WBB Securities, LLC

Steve Brozak, DMH • sbrozak@wbbsec.com • (908) 518-7610

Sarepta Therapeutics, Inc. (NasdaqGS: SRPT) — Updating Coverage

Updating Coverage by Maintaining a Strong Buy Rating and Increasing our 12-Month Price Target to $185

December 29, 2023

2024 The Year of Sarepta

Sarepta Therapeutics, Inc. (SRPT) is a commercial-stage biopharmaceutical company focused on RNA targeted therapeutics, gene therapy and gene editing for treatment of Duchenne Muscular Dystrophy (DMD) and Limb-Girdle Muscular Dystrophy (LGMD). Both diseases are rare, inherited, genetic disorders characterized by progressive muscular weakness. DMD is found primarily in boys whereas LGMD is found equally in both sexes.

The company pipeline includes 40 pre-clinical and clinical products.

SRPT markets four commercial products that received FDA accelerated approval. Net product revenue for 2022 was $843.77 million and $779.8 million for the first three quarters of 2023:

Current Price	**$97.78**
12 Month Target Price	**$185.00**
12 Month Trading Range	$55.25-$159.89
Market Capitalization (Bil)	$9.147
Shares Outstanding (Mil)	*93,546,681
Avg. Daily Volume	1,669,693
L. T. Debt (Mil)	**1,236,755
Dividend/Yield	N/A
Book Value P/S	8.17
NASDAQ Composite	15,095.14
S&P 500	4,783.35

*As of 10-27-2023
Per 10Q 3Q-2023
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- EXONDYS 51 (Eteplirsen) injection, approved September 19, 2016; 2023 net revenue for 3 quarters $409.6 million.
- VYONDIS 53 (Golodirsen) injection, approved December 12, 2019; 2023 net revenue for 3 quarters $97.3 million.
- AMONDYS 45 (casimersen) Injection approved February 25, 2021; net revenue for 3 quarters $203.8 million.
- ELEVIDYS (delandistrogene moxeparvovec-rokl), approved on June 22, 2023; net revenue for 3 quarters $69.1 million.

SRPT has demonstrated over and over again, the ability to bring a therapeutic drug from development stage, through approval by the FDA, to a marketed product with significant revenue possibility. We now also believe there is a reasonable possibility that we can see takeover interest in the franchise, if we do not see the expected price appreciation we believe is merited.

As such, looking at SRPT's PPMO products and the potential for ELEVIDYS expansion, we have great comfort in maintaining our Strong Buy rating and increasing our 12-month price target to $185.00.

Valuation

Rating Legend:

Strong Buy – Should be aggressively purchased.
Buy – Should be purchased on market weakness.
Hold – Fairly valued.
Sell – Stock should be sold on market strength.
Sell Short – Should be aggressively sold.
Speculative Buy – For aggressive accounts only.
Core Holding – Essential holding of a long-term account.

With today's update, we believe that SRPT has proven itself to be a unique franchise within the field of drug discovery and development. And in these unpredictable pharmaceutical markets with risk-avoidance as a chief part in any valuation model, we have great comfort in recognizing SRPT's potential for price appreciation.

Using a share count of 87.6 million shares and a discount rate of 10% with a 2% long-term growth rate, with our terminal value model of cash flow we arrive at a value of $168.3. Adding cash and marketable securities we arrive at a 12-month price target of $185 per share.

About DMD

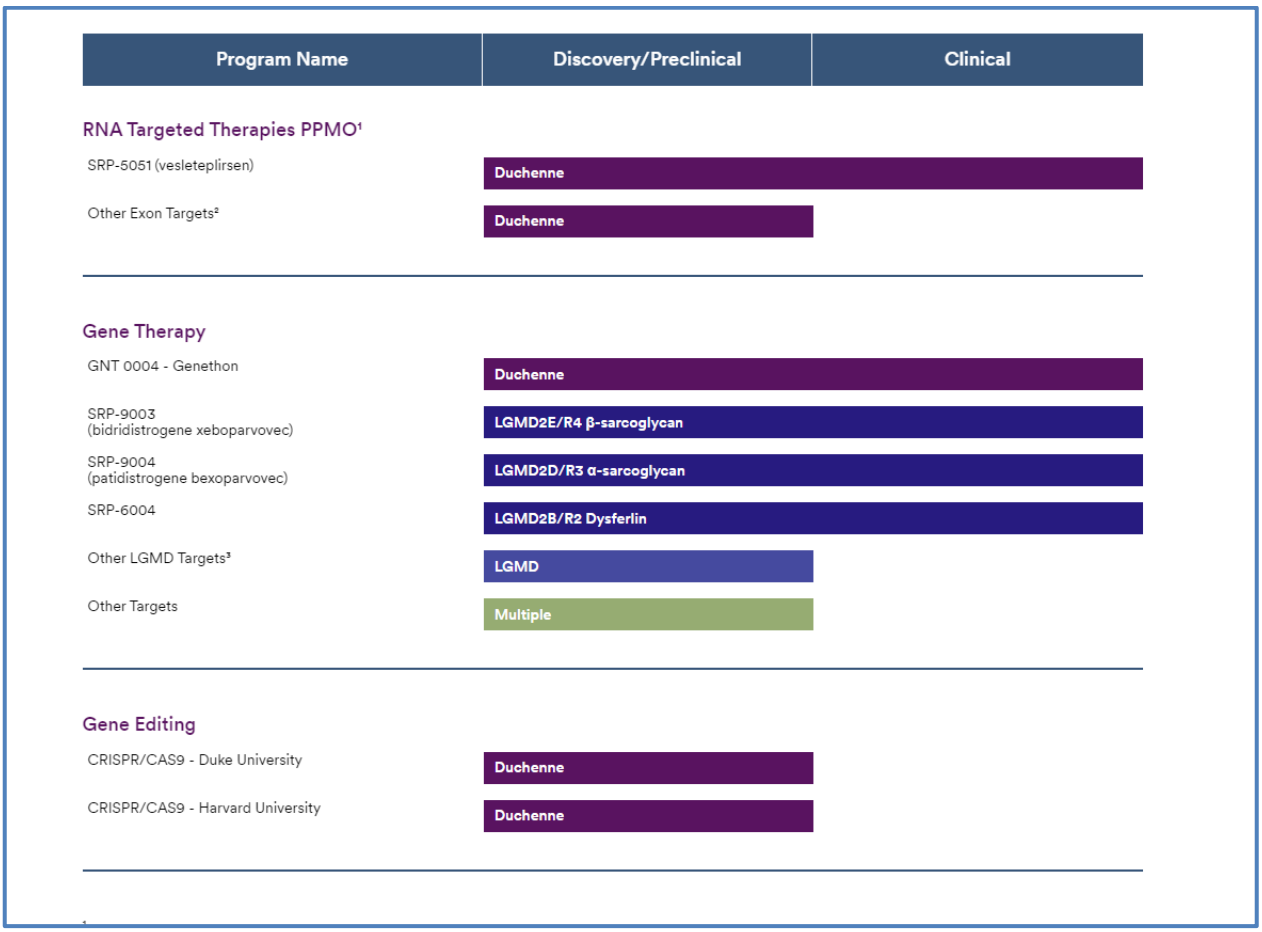
DMD is one of the most common fatal genetic disorders, affecting approximately one in every 3,500-5,000 male births worldwide. The condition is universally fatal, with death usually occurring before the age of 30 due to respiratory or cardiac failure.

DMD is associated with specific errors in the gene that codes for the synthesis of dystrophin. Dystrophin is part of a group of proteins (a protein complex) that work together to strengthen muscle fibers and protect them from injury as muscles contract and relax. The disease manifests itself as a progressive muscle weakness that starts in the lower limbs and then advances to affect the arms, neck, heart and other areas of the body.

DMD is caused by the deletion of one or more exons in the dystrophin gene. (Exons are coding sections of RNA necessary for protein production.) The deletions cause a misalignment during transcription that yields little or no functional dystrophin. The reduction, or total lack of dystrophin, leads to a cycle of muscle cell degeneration, inflammation and scarring characterized by loss of muscle mass and muscle wasting.

LGMD is a group of 33 diseases that affect both genders. LGMD2A and LGMD2B account for as many as 75% of the patients worldwide. All the LGMD variants cause weakness and wasting of the muscles, generally starting with the muscles around the hips and shoulders and eventually progressing to the arms and legs. Other subtypes start weakness and wasting of leg or arm muscles and then progress to the hip and shoulder muscles. LGMD can be caused by a single gene defect that affects specific proteins within the muscle cell responsible for keeping the muscle membrane intact. Symptoms may appear at any age. Depending on the subtype of LGMD, the disease may tend to progress faster in younger patients. Some forms of the disease lead to heart and breathing problems and early death.

Pipeline



Source: SRPT Web site 12-14-23

Commercial Products

The following three products use exon skipping technology to promote production of a functional but shortened dystrophin protein. They use SRPT's phosphorodiamidate morpholino oligomer (PMO) chemistry and exon-skipping technology:

• EXONDYS 51 (eteplirsen) Injection for treating Duchenne patients with a dystrophin gene mutation by skipping exon 51.

• VYONDYS 53 (golodirsen) Injection ("VYONDYS 53") for treating Duchenne patients with a dystrophin gene by skipping exon 53.

AMONDYS 45 (casimersen) Injection ("AMONDYS 45") for treating Duchenne patients dystrophin gene mutation by skipping exon 45.

• ELEVIDYS (delandistrogene moxeparvovec-rokl) is an adeno-associated virus-based gene therapy for treating ambulatory DMD patients who are 4 - 5 years old. ELEVIDYS is contraindicated in patients with any deletion in exon 8 and/or exon 9 in the Duchenne gene. SRPT is seeking to expand the label of ELEVIDYS.

Study SRP-9001-301 is a Phase 3, randomized, double-blind, placebo-controlled, clinical trial of 126 participants to evaluate safety and efficacy of gene transfer therapy in boys with DMD. The study is being conducted with SRPT's collaborator, Hoffmann-La-Roche. Each participant will receive either two infusions of Elevidys spaced one year apart or one of placebo followed a year later with Elevidys. Elevidys achieved statistical significance on all pre-specified key secondary endpoints and in each age subgroup of the key secondary endpoints. Top-line results were announced in October 2023. The company announced submission of an efficacy supplement to the BLA for ELEVIDYS that would remove age and ambulation restrictions from the approved indication.

Primary Outcome Measure:
Change From Baseline in North Star Ambulatory Assessment (NSAA) Total Score at Week 52 compared to the baseline.

Secondary Outcome Measures :

- Quantity of Delandistrogene Moxeparvovec Dystrophin Expression at Week 12 as Measured by Western Blot.
- Change From Baseline in Time to Rise From the Floor, Time to Complete 100 and 10 Meter Walk/Run, and the Timed Stair Ascend 4 Steps Test at Week 52.
- Change From baseline in Stride Velocity 95th percentile (SV95C) measured by a wearable device.
- Change from Baseline in Patient-Reported Outcomes Measurement Information System (PROMIS) score in mobility and upper extremity function to week 52. (PROMIS is a family of instruments developed and validated to assess health-related quality of life.)

Key Product Candidates

SRP-5051 skips exon 51 of the dystrophin gene. It uses SRPT's next-generation chemistry platform, cell-penetrating peptide-conjugated PMO (PPMO), and exon-skipping technology. In May 2021, SRPT announced results from the 30 mg/kg cohort of Part A of Study 5051-201.

Part B of Study 5051-201 was initiated in 4-Q 2021. In July 2022, the Study 5051-201 was placed on clinical hold following a serious adverse event of hypomagnesemia (magnesium deficiency). The clinical hold was lifted in August 2022. Enrollment in Part B of the study was completed in 1Q-2023 and top-line results are expected to be reported by end of year. If successful, Part B could potentially become a pivotal trial.

SRP-9003 is intended to transfer a gene that codes for and restores the beta-sarcoglycan protein, the absence of which causes LGMD. It utilizes the same vector used in the SRP-9001 gene therapy program. A Phase 1/2a trial of SRP-9003 began in 4Q-2018. In March 2022, SRPT announced 36-month functional data from three clinical trial participants in the low-dose cohort of the trial and 24-month functional data from two clinical trial participants in the high-dose cohort. SRPT plans to initiate a follow-up trial that could potentially be a pivotal trial by the end of 2023.

Competitors

NS Pharma, the U.S. subsidiary of Nippon Shinyaku Co. Ltd. (ADR CIK#), Viltepso® (vitolarsen) injection. Received accelerated approval for treatment of DMD by skipping Exon 53. Five clinical stage and three preclinical product candidates. (2022 worldwide sales were 14,341 million Japanese Yen or $99.8 million U.S. Dollars.)

PTC Therapeutics, Inc. (PTCT) Emflaza® (deflazacort), a corticosteroid treatment for patients with Limb-Girdle Muscular Dystrophy and TRANSLARNA™ (ataluren) (PTC 24) an inhibitor of nonsense mutation in patients with Nonsense Mutation Muscular Dystrophy. It is approved in EU, not in U.S.

Catalyst Pharmaceuticals, Inc.(CPRX) AGAMREE®,a corticosteroid for treatment of DMD.

WAVE Life Sciences Ltd. (WVE) One potentially registrational Phase 2 trial of WVE-531 (Forward-53 trial WVE-N531) an Exon 53 skipping candidate, and un-named preclinical candidates.

Pfizer, Inc. (PFE) is conducting two clinical trials in the U.S. of a gene therapy for Duchenne Muscular Dystrophy:

- a long-term Phase 3 study (NCT05689164) of fordadistrogene movaparvovec (PF-06939926) a gene therapy to treat Duchenne Muscular Dystrophy begun March 2023. Participants from previous Pfizer interventional studies will be followed for 10 years after the end of their previous study. Participants will have one annual onsite visit and a few annual remote visits to determine long-term safety and efficacy.

- a single-arm Phase 2 study of 10 boys ages two to four in early-state Duchenne Muscular Dystrophy, to evaluate safety and dystrophin expression after infusion of one dose of fordadistrogene movapar. (NCT05429372). Trial begun in August 2022 with expected completion date in July 2024.

Risks

In addition to the risks normally anticipated in a commercial stage biotechnology company and previously outlined by SRPT in regulatory filings, we note the following specific risks in attaining our price target:

Commercial Risk: SRPT is dependent on product revenue for the majority of the company's current revenue stream. As is common with many biotech companies, SRPT also experiences increasing competition.

Regulatory Risk: SRPT's commercial products received accelerated approval. Under the accelerated approval pathway, continued approval may be contingent upon verification of clinical benefit in confirmatory trials. Failure to meet post-approval commitments and requirements, including completion of enrollment, would lead to negative regulatory action from the FDA and/or withdrawal of regulatory approval.

Reimbursement Risk: SRPT's ability to successfully maintain and/or increase sales of the company's products in the U.S. partly depends on the coverage and reimbursement levels set by government authorities, private health insurers and other third-party payers. Third party payers are increasingly challenging the effectiveness of, and prices

charged for medical products and services. SRPT may not be able to obtain or maintain adequate third-party coverage or reimbursement for its products, and/or may be required to provide discounts or rebates to obtain or maintain adequate coverage.

Management

Douglas Ingram, President, CEO and Board Member since 2017. Prior experience includes President of Allergan from 1996 to 2013 when Allergan was acquired by Actavis. President and CEO of Chase Pharmaceuticals before coming to Sarepta. Mr. Ingram received a JD, summa cum laude, from the University of Arizona and a BS, magna cum laude, from Arizona State University. He sits on Relay Therapeutics' Board of Directors.

Ian M. Estepan, Executive Vice President, Chief Financial Officer since 2020. Previously, he served as Head of Investor Relations and Chief of Staff beginning when he joined Sarepta in 2015.

From 2017 to 2020, Mr. Estepan led the development of Sarepta's strategy and was a key architect in securing $2.5 billion in capital to support the Company's growth. Prior experience includes Health Care Sector Analyst at Salomon Smith Barney, two years at The Music Booth, LLP, and Spectra Financial Group.

Mr. Estepan holds a BA in psychology with a concentration in pre-medicine from Columbia University, where he graduated magna cum laude. He sits on Cellarity's Board of Directors. In 2022, he was recognized as a Boston Business Journal CFO of the Year.

Bilal Arif Chief Technical Operations Officer since December 2022. As head of technical operations, Mr. Bilal is responsible for the Company's CMC strategy and global supply chain management for its RNA and gene therapy portfolio. Before holding his present position, he served as Sarepta's Senior Vice President, Head of Strategy and Technical Operations beginning in 2019.

Prior experience includes Vice President, Product Strategy & Planning, Technical Operations at Shire. At Shire, Mr. Arif also was responsible for leading the TechOps team responsible for conducting due diligence/integration of new technologies and M&A assets.

Mr. Arif received a Bachelor of Engineering degree in chemical engineering from McGill University, a Master of Science in Biotechnology from Tufts University, and an MBA from Brown University'/Instituto de Empresa (IE) Business School.

Diane Berry, PhD, Executive Vice President, Chief Policy & Advocacy Officer since 2011. Prior experience includes: senior positions in both the executive and legislative branches of the U.S. government, including Subcommittee Staff Director and Senior Professional Staff member for the House Committee on Homeland Security and Chief Scientist, Director of Threat Characterization and Countermeasures, and Senior Biodefense Advisor in the Department of Homeland Security. Prior to government service, Dr. Berry was Senior Science Advisor at McKenna Long & Aldridge, an international law and public policy law firm.

Dr. Berry earned a PhD in chemical engineering from Northwestern University and a BS and MS in chemical/biochemical engineering from Tufts University. In 2019 she joined the BioOhio Board of Trustees and was named one of The Top 25 Women Leaders n Biotech by The Healthcare Technology Report.

Ryan E. Brown, JD, Executive Vice President, Chief General Counsel since 2021. He previously served as Vice President, Global Chief Compliance Officer and Regulatory Counsel when he joined Sarepta in 2018 and he became a member of the Executive Committee in December 2020.

Before entering the biotechnology and pharmaceuticals industry, Mr. Ryan specialized in corporate criminal investigations at the international law firm of Jones Day. In 2008, he joined Allergan as Vice President, Chief Compliance Officer. Then became General Counsel for subsidiary SkinMedica; and Chief of staff to the office of the president. After Allergan, he served as Vice President, Chief Compliance Officer at Acadia Pharmaceuticals.

Mr. Ryan received a Bachelor of Arts degree in Political Science from Loyola Marymount University and a Juris Doctor degree from Harvard Law School.

Dallan Murray Executive Vice President, Chief Customer Officer since 2021. He joined Sarepta in 2013 as Vice President, Marketing. In December 2020, he was named Senior Vice President, Chief Commercial Officer, and Vice President, Commercial Strategy and Portfolio Management. Prior experience includes commercial leadership roles at Vertex Pharmaceuticals, Gilead Sciences, Biogen, and Janssen Ortho.

Mr. Dallan holds a Bachelor of Commerce degree from University of Alberta, and a Master's in Business Administration from Queen's University.

Alison Nasisi, Executive Vice President, Chief People Officer since 2021, and a member of Sarepta's executive committee. She joined Sarepta in September 2019, as Senior Director, Global Total Rewards

Before joining Sarepta, Ms. Nasisi was director of compensation, benefits work-life at the Broad Institute of MIT and Harvard and held compensation and benefits positions at Forrester Research, Giga Information Group, Inc., Sappi and Children's Hospital Boston.

Ms. Nasisi received a Bachelor of Arts degree in Industrial Relations from McGill University and an MBA from the D'Amore-McKim School of Business at Northeastern University.

Louise R. Rodino-Klapac, PhD, Executive Vice President, Head of R&D, Chief Scientific Officer since 2021. Previously, Dr. Rodino-Klapac served as Sarepta's Senior Vice President, Gene Therapy. She is a National Institutes of Health (NIH) Fellow appointee, and a Board member of the Alliance for Regenerative Medicine, as well as a member of the American Society for Gene and Cell Therapy, and the American Academy of Neurology. She is the former head of the Laboratory for Gene Therapy Research at Nationwide Children's Hospital and co-founded and served as chief scientific officer of Myonexus Therapeutics before it was acquired by Sarepta in 2019.

At Nationwide Children's Hospital, as co-inventor, Dr. Rodino-Klapac's efforts drove the multi-decade research project that led to Sarepta's gene therapy treatment for Duchenne muscular dystrophy. She also is the inventor of five of Sarepta's limb-girdle muscular dystrophy programs. Overall, her work has led to 11 investigational new drug applications.

Dr. Rodino-Klapac holds a Bachelor of Science degree in biology from King's College and a PhD in molecular genetics from The Ohio State University.

Will Tilton, Senior Vice President, Head of Strategy, Chief of Staff He joined Sarepta in 2019. Prior experience includes research scientist at Perrigo and Shire Group Vice President, Business Development Due Diligence, where he led the Shire side of the Takeda/Shire ($60B) merger.

Mr. Tilton received an MBA from The Wharton School, University of Pennsylvania, majoring in Finance, and a B.S. in Chemical Engineering from Michigan State University. He also serves on the Advisory Board of Directors for Company One, a professional theater organization in Boston, MA.

Historical & Future EPS Performance

EPS	2022	2023	2024
Q1	(1.20A	(5.86)A	(0.80)E
Q2	(2.65)A	(0.27)A	(0.10)E
Q3	(2.94)A	(0.46)A	0.15E
Q4	(1.24)A	0.09E	0.25E
Year	(8.03)A	(6.50)E	(0.50)E
P/E	NM	NM	NM
EPS Growth	NM	NM	NM
FY Rev. (Mil)	843.8A	1,096E	1,548E
FY:DEC			

Other Companies Mentioned in this Report.

Hoffmann-La-Roche
NS Pharma, the U.S. subsidiary of Nippon Shinyaku Co. Ltd. (ADR CIK#)
Catalyst Pharmaceuticals, Inc.(CPRX)
WAVE Life Sciences Ltd. (WVE)
PTC Therapeutics, Inc. (PTCT)

Price and Volume

Initiated Coverage of Sarepta as AVI Biopharma, Inc. (AVII) on December 29, 2010

1	Updated coverage of SRPT on 12/30/22 at $127.26 with a Strong Buy Rating and a 12-month price target of $170.00

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	Percentage of Covered Securities	Percentage of Banking Clients
Buy	84%	6.25%
Hold	11%	
Sell	05%	

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