



## **Sarepta Therapeutics Enters into Long-term Strategic Manufacturing Partnership with Paragon Bioservices, Greatly Enhancing its Commercial Capacity for Future Gene Therapies**

-- Partnership significantly expands commercial capacity for Sarepta's micro-dystrophin gene therapy program, as well as bolsters the Company's clinical and commercial capacity for its other pipeline programs --

CAMBRIDGE, Mass., October 08, 2018 (GLOBE NEWSWIRE) -- Sarepta Therapeutics, Inc. (NASDAQ:SRPT), a commercial-stage biopharmaceutical company focused on the discovery and development of precision genetic medicine to treat rare neuromuscular diseases, announced today that it has entered into a long-term strategic manufacturing partnership with Paragon Bioservices (Paragon), which will provide Sarepta access to additional commercial manufacturing capacity for its micro-dystrophin Duchenne muscular dystrophy (DMD) gene therapy program, as well as a manufacturing platform for future gene therapy programs, such as Limb-girdle muscular dystrophy (LGMD).

"We are rapidly building a formidable gene therapy engine, the hallmark of which will be the establishment of our *Gene Therapy Center of Excellence* in Columbus, Ohio. Therefore, it is incumbent upon us to ensure that our ambition is matched with a sophisticated, robust and scalable manufacturing approach that can accelerate a steady stream of gene therapies to treat life-robbing genetic diseases for the near and long-term," stated Doug Ingram, Sarepta's president and chief executive officer.

Mr. Ingram continued, "Consistent with our hybrid manufacturing strategy, we are proud to welcome Paragon, a preeminent global biomanufacturer with a proven track record and expertise in the complex field of biotherapeutic manufacturing, to our coalition of the world's leading gene therapy organizations. Our partnership with Paragon provides additional scalable capacity for our micro-dystrophin program and our future programs, which currently include Duchenne, LGMD, Pompe, and CNS. Our partnership also grants Sarepta access to Paragon's world-class team, some 300-plus strong, whose varied expertise we can draw upon as we continue on our path to becoming among the most meaningful genetic companies in the world."

"Paragon is one of the few gene therapy manufacturers that has the expertise to develop and successfully manufacture complex biotherapeutics using commercially-scalable processes," said Pete Buzy, Paragon Bioservices President and CEO. "As this agreement with Sarepta highlights, we have a world-class manufacturing team, we are seen as a center of excellence for gene therapy, and we are trusted by top biopharmaceutical companies."

Paragon, one of Baltimore's largest biotechnology companies, employs a team of 300+ at two locations in Maryland. Paragon is constructing a new, world-class, 151,000 square-foot, GMP gene therapy biomanufacturing facility, which will be online in February 2019 and is located in Anne Arundel County. It will include several 500L and 2000L single-use bioreactors for clinical trial and commercial material production. Paragon also has facilities at the University of Maryland, Baltimore (UMB) BioPark where the Company currently provides full process, analytical development, and cGMP clinical manufacturing services from its approximately 100,000 square-foot facility. The BioPark facility complies with both European Medicines Agency (EMA) and U.S. Food and Drug Administration (FDA) early-phase manufacturing requirements for biopharmaceutical manufacturing. The newly constructed facility is being built to comply with these regulations, as well.

#### **About Sarepta Therapeutics**

Sarepta Therapeutics is a commercial-stage biopharmaceutical company focused on the discovery and development of precision genetic medicine to treat rare neuromuscular diseases. The Company is primarily focused on rapidly advancing the development of its potentially disease-modifying Duchenne muscular dystrophy (DMD) drug candidates. For more information, please visit [www.sarepta.com](http://www.sarepta.com).

#### **About Paragon Bioservices, Inc.**

Paragon Bioservices is an industry-leading, private-equity backed CDMO whose focus is the development and manufacturing of cutting-edge biopharmaceuticals. Paragon aims to build strong client partnerships with the world's best biotech and pharma companies, focusing on transformative technologies, including gene therapies (AAV), next-generation vaccines, oncology immunotherapies and oncolytic viruses, therapeutic proteins, and other complex biologics. For more information, please visit [www.paragonbioservices.com](http://www.paragonbioservices.com).

## **Forward-Looking Statements**

*This press release contains "forward-looking statements." Any statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "will," "intends," "potential," "possible" and similar expressions are intended to identify forward-looking statements. These forward-looking statements include statements regarding the manufacturing partnership with Paragon providing Sarepta access to additional commercial manufacturing capacity for its micro-dystrophin DMD gene therapy program, as well as a manufacturing platform for future gene therapy programs, such as LGMD; Sarepta rapidly building a formidable gene therapy engine, the hallmark of which will be the establishment of its Gene Therapy Center of Excellence in Columbus, Ohio; the ability of Sarepta's manufacturing approach to accelerate a steady stream of gene therapies to treat life-robbing genetic diseases for the near and long-term; and Sarepta's goal to becoming among the most meaningful genetic companies in the world.*

*These forward-looking statements involve risks and uncertainties, many of which are beyond Sarepta's control. Known risk factors include, among others: the expected benefits and opportunities related to the agreement with Paragon may not be realized or may take longer to realize than expected; Sarepta's dependence on Paragon to produce its products and/or product candidates, including any inability on Sarepta's part to accurately anticipate product demand and timely secure manufacturing capacity to meet product demand, may impair the availability of products to successfully support various programs, including research and development and the potential commercialization of Sarepta's gene therapy product candidates; if Paragon were to cease providing quality manufacturing and related services to Sarepta, and Sarepta is not able to engage appropriate replacements in a timely manner, Sarepta's ability to manufacture its gene therapy product candidates in sufficient quality and quantity would adversely affect Sarepta's various product research, development and commercialization efforts; if Paragon fails to adhere to applicable cGMP and other applicable government regulations, or experiences manufacturing problems, Sarepta will suffer significant consequences, which could significantly delay or negatively impact the success of Sarepta's development efforts for its product candidates; Sarepta may not be able to successfully scale up manufacturing of its product candidates in sufficient quality and quantity or within sufficient timelines, or be able to secure ownership of intellectual property rights developed in this process, which could negatively impact the development of its product candidates; Sarepta's gene therapy programs may not result in any viable treatments suitable for clinical research or commercialization due to a variety of reasons, including the results of future research may not be consistent with past positive results or may fail to meet regulatory approval requirements for the safety and efficacy of product candidates; and even if Sarepta's gene therapy programs result in new commercialized products, Sarepta may not achieve any significant revenues from the sale of such products; and those risks identified under*

*the heading "Risk Factors" in Sarepta's most recent Annual Report on Form 10-K for the year ended December 31, 2017 and most recent Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) as well as other SEC filings made by the Company which you are encouraged to review.*

*Any of the foregoing risks could materially and adversely affect the Company's business, results of operations and the trading price of Sarepta's common stock. For a detailed description of risks and uncertainties Sarepta faces, you are encouraged to review Sarepta's 2017 Annual Report on Form 10-K and most recent Quarterly Report on Form 10-Q filed with the SEC as well as other SEC filings made by Sarepta. We caution investors not to place considerable reliance on the forward-looking statements contained in this press release. Sarepta does not undertake any obligation to publicly update its forward-looking statements based on events or circumstances after the date hereof.*

#### **Internet Posting of Information**

*We routinely post information that may be important to investors in the 'For Investors' section of our website at [www.sarepta.com](http://www.sarepta.com). We encourage investors and potential investors to consult our website regularly for important information about us.*

Source: Sarepta Therapeutics, Inc.

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