Sarepta Therapeutics, Inc. Q3 2022 Earnings Conference Call
Forward Looking Statements

Wednesday, November 2, 2022 – 4:30 p.m. Eastern Time

In order to provide Sarepta's investors with an understanding of its current results and future prospects, forward-looking statements will be made during this conference call. Any statements made by Sarepta that are not statements of historical fact may be deemed to be forward-looking statements. Words such as "believe," "anticipate," "plan," "expect," "will," "may," "intend," "prepare," "look," "potential," "possible" and similar expressions are intended to identify forward-looking statements. These forward-looking statements include, without limitation, statements relating to our future operations, financial performance and projections, business plans, market opportunities, priorities, research and development programs, and the potential benefits of our product candidates; our full-year net product revenue guidance of between $825 to $840 million and $905 to $920 total revenue guidance; our expectation that the AMONDYS 45 quarter-over-quarter growth rate will modestly rebound in the fourth quarter; our belief that we meet the criteria for accelerated approval for SRP-9001, including our belief that the shortened functional dystrophin produced by SRP-9001 is a surrogate endpoint reasonably likely to predict clinical benefit; our goal to reach as many individuals living with Duchenne as possible; the potentially transformative benefits of SRP-9001, including its safety profile and that the SRP-9001 intended commercial process material improves motor function; our confidence in the probability of success for our Phase 3 study (EMBARK) for SRP-9001, based in part on the clinical results from ENDEAVOR; our belief that the issuance of the 2027 convertible notes along with our current cash and projected revenue are sufficient to fund operations to profitability; the potential for MyoAAV to be a breakthrough in genetic medicine delivery based on early research showing greater gene expression at lower doses compared to natural serotype capsids; and expected timelines, plans and milestones, including our expectation that the FDA will accept the BLA for SRP-9001 for filing at the end of November of this year, that we will receive a PDUFA date in May of 2023 for SRP-9001, and if successful, we will launch by middle of 2023, our expectation not to publicly share additional data cuts for SRP-9001 leading up to 2023 regulatory milestones and the EMBARK data read out, ramping up manufacturing, bolstering commercial, medical affairs, and patient services, and engaging with key sites and access teams in anticipation of a potential launch of SRP-9001, if approved, finalizing the protocol for the commencement of ENVISION as we look to expand the label for SRP-9001 to the non-ambulatory patients as soon as possible, starting a study with Hansa Biopharma next year to explore the use of imlifidase to cleave IgG in rh74 positive Duchenne patients with the goal of safely and effectively permitting dosing with SRP-9001, completing enrollment of MOMENTUM Part B this year and having a data readout in 2023, commencing an additional study for SRP-9003 using clinical material for LGMD2E with the goal of expanding our clinical experience in more advanced ambulatory and nonambulatory patients, starting a study with commercial process material for SRP-9003 in 2023, commencing a systemic pilot study for our SRP-6004 dual-vector RH74-mediated gene therapy to potentially treat LGMD2B, characterized by the absence of the protein dysferlin, starting an extension study for our gene therapy studies to enable us to follow patients out for a minimum of 5 years, and continuing to leverage our learnings from SRP-9001 and applying them to the candidates in our deep genetic medicine pipeline.

These forward-looking statements involve risks and uncertainties, many of which are beyond our control. Actual results could materially differ from those stated or implied by these forward-looking statements as a result of such risks and uncertainties. Known risk factors include the following: we may not be able to meet expectations with respect to sales of our products or attain the anticipated net revenues, profitability or positive cash-flow from operations; we may not be able to comply with all FDA post-approval commitments and requirements with respect to our products in a timely manner or at all; the possible 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 dependence on certain manufacturers to produce our products and product candidates, including any inability on our part to accurately anticipate product demand and timely secure manufacturing capacity to meet product demand, may impair the availability of product to successfully support various programs; our data for SRP-5051, SRP-9001, the LGMD programs, including SRP-9003, and/or other programs may not be sufficient for obtaining regulatory approval; success in preclinical and clinical trials, especially if based on a small patient sample, does not ensure that later clinical trials will be successful, and 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; the commencement and completion of our clinical trials and announcement of results may be delayed or prevented for a number of reasons, including, among others, denial by the regulatory agencies of permission to proceed with our clinical trials, or placement of a clinical trial on hold, challenges in identifying, recruiting, enrolling and retaining patients to participate in clinical trials and inadequate quantity or quality of supplies of a product candidate or other materials necessary to conduct clinical trials; different methodologies, assumptions and applications we use to assess particular safety or efficacy parameters may yield different statistical results, and even if we believe the data collected from clinical trials of our product candidates are positive, these data may not be sufficient to support approval by the FDA or other global regulatory authorities; if the actual number of patients living with the diseases we aim to treat is smaller than estimated, our revenue and ability to achieve profitability may be adversely affected; we may not be able to execute on our business plans, including meeting our expected or planned regulatory milestones and timelines, research and clinical development plans, and bringing our product candidates to market, for various reasons, many of which may be outside of our control, including possible limitations of company financial and other resources, manufacturing limitations that may not be anticipated or resolved for in a timely manner, regulatory, court or agency decisions, such as decisions by the United States Patent and Trademark Office with respect to patents that cover our product candidates, and the ongoing COVID-19 pandemic; and those risks identified under the heading "Risk Factors" in our most recent Annual Report on Form 10-K for the year ended December 31, 2021 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. You should not place undue reliance on forward-looking statements. Sarepta does not undertake any obligation to publicly update its forward-looking statements based on events or circumstances after the date hereof, except to the extent required by applicable law or SEC rules.