Sarepta Therapeutics

Peter Marks reiterates FDA commitment to bring more gene therapies to patients

Maintain Rating: BUY | PO: 164.00 USD | Price: 102.61 USD

Stabilizing non-ambulatory DMD pts could be "huge win"

Peter Marks, Director of the FDA Center for Biologics Evaluation and Research (CBER), presented yesterday at the Informa Biotech Showcase in San Francisco to discuss FDA's commitment to facilitate the approval of more gene therapies, particularly for rare diseases. He highlighted how approved gene therapies like Zolgensma for spinal muscular atrophy (SMA) have been transformational emphasizing the potential for gene therapy. He specifically commented that in Duchenne muscular dystrophy (DMD) having something that could help stabilize a non-ambulatory or almost non-ambulatory patient could be "a huge win". We highlight that Dr. Marks has been a long-standing proponent of gene therapy. We think these comments reinforce our view that a label expansion for Elevidys is likely and could signal that a broad label inclusive of all DMD patients regardless of age or ambulatory status is not out of the question. Recall, SRPT submitted the efficacy supplement requesting a broad label expansion and conversion to traditional approval in December. The company expects a PDUFA (Prescription Drug User Fee Act) date in August based on standard regulatory timelines but has noted a more expedited review is possible. We are encouraged by FDA leadership's continued support in the approval of gene therapies and commentaries on non-ambulatory patients, which has been a topic of discussion given no data is available yet in this patient population. We maintain our Buy rating on the shares with \$164 PO.

Estimates (Dec) (US\$)	2021A	2022A	2023E	2024E	2025E
EPS	(5.15)	(8.03)	(7.58)	0.67	13.37
EPS Change (YoY)	27.6%	-55.9%	5.6%	NM	NM
Consensus EPS (Bloomberg)			(3.37)	3.86	9.27
DPS	0	0	0	0	0
Valuation (Dec)					
P/E	NM	NM	NM	153.1x	7.7x
EV / EBITDA*	NM	NM	NM	74.8x	8.2x
Free Cash Flow Yield*	-5.0%	-3.7%	-4.4%	3.5%	16.0%
* For full definitions of <i>IQ</i> method SM measures, see page 5.					

09 January 2024

Equity

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Stock Data

102.61 USD Price 164.00 USD Price Objective Date Established 30-Oct-2023 Investment Opinion C-1-9 52-Week Range 55.25 LISD - 159.89 LISD Mrkt Val (mn) / Shares Out 9.599 USD / 93.5 (mn) Free Float 95.6% Average Daily Value (mn) 116.54 USD BofA Ticker / Exchange SRPT / NAS Bloomberg / Reuters SRPT US / SRPT.OQ ROE (2023E) -350.9% Net Dbt to Eqty (Dec-2022A) 150.0% FSGMeter™ Medium

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Refer to important disclosures on page 6 to 8. Analyst Certification on page 4. Price Objective Basis/Risk on page 4.

