREPTA THERAPEUTICS, INC. ("Borrower"), certain Guarantors, BIOPHARMA CREDIT PLC (as the "Collateral Agent" and a "Lender"), and BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP (as a "Lender"), each Lender has agreed to make extensions of credit to Borrower upon the terms and subject to the conditions set forth therein;

WHEREAS, Grantor [(other than Borrower)] has agreed, pursuant to a Guaranty and Security Agreement dated as of December 20, 2019 in favor of the Collateral Agent for the benefit of Lenders and the other Secured Parties (as such agreement may be amended, amended and restated, supplemented or otherwise modified from time to time, the "Guaranty and Security Agreement"), to guarantee the Obligations (as defined in the Loan Agreement) of Borrower; and

WHEREAS, Grantor is party to the Guaranty and Security Agreement pursuant to which Grantor is required to execute and deliver this [Copyright] [Patent] [Trademark] Security Agreement;

NOW, THEREFORE, in consideration of the mutual covenants, terms and conditions set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree, intending to be legally bound, as follows:

Section 1. Defined Terms. Capitalized terms used herein without definition are used as defined in the Guaranty and Security Agreement.

Section 2. Grant of Security Interest in [Copyright] [Trademark] [Patent] Collateral. Grantor, as collateral security for the prompt and complete payment and performance when due (whether at stated maturity, by acceleration or otherwise) of the Secured Obligations, hereby mortgages, pledges and hypothecates to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, and grants to the Collateral Agent, for the benefit of Lenders and the other Secured Parties, a Lien on and security interest in, all of its right, title and interest in, to and under the following Collateral of Grantor, in each case, solely to the extent constituting Collateral (and excluding any Excluded Property) (the "[Copyright] [Patent] [Trademark] Collateral"):

a) [any and all of its Copyrights and all IP Licenses (including, without limitation, any IP Licenses under the Current Company IP Agreements to which Grantor is a party and the rights of Grantor thereunder, and all of Grantor's right, title and interest in, to and under any Internet Domain Names and Software) and IP Ancillary Rights providing for the grant by or to Grantor of any right under any Copyright, including, without limitation, those referred to on Schedule 1 hereto;

b) all renewals, reversions and extensions of the foregoing; and

c) all income, royalties, proceeds and liabilities at any time due or payable or asserted under and with respect to any of the foregoing, including, without limitation, all rights to sue and recover at law or in equity for any past, present and future infringement, misappropriation, dilution, violation or other impairment thereof.]

a) [all of its Patents and all IP Licenses (including, without limitation, any IP Licenses under the Current Company IP Agreements to which Grantor is a party and the rights of Grantor thereunder, and all of Grantor's right, title and interest in, to and under any Internet Domain Names and Software) and IP Ancillary Rights providing for the grant by or to Grantor of any right under any Patent, including, without limitation, those referred to on Schedule 1 hereto;

b) all reissues, reexaminations, continuations, continuations-in-part, divisionals, substitutes, renewals and extensions of the foregoing; and

c) all income, royalties, proceeds and liabilities at any time due or payable or asserted under and with respect to any of the foregoing, including, without limitation, all rights to sue and recover at law or in equity for any past, present and future infringement, misappropriation, dilution, violation or other impairment thereof.]

or

a) [all of its Trademarks and all IP Licenses (including, without limitation, any IP Licenses under the Current Company IP Agreements to which Grantor is a party and the rights of Grantor thereunder, and all of Grantor's right, title and interest in, to and under any Internet Domain Names and Software) and IP Ancillary Rights providing for the grant by or to Grantor of any right under any Trademark, including, without limitation, those referred to on Schedule 1 hereto, but excluding any "intent to use" Trademark applications for which a statement of use has not been filed (but only excluding such applications until such statement is filed);

b) all renewals and extensions of the foregoing;

c) all goodwill of the business connected with the use of, and symbolized by, each such Trademark; and

d) all income, royalties, proceeds and liabilities at any time due or payable or asserted under and with respect to any of the foregoing, including, without limitation, all rights to sue and recover at law or in equity for any past, present and future infringement, misappropriation, dilution, violation or other impairment thereof.]

Section 3. Guaranty and Security Agreement. The security interest granted pursuant to this [Copyright] [Patent] [Trademark] Security Agreement is granted in conjunction with the security interest granted to the Collateral Agent for the benefit of Lenders and the other Secured Parties, pursuant to the Guaranty and Security Agreement and Grantor hereby acknowledges and agrees that the obligations, rights and remedies of Grantor and of the Collateral Agent on behalf of Lenders and the other Secured Parties with respect to the security interest in the [Copyright] [Patent] [Trademark] Collateral made and granted hereby are more fully set forth in the Guaranty and Security Agreement, the terms and provisions of which are incorporated by reference herein as if fully set forth herein.

Section 4. Grantor Remains Liable. Grantor hereby agrees that, anything herein to the contrary notwithstanding, Grantor shall assume full and complete responsibility for the prosecution, defense, enforcement or any other reasonably necessary actions in connection with their [Copyrights] [Patents] [Trademarks] and IP Licenses subject to a security interest hereunder.

Section 5. Termination. This [Copyright] [Patent] [Trademark] Security Agreement shall terminate and the Lien on the security interest in the [Copyright] [Patent] [Trademark] Collateral shall be released upon the payment and performance of the Secured Obligations (other than inchoate indemnity obligations). Upon the termination of this [Copyright] [Patent] [Trademark] Security Agreement, the Collateral Agent shall execute all documents, make all filings, and take all other actions reasonably requested by the Grantor to evidence and record the release of the Lien on and security interests in the [Copyright] [Patent] [Trademark] Collateral granted herein.

Section 6. Counterparts. This [Copyright] [Patent] [Trademark] Security Agreement may be executed in any number of counterparts and by different parties in separate counterparts, each of which when so executed shall be deemed to be an original and all of which taken together shall constitute one and the same agreement. Signature pages may be detached from multiple separate counterparts and attached to a single counterpart. Delivery of an executed signature page of this [Copyright] [Patent] [Trademark] Security Agreement by facsimile or electronic transmission shall be as effective as delivery of a manually executed counterpart hereof.

Section 7. Governing Law. This [Copyright] [Patent] [Trademark] Security Agreement and the rights and obligations of the parties hereto shall be governed by, and construed and interpreted in accordance with, the law of the State of New York without regard to any principle of conflicts of law that could require the application of the law of any other jurisdiction.

IN WITNESS WHEREOF, Grantor has caused this [Copyright] [Patent] [Trademark] Security Agreement to be executed and delivered by its duly authorized officer as of the date first set forth above.

Very truly yours,
[GRANTOR]
as Grantor

By: _____
Name:
Title:

ACCEPTED AND AGREED
as of the date first above written:

BIOPHARMA CREDIT PLC,
as Collateral Agent

By: Pharmakon Advisors, LP,
its Investment Manager

By: Pharmakon Management I, LLC,
its General Partner

By _____
Name: Pedro Gonzalez de Cosio
Title: Managing Member

ANNEX 4
TO
GUARANTY AND SECURITY AGREEMENT
FORM OF UNCERTIFICATED STOCK CONTROL AGREEMENT

This UNCERTIFICATED STOCK CONTROL AGREEMENT (this "**Agreement**"), dated as of _____ __, 20__, is made by and among [APPLICABLE GRANTOR], a [JURISDICTION OF ORGANIZATION] [ENTITY TYPE] (the "**Grantor**"), BIOPHARMA CREDIT PLC, a public limited company organized under the laws of England and Wales, as collateral agent on behalf of the Secured Parties (the "**Collateral Agent**"), and [APPLICABLE INTEREST ISSUING COMPANY], a [JURISDICTION OF ORGANIZATION] [ENTITY TYPE] (the "**Issuer**"). All capitalized terms used but not otherwise defined herein shall have the meanings assigned to such terms in the Security Agreement (as defined below) or the Loan Agreement (as defined below), as applicable.

WHEREAS, SAREPTA THERAPEUTICS, INC., a Delaware corporation (as "**Borrower**"), certain Guarantors, the Collateral Agent and the Lenders have entered into that certain Loan Agreement, dated as of December 13, 2019 (as may be amended, restated, supplemented or otherwise modified from time to time, the "**Loan Agreement**");

WHEREAS, the Grantor is the registered holder of [DESCRIBE PLEDGED UNCERTIFICATED STOCK] issued by the Issuer (the "**Pledged Stock**");

WHEREAS, pursuant to the Guaranty and Security Agreement, dated as of December 20, 2019, by and among the Grantor, the Collateral Agent and the other parties thereto (as amended, amended and restated, supplemented or otherwise modified from time to time, the "**Security Agreement**"), the Grantor has granted a continuing Lien on and security interest (the "**Security Interest**") in, all of its right, title and interest in, to and under the Pledged Stock (other than Excluded Equity Interests), whether now existing or hereafter arising or acquired; and

WHEREAS, it is a condition precedent to the making of the Tranche A Loans and maintaining of the Term Loans by Lenders under the Loan Agreement that the parties hereto execute and deliver this Agreement in order to perfect a first priority Security Interest in the Pledged Stock.

NOW, THEREFORE, in consideration of the mutual covenants, terms and conditions set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree, intending to be legally bound, as follows:

1. The Issuer confirms that:

(a) The Pledged Stock is Equity Interests that are not represented by certificates;

(b) The Issuer is the issuer of the Pledged Stock and the Grantor is registered on the books and records of the Issuer as the registered holder of the Pledged Stock; and

(c) The Security Interest in the Pledged Stock is registered on the books and records of the Issuer.

2. The Grantor hereby irrevocably agrees that, for so long as this Agreement remains in effect, the Collateral Agent, for the benefit of Lenders and the other Secured Parties, shall have exclusive control of the Pledged Stock. In furtherance of such agreement, the Grantor hereby irrevocably authorizes and directs the Issuer, and the Issuer hereby agrees:

(d) Subject to the provisions of Section 3 hereof, to comply with any and all written instructions delivered to the Issuer which directs that the transfer of any or all of the Pledged Stock to the Collateral Agent be registered on the books and records of the Issuer in the name of the Collateral Agent as the holder thereof, for the benefit of Lenders and the other Secured Parties, without further consent by the Grantor or any other Person; and

(e) Subject to the provisions of Section 3 hereof, not to comply with any instructions relating to any or all of the Pledged Stock originated by any Person other than the Collateral Agent, on behalf of Lenders and the other Secured Parties, or a court of competent jurisdiction. In the event of any conflict between any instruction originated by the Collateral Agent and any instruction originated by any other Person, the Issuer shall comply only with the instruction originated by the Collateral Agent.

3. In addition to, and not in lieu of, the obligation of the Issuer to honor instructions as agreed in Section 2 hereof, the Issuer and the Collateral Agent hereby agree as follows:

(f) Subject to the rights of the Grantor described herein, the Issuer agrees that, from and after the date hereof, the Pledged Stock shall be under the exclusive dominion and control of the Collateral Agent;

(g) So long as the Issuer has not received a written notice from the Collateral Agent that it is exercising exclusive control over the Pledged Stock (a "**Notice of Exclusive Control**"), the Issuer may comply with instructions of the Grantor concerning the Pledged Stock, which Notice of Exclusive Control shall only be given by the Collateral Agent following the occurrence and during the continuance of an Event of Default. After the Issuer receives a Notice of Exclusive Control from the Collateral Agent, the Issuer will not accept any instructions concerning the Pledged Stock from any Person other than the Collateral Agent, unless otherwise ordered by a court of competent jurisdiction; and

(h) Until the Issuer receives a Notice of Exclusive Control, the Grantor shall be entitled to direct the Issuer with respect to voting the Pledged Stock.

4. This Agreement shall not subject the Issuer to any obligation or liability except as expressly set forth herein and under any Requirements of Law. In particular, the Issuer need not investigate whether the Collateral Agent is entitled under the Security Agreement or otherwise to give an instruction or Notice of Exclusive Control.

5. The Issuer hereby represents, warrants and covenants with the Collateral Agent that:

(i) This Agreement has been duly authorized, executed and delivered by the Issuer and constitutes a legal, valid and binding obligation of the Issuer enforceable in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium or other similar laws affecting creditors' rights generally and subject to equitable principles (regardless of whether enforcement is sought in equity or at law);

(j) The Issuer has not entered into, and until termination of this Agreement will not enter into, any agreement with any other Person relating to the Pledged Stock pursuant to which it has agreed, or will agree, to comply with instructions provided by such Person in a circumstance which would conflict with the instructions of the Collateral Agent. The Issuer has not entered into any other agreement with the Grantor purporting to limit or condition the obligation of the Issuer to comply with instructions as agreed in Section 3 hereof;

(k) Except for the claims and interests of the Collateral Agent, on behalf of Lenders and the other Secured Parties, and the Grantor in the Pledged Stock, the Issuer does not know of any claim to, or interest in, the Pledged Stock (except to the extent constituting Permitted Liens). If any Person asserts any Lien or adverse claim (including any writ, garnishment, judgment, attachment, execution or similar process) against the Pledged Stock (other than Permitted Liens), the Issuer will promptly notify the Collateral Agent and the Grantor thereof;

(l) In the event of any conflict between this Agreement (or any portion hereof) and any between the Issuer and the Grantor or among the Issuer, the Grantor and any third Person with respect to the Pledged Stock, whether now existing or hereafter entered into, the terms of this Agreement shall prevail; and

(m) The granting by the Grantor of the Security Interest in the Pledged Stock to the Collateral Agent for the benefit of Lenders and the other Secured Parties does not violate the Operating Documents or any other agreement governing the Issuer or the Pledged Stock.

6. This Agreement shall be binding upon, and shall inure to the benefit of, the parties hereto and their respective successors and assigns.

7. Each notice, request or other communication to a party hereto under this Agreement shall be in writing, will be sent to such party's address set forth under its name below or to such other address as such party may notify the other parties hereto and will be effective on receipt.

8. No amendment or modification of this Agreement or waiver of any right hereunder shall be binding on any party hereto unless it is in writing and is signed by all the parties hereto.

9. The rights and powers granted herein to the Collateral Agent (a) have been granted in order to perfect the Security Interest in the Pledged Stock, (b) are powers coupled with an interest and (c) will not be affected by any bankruptcy of the Grantor or any lapse in time. The obligations of the Issuer hereunder shall continue in effect until the Collateral Agent has notified the Issuer in writing that the Security Interest in the Pledged Stock has been terminated pursuant to the Security Agreement.

10. This Agreement shall be governed by and construed in accordance with the laws of the [ISSUER'S JURISDICTION OF ORGANIZATION].

11. If any term or provision of this Agreement is invalid, illegal or unenforceable in any jurisdiction, such invalidity, illegality or unenforceability shall not affect any other term or provision of this Agreement or invalidate or render unenforceable such term or provision in any other jurisdiction.

12. This Agreement may be executed in any number of counterparts and by different parties in separate counterparts, each of which when so executed shall be deemed to be an original and all of which taken together shall constitute one and the same agreement. Signature pages may be detached from multiple separate counterparts and attached to a single counterpart. Delivery of an executed signature page of this Agreement by facsimile transmission or by electronic transmission shall be as effective as delivery of a manually executed counterpart hereof.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first written above.

[GRANTOR]
By: _____
Name: _____
Title: _____

Address for Notices:

[ISSUER]
By: _____
Name: _____
Title: _____

Address for Notices:

Sarepta Therapeutics, Inc.
215 First Street, Suite 415
Cambridge, MA 02142
Attention: [**]
Telephone: [**]
Email: [**]

Sarepta Therapeutics, Inc.
215 First Street, Suite 415
Cambridge, MA 02142
Attention: [**]
Telephone: [**]
Email: [**]

Sarepta Therapeutics, Inc.
215 First Street, Suite 415
Cambridge, MA 02142
Attention: [**]
Telephone: [**]
Email: [**]

with a copy to (which shall not constitute notice) to:

Ropes & Gray LLP
Prudential Tower, 800 Boylston Street
Boston, MA 02199-3600
Attn: [**]
Telephone: [**]
Facsimile: [**]
Email: [**]

BIOPHARMA CREDIT PLC,
a public limited company

By: Pharmakon Advisors, LP,
its Investment Manager

By: Pharmakon Management I, LLC,
its General Partner

By _____
Name: Pedro Gonzalez de Cosio
Title: Managing Member

Address for Notices:

BIOPHARMA CREDIT PLC
c/o Beaufort House
51 New North Road
Exeter EX4 4EP
United Kingdom
Attention: Company Secretary
Telephone: [**]
Facsimile: [**]

with copies (which shall not constitute notice) to:

Pharmakon Advisors LP
110 East 59th Street, #3300
New York, NY 10022
Attn: Pedro Gonzalez de Cosio
Phone: [**]
Fax: [**]
Email: [**]

and

Akin Gump Strauss Hauer & Feld LLP
One Bryant Park
New York, NY 10036-6745
Attn: [**]
Phone: [**]
Fax: [**]
Email: [**]

SAREPTA THERAPEUTICS, INC.
NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

(As adopted December 10, 2019)

Sarepta Therapeutics, Inc. (the "**Company**") believes that the granting of equity and cash compensation to its directors represents a powerful tool to attract, retain and reward directors who are not employees of the Company ("**Outside Directors**") and to align the interests of our Outside Directors with those of our stockholders. This Non-Employee Director Compensation Policy (the "**Compensation Policy**") is intended to formalize the Company's policy regarding grants of equity and cash compensation to its Outside Directors. The Compensation Committee of the Company's Board of Directors (the "**Board**") may make recommendations to the Board regarding changes to the compensation of Outside Directors and may authorize payments and make grants of equity pursuant to this Compensation Policy and to the extent permitted under any of the Company's plans, including the Company's 2018 Equity Incentive Plan or any successor plan(s) thereto (the "**Plan**"). Unless otherwise defined herein, capitalized terms used in this Compensation Policy will have the meaning given such term in the Plan. Outside Directors shall be solely responsible for any tax obligations they incur as a result of any grant of equity and cash payments, whether paid under the Plan or otherwise. This Compensation Policy supersedes and replaces the AVI BioPharma, Inc. Non-Employee Director Compensation Policy adopted September 27, 2010, and shall remain in effect until it is rescinded or replaced by further action of the Board.

1. Equity Compensation

Outside Directors will be entitled to receive all types of Awards (except Incentive Stock Options) under the Plan, including discretionary Awards not covered under this Compensation Policy. All grants of Awards to Outside Directors pursuant to Sections 1(c) and 1(d) of this Compensation Policy will be automatic and nondiscretionary, except as otherwise provided herein, and will be made in accordance with the following provisions:

(a) Type of Option; Terms of Plan. Options granted pursuant to this Compensation Policy will be Nonstatutory Stock Options (an "Option"). Except as otherwise provided herein, Awards granted pursuant to this Compensation Policy will be subject to the other terms and conditions of the Plan.

(b) No Discretion. No person will have any discretion to select which Outside Directors will be granted Awards under this Compensation Policy or to determine the number of Shares to be covered by such Awards (except as provided in Section 1(e) below and the Plan).

(c) Initial Award. The Board shall automatically grant on the date each person first becomes an Outside Director (whether through election by the stockholders of the Company or by appointment by the Board to fill a vacancy) an initial equity Award. The Board, in its sole discretion, shall determine the Award value and may divide such Award into any combination of restricted stock units ("**RSUs**"), restricted stock awards ("**RSAs**") and/or an Option to purchase shares of the Company's common stock ("**Initial Option**"); provided, however, that a director who is an employee (an "**Inside Director**") who ceases to be an Inside Director, but who remains a director, will not receive an Initial Award. Notwithstanding the foregoing, if, on the date a person joins the Board as an Outside Director, the Company is subject to a blackout period pursuant to the terms of the Company's Procedures and Guidelines Governing Insider Trading and Tipping, then the grant of the RSUs, RSAs and/or the Initial Option will be delayed until the expiration of the blackout period. The term of the Initial Option will be ten (10) years and the exercise price of the Initial Option will equal the closing sales price of the Company's common stock as reported by The NASDAQ Global Market on the date of grant. The RSUs, RSAs and/or the Initial Option shall vest pursuant to a vesting schedule established by the Board in its sole discretion and pursuant to the Plan, and provided that the Outside Director continues to serve as a director through such vesting dates.

(d) Annual Awards.

(i) The Board shall automatically grant each Outside Director in the first quarter of each year an annual equity Award. The Board, in its sole discretion, shall determine the Award value and may divide such Award into any combination of an option to purchase shares of the Company's common stock ("**Annual Option**"), RSUs and/or RSAs. The term of the Annual Option will be ten (10) years and the exercise price will be determined in accordance with the Plan on the date of the grant. The RSAs, RSUs and Annual Option shall vest pursuant to a vesting schedule established by the Board in its sole discretion and pursuant to the Plan, and provided that the Outside Director continues to serve as a director through such vesting dates.

(e) Revisions. The Board or a committee of the Board in its discretion may change and otherwise revise the terms of Awards granted under this Compensation Policy, including, without limitation, the number of Shares subject thereto, for Awards of the same or different type granted on or after the date the Board or a committee of the Board determines to make any such change or revision.

(f) Adjustments. If the Company shall at any time increase or decrease the number of its outstanding shares of stock or change in any way the rights and privileges of such shares by means of the payment of a stock dividend or any other distribution upon such shares payable in stock, or through a stock split, subdivision, consolidation, combination, reclassification or recapitalization involving the stock, then the Board or a committee of the Board in its discretion, in order to prevent diminution or enlargement of the benefits or potential benefits intended to be made available under this Compensation Policy, may adjust the number of Shares issuable pursuant to Sections 1(c) and 1(d) of this Compensation Policy and the Plan.

(g) Vesting Limitations on Awards. Notwithstanding any other provision of this Policy to the contrary, Awards shall become vested over a period of not less than one year following the date the Award is made; provided, however, that, notwithstanding the foregoing, (i) the Administrator may provide that such vesting restrictions lapse or be waived upon the Outside Director's Disability, retirement, Change in Control, or other event determined by the Board, (ii) such vesting restrictions shall lapse upon the Outside Director's death while providing services to the Company, and (iii) Awards that result in the issuance of an aggregate of up to 5% of the shares of Common Stock available pursuant to Section 3(a) of the Plan may be granted to any Outside Directors without respect to such minimum vesting provisions.

2. Cash-Based Compensation

(a) Annual Fee. The Company will pay each Outside Director an annual fee. The Board, in its sole discretion, shall determine the amount of such fee (which may be zero) (the "**Annual Fee**"). The Annual Fee will be paid to each Outside Director in four equal installments on a quarterly basis at the end of the applicable quarter provided the individual served as an Outside Director during the full quarter, with the amount prorated for any Outside Director who did not serve the full quarter.

(b) Chairperson Annual Fee. If an Outside Director is serving as the chairperson of the Board (the "**Non-Executive Chairperson**"), then, in addition to the Annual Fee, the Company will pay to the Non-Executive Chairperson an additional annual fee. The Board, in its sole discretion, shall determine the amount of such additional annual fee (which may be zero) (the "**Chairperson Fee**"). The Chairperson Fee will be paid to the Non-Executive Chairperson in four equal installments on a quarterly basis at the end of the applicable quarter provided the individual served as the Non-Executive Chairperson during the full quarter, with the amount prorated in the event the Non-Executive Chairperson did not serve in such capacity for the full quarter.

(c) Committee Chairperson Fees. The Company will pay each Outside Director who serves as chairperson of the Audit Committee, Compensation Committee, Nominating and Corporate Governance Committee or Research and Development Committee the applicable annual fee for serving as the chairperson.

The Board, in its sole discretion, shall determine the amount of such annual fee (which may be zero) (the "**Annual Chairperson Fee**"). The Annual Chairperson Fee shall be paid in four equal installments on a quarterly basis at the end of the applicable quarter provided the individual served as chairperson of the relevant committee during the full quarter, with the amount prorated for any chairperson who did not serve as the chairperson of the relevant committee for the full quarter.

(d) Committee Member Fees. The Company will pay each Outside Director who serves as a member of the Audit Committee, Compensation Committee, Nominating and Corporate Governance Committee or Research and Development Committee an annual fee for serving as a member. The Board, in its sole discretion, shall determine the amount of such annual fee (which may be zero) (the "**Annual Committee Fee**"). The Annual Committee Fee shall be paid in four equal installments on a quarterly basis at the end of the applicable quarter provided the individual served as a member of the relevant committee during the full quarter, with the amount prorated for any member who did not serve as a member of the relevant committee for the full quarter. For the avoidance of doubt, any Outside Director who serves as chairperson of a committee shall not be entitled to the Annual Committee Fee for the same committee.

(e) Revisions. The Board or a committee of the Board in its discretion may change and otherwise revise the terms of the cash compensation granted under this Compensation Policy, including, without limitation, the amount of cash compensation to be paid, on or after the date the Board or a committee of the Board determines to make any such change or revision.

(f) Section 409A. In no event shall cash compensation payable pursuant to this Compensation Policy be paid later than March 15 following the calendar year in which the applicable quarter ends (or if the individual did not serve as an Outside Director for the full quarter, then March 15 following the calendar year in which the Outside Director's service terminated with the Company), in compliance with the "short-term deferral" exception to Section 409A of the Internal Revenue Code of 1986, as amended and the regulations and guidance promulgated thereunder ("**Section 409A**"). Although the Company does not guarantee to Outside Directors the particular tax treatment of the compensation granted hereunder, the Compensation Policy is intended to provide for compensation that is exempt from, or complies with, the requirements of Section 409A so that none of the compensation to be provided hereunder shall be subject to the additional tax imposed under Section 409A, and any ambiguities herein shall be interpreted to so comply with, or otherwise be exempt from, Section 409A.

3. Compensation Limits

The aggregate value of equity-based Awards awarded to Outside Directors, solely with respect to the individual's service as a non-employee director, pursuant to the Plan plus cash-based compensation, is limited to $1,000,000 each Fiscal Year (except the limit is $1,500,000 with respect to the initial fiscal year in which the Outside Director commenced service). The limit is based on the aggregate Fair Market Value (determined as of the date of grant) of any equity-based Awards plus the aggregate value (determined as of the date of grant) of any cash-based compensation.

Effective: December 10, 2019

EXHIBIT 10.56

November 11, 2019

William Ciambrone
[**]

Dear Bill,

On behalf of Sarepta Therapeutics, Inc. ("Sarepta" or the "Company"), it is a great pleasure to extend you this offer of employment as Executive Vice President, Technical Operations in the Andover, Massachusetts, office effective on a date agreed upon following your acceptance of this offer ("Hire Date"), reporting to Douglas Ingram, President & Chief Executive Office.

Base Salary.
In this position, you will earn an annual base salary of $445,000.14 subject to applicable taxes and withholdings, which will be paid on a bi-weekly basis.

Future Salary Increases.
Your Base Salary shall be subject to annual review as part of the Annual Compensation Review process which typically takes place in the first quarter of the calendar year. Salary merit increases, if any, will be awarded at the Company's discretion on the basis of your performance. You will not be eligible for a merit increase for your performance in 2019.

Annual Bonus Program.
During your employment, you will also be eligible to participate in Sarepta's annual bonus program. The target bonus opportunity for your position is 45% of your annual base salary, with the actual amount of such bonus, if any, being determined by the Company in its sole discretion, based on your performance and that of the Company against goals established by the Board. You will not be eligible for a bonus for your performance in 2019. You must be employed through the date bonuses are disbursed to employees and have not given notice of intent to terminate in order to be eligible for the bonus. Additional details regarding Sarepta's bonus program will be provided to you upon commencing employment.

New Hire Option Grant.
On the Hire Date, as an inducement for acceptance of the terms of the offer letter, the Company plans to grant to you, subject to Compensation Committee approval, the option to purchase 80,000 shares of Company Common Stock (the "Option") pursuant to the 2014 Employment Commencement Incentive Plan, as amended (the "2014 Incentive Plan"), a copy of which will be provided to you upon you signing this offer letter.

The exercise price of the Option will equal the closing sales price of the Company's Common Stock as reported by The NASDAQ Global Market on the Hire Date. 1/4th of the shares underlying the Option will vest and become exercisable on the first anniversary of the Hire Date, and 1/48th of the shares underlying the Option will vest and become exercisable on each monthly anniversary of the Hire Date thereafter, such that the shares underlying the Option will be fully vested and exercisable on the fourth anniversary of the Hire Date, subject to your continued employment through each such vesting date. The Option will be subject to the terms and conditions under the 2014 Incentive Plan and the Company's form of Option Agreement under the 2014 Incentive Plan, a copy of which will be provided to you upon you signing this offer letter.

Annual Equity Grant Program
You may also be eligible to be considered for the Company's annual equity grant program based on your performance. Any such equity grants will be subject to the terms and conditions of the applicable equity plan and the Company's forms of award agreements. You will not be eligible to be considered for the Company's annual equity grant program based on your performance in 2019.

Benefits.
You will be eligible to participate in the benefit plans and programs made available by the Company from time to time for employees generally, subject to plan terms and generally applicable Company policies. These currently include, but are not limited to:

- health insurance such as medical, dental and vision;
- company-paid basic life insurance, accidental death and dismemberment, and short- and long-term disability;
- paid time off such as accrued vacation, sick leave and company-paid holidays;
- 401(k) retirement savings plan; and employee stock purchase plan;
- Partially subsidized onsite parking and T / Commuter Pass.

For additional details, please review the enclosed *Employees Benefits You Can Count On* document.

Background Check and Reference Check.
As a part of Sarepta's employment process, we reserve the right to conduct background checks and/or reference checks on all potential employees to the fullest extent permitted under applicable law. This offer of employment, therefore, is contingent upon your successful completion of these checks.

Employment At-Will.
This letter and your response are not intended to constitute a contract of employment for a definite term. If you accept our offer of employment, you will be an employee at-will, meaning that either you or the Company may terminate our employment relationship at any time for any reason, with or without cause and with or without advance notice. None of the benefits offered to you by the Company create a right to continue in employment for any particular period of time. The terms and conditions of your employment, including without limitation your job title, hours of work, work location, compensation, the stock option plan, and other employee benefits may change over the course of employment at the Company's sole discretion.

Proprietary Rights Agreement.
As a condition of your employment, you are required to sign a Confidential Proprietary Rights and Non-Disclosure Agreement ("CDA"). The CDA is enclosed to give you an opportunity to read it carefully prior to your Hire Date. The CDA must be signed on or before your Hire Date as a condition of employment.

We would like to emphasize the importance we place on the proper treatment of all proprietary information, including that which you may have come into contact with in your prior employment. The Company is extending this offer to you based upon your general skills and abilities, and not your possession of any trade secret, confidential or proprietary information of a former employer. The Company requires that you do not obtain, keep, use for Sarepta's benefit, or disclose this type of information from any prior employers to Sarepta. By accepting this offer, you will also be affirming to the Company that you are not a party to any agreement with a prior employer that would prohibit your employment with us.

Moreover, you agree that during the term of your employment, you will not engage in any other employment, occupation, consulting, or other business activity directly related to the business in which the Company is now involved or becomes involved during the term of your employment, nor will you engage in any other activities that conflict with your obligations to the Company.

Change in Control Agreement and Severance Agreement
You will be eligible to enter into the attached Change in Control and Severance Agreement ("CIC Agreement") and Severance Agreement, subject to Compensation Committee approval.

Eligibility for Employment.
In compliance with the United States' Citizenship and Immigration Services, Sarepta must verify your identity and eligibility for employment in the United States within 3 business days of your Hire Date. For a list of acceptable documents, please visit http://www.uscis.gov/i-9. Please bring the appropriate documents listed on that form with you when you report for work. Sarepta will not be able to employ you if you fail to comply with this requirement.

In addition, since the Company is a Federal contractor, we participate in e-Verify, an Internet-based system that allows businesses to determine the eligibility of their employees to work in the United States. For more information on this service, please visit http://www.uscis.gov/e-verify.

Acceptance.
If you wish to accept this offer of employment with Sarepta, please sign below and return one signed copy to me. This offer of employment will expire on November 15, 2019.

This offer of employment, the CDA, the CIC Agreement and the Severance Agreement constitute the entire agreement, and supersedes all prior agreements, understanding or statements concerning your employment and all related matters, including, but not limited to, any representations made during your interviews or relocation negotiations, whether written or oral. This offer of employment letter, including, but not limited to, its at-will employment provision, may not be modified or amended, and no breach is regarded as waived, except by a written agreement signed by the Company's CEO and President and you.

We are pleased to welcome you to Sarepta. If you have any questions, please do not hesitate to contact me at [**].

Sincerely,

/s/ Joan Nickerson

Joan Nickerson
Senior Vice President, Human Resources

Enclosures

AGREED TO AND ACCEPTED:
I accept the written terms in this offer of employment letter.

Signature /s/ William Ciambrone Date: 11/12/2019

EXHIBIT 10.57

November 15, 2019

William Ciambrone
[**]

Re: **Amendment to Offer Letter of November 11, 2019**

Dear Bill,

This letter amends the offer letter previously signed by you dated November 11, 2019 (the "Offer Letter") to correct the reference to the Company equity plan under which your option award will be granted. Except as specifically set forth below, all provisions of the Offer Letter will remain in full force and effect and all capitalized terms used herein not defined in this Amendment will have the meanings in the Offer Letter.

Amendment

The sections in the Offer Letter headed "New Hire Option Grant" will be replaced by the following section:

> **New Hire Option Grant**.
>
> On the Hire Date, the Company plans to grant to you, subject to Compensation Committee approval, the option to purchase 80,000 shares of Company Common Stock (the "Option") pursuant to the Company's 2018 Equity Incentive Plan (the "2018 Plan"), a copy of which will be provided to you on the Hire Date.
>
> The exercise price of the Option will equal the closing sales price of the Company's Common Stock as reported by The NASDAQ Global Market on the Hire Date. 1/4th of the shares underlying the Option will vest and become exercisable on the first anniversary of the Hire Date, and 1/48th of the shares underlying the Option will vest and become exercisable on each monthly anniversary of the Hire Date thereafter, such that the shares underlying the Option will be fully vested and exercisable on the fourth anniversary of the Hire Date, subject to your continued employment through each such vesting date. The Option will be subject to the terms and conditions under the 2018 Plan and the Company's form of Stock Option Award Agreement under the 2018 Plan, a copy of which will be provided to you on the Hire Date.

Please sign below if you agree and accept the foregoing Amendment.

Sincerely,

/s/ Joan Nickerson
Joan Nickerson
Senior Vice President, Human Resources

ACCEPTED:

I accept this Amendment.

Signature /s/ William Ciambrone Date: 11/18/19

EXHIBIT 21.1

Sarepta Therapeutics, Inc.
Subsidiaries of the Registrant

Name	Jurisdiction of Incorporation
Sarepta Securities Corp.	Massachusetts, USA
Myonexus Therapeutics, Inc.	Delaware, USA
ST International Holdings Two, Inc.	Delaware, USA
Sarepta Therapeutics Three, LLC	Delaware, USA

EXHIBIT 23.1

Consent of Independent Registered Public Accounting Firm

The Board of Directors
Sarepta Therapeutics, Inc.:

We consent to the incorporation by reference in the registration statements (Nos. 333-209709, 333-234698 and 333-2229934) on Form S-3ASR and (Nos. 333-101826, 333-172823, 333-175031, 333-192287, 333-199037, 333-209710, 333-213022, 333-34047, 333-49994, 333-49996, 333-221271, 333-228719 and 333-233715) on Form S-8 of Sarepta Therapeutics, Inc. and subsidiaries of our report dated February 26, 2020, with respect to the consolidated balance sheets of Sarepta Therapeutics, Inc. and subsidiaries as of December 31, 2019 and 2018, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2019, and the related notes (collectively, the consolidated financial statements), and the effectiveness of internal control over financial reporting as of December 31, 2019, which report appears in the December 31, 2019 annual report on Form 10-K of Sarepta Therapeutics, Inc. and subsidiaries.

Our report refers to a change in the method of accounting for leases as of January 1, 2019 due to the adoption of Accounting Standards Update (ASU) No. 2016-02, *Leases (Topic 842)*.

/s/ KPMG LLP

Cambridge, Massachusetts
February 26, 2020

EXHIBIT 31.1

CERTIFICATION

I, Douglas S. Ingram, certify that:

1. I have reviewed this Annual Report on Form 10-K of Sarepta Therapeutics, Inc., (the "Registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;

4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and

5. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

February 26, 2020

/s/ Douglas S. Ingram

Douglas S. Ingram
President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

I, Sandesh Mahatme, certify that:

1. I have reviewed this Annual Report on Form 10-K of Sarepta Therapeutics, Inc., (the "Registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;

4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and

5. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

February 26, 2020

/s/ Sandesh Mahatme
Sandesh Mahatme
Executive Vice President, Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002
(18 U.S.C. SECTION 1350)

I, Douglas S. Ingram, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of Sarepta Therapeutics, Inc. on Form 10-K for the fiscal year ended December 31, 2019, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Annual Report on Form 10-K fairly presents, in all material respects, the financial condition and results of operations of Sarepta Therapeutics, Inc.

February 26, 2020

/s/ Douglas S. Ingram
Douglas S. Ingram
President and Chief Executive Officer
(Principal Executive Officer)

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to Sarepta Therapeutics, Inc. and will be retained by Sarepta Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies this Report on Form 10-K pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by such Act, be deemed filed by Sarepta Therapeutics, Inc. for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that Sarepta Therapeutics, Inc. specifically incorporates it by reference.

EXHIBIT 32.2

CERTIFICATION PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002
(18 U.S.C. SECTION 1350)

I, Sandesh Mahatme, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of Sarepta Therapeutics, Inc. on Form 10-K for the fiscal year ended December 31, 2019, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Annual Report on Form 10-K fairly presents, in all material respects, the financial condition and results of operations of Sarepta Therapeutics, Inc.

February 26, 2020

/s/ Sandesh Mahatme
Sandesh Mahatme,
Executive Vice President, Chief Financial Officer
(Principal Financial and Accounting Officer)

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to Sarepta Therapeutics, Inc. and will be retained by Sarepta Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies this Report on Form 10-K pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by such Act, be deemed filed by Sarepta Therapeutics, Inc. for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that Sarepta Therapeutics, Inc. specifically incorporates it by reference.