iQprofile[™] Sarepta Therapeutics

(US\$ Millions)	2021A	2022A	2023E	2024E	2025
Return on Capital Employed	-15.7%	-18.5%	-13.1%	3.8%	35.0%
Return on Equity	-49.6%	-10.5%	-15.1%	32.8%	106.8%
Operating Margin	-49.0%	-57.5%	-27.2%	5.4%	42.6%
Free Cash Flow	(482)	(356)	(421)	334	1,53
Tiee Casiff low	(402)	(550)	(421)	334	1,55
Q method [™] – Quality of Earnings*					
(US\$ Millions)	2021A	2022A	2023E	2024E	2025
Cash Realization Ratio	NM	NM	NM	6.1x	1.3
Asset Replacement Ratio	1.0x	0.7x	0.7x	0.7x	0.7
Tax Rate	0%	NM	NM	0.8%	09
Net Debt-to-Equity Ratio	-109.8%	150.0%	NM	137.9%	-44.59
Interest Cover	-6.7x	-15.3x	-9.6x	2.7x	36.4
Income Statement Data (Dec)					
(US\$ Millions)	2021A	2022A	2023E	2024E	2025
Sales	702	933	1,234	1,792	2,99
% Change	30.0%	32.9%	32.3%	45.2%	67.39
Gross Profit	605	793	1,078	1,611	2,72
% Change	26.9%	31.1%	35.9%	49.5%	69.09
EBITDA	(422)	(494)	(290)	147	1,332
% Change	21.8%	-17.2%	41.3%	NM	806.89
Net Interest & Other Income	41	(154)	(320)	(35)	(35
Net Income (Adjusted)	(419)	(703)	(673)	61	1,24
% Change	24.4%	-68.0%	4.4%	NM	NN
US\$ Millions)	2021A	2022A	2023E	2024E	2025
Net Income from Cont Operations (GAAP)	(419)	(703)	(673)	61	1,24
Depreciation & Amortization	38	42	46	51	5
Change in Working Capital	(98)	(39)	(16)	(22)	(30
Deferred Taxation Charge	NA 2C	NA 276	NA	NA	N ₂₁
Other Adjustments, Net	36	376	256	282	31
Capital Expenditure	(38)	(31)	(34)	(37)	(41
Free Cash Flow % Change	-482 NM	-356 26.1%	-421 -18.1%	334 NM	1,530 360.2%
Share / Issue Repurchase	549	20.170	-10.170	0	300.27
Cost of Dividends Paid	NA	NA	NA NA	NA	N
Change in Debt	0	202	0	0	I N
	Ü	202	Ü	U	
Balance Sheet Data (Dec)	20214	20224	20225	20245	2025
(US\$ Millions)	2021A	2022A	2023E	2024E	2025
Cash & Equivalents	2,116	967	738	1,032	2,41
Trade Receivables	153	215	258	309	37
Other Current Assets	335	1,376	1,250	1,358	1,58
Property, Plant & Equipment	191	180	168	155	14
	353 3,148	390	390	390	39
Other Non-Current Assets		3,128	2,804	3,245	4,90
Total Assets			0	0	
Total Assets Short-Term Debt	0	620	602	750	റാ
Total Assets Short-Term Debt Other Current Liabilities	0 453	620	682 1 544	750 1 544	
Total Assets Short-Term Debt Other Current Liabilities Long-Term Debt	0 453 1,097	620 1,544	1,544	1,544	1,54
Total Assets Short-Term Debt Other Current Liabilities Long-Term Debt Other Non-Current Liabilities	0 453 1,097 670	620 1,544 580	1,544 580	1,544 580	82: 1,54 58:
Total Assets Short-Term Debt Other Current Liabilities Long-Term Debt Other Non-Current Liabilities Total Liabilities	0 453 1,097 670 2,220	620 1,544 580 2,743	1,544 580 2,805	1,544 580 2,874	1,54 58 2,94 9
Total Assets Short-Term Debt Other Current Liabilities Long-Term Debt Other Non-Current Liabilities	0 453 1,097 670	620 1,544 580	1,544 580	1,544 580	1,54

Company Sector

Biotechnology

Company Description

Sarepta (SRPT) is a biopharmaceuticals company developing exon-skipping therapeutics and gene therapy for the treatment of Duchenne muscular dystrophy (DMD) and Limb Girdle muscular dystrophy (LGMD). The company's approved assets include Exondys, approved for DMD amenable to exon 51 skipping, Vyondys, approved for DMD amenable to exon 53 skipping, and Amondys, approved for DMD amenable to exon 45 skipping. SRPT also has a next-gen PPMO platform and gene therapy programs in DMD and LGMD.

Investment Rationale

We rate SRPT shares Buy. We believe SRPT's assets address the current under-met need in the treatment of rare muscular dystrophies. The exon skipping assets, in our view, should continue to provide floor valuation and generate sustained revenue streams. We believe the company is well positioned to drive upside potential and deliver shareholder value over time given existing assets and strategic partnerships in gene therapy programs with Nationwide, Lacerta, and Lysogene.

Stock Data

Average Daily Volume

Quarterly Earnings Estimates

	2022	2023
Q1	-1.20A	-5.85A
Q2	-2.65A	-0.27A
Q3	-2.94A	-0.46A
Ω4	-1 24Δ	-1 03F

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Price objective basis & risk

Sarepta Therapeutics (SRPT)

Our \$164 PO is based on a probability-adjusted net present value (NPV) analysis that includes \$17/share for Exondys, \$8/share for Vyondys, \$22/share for Amondys, \$78/share for micro-dystrophin gene therapy, \$38/share for LGMD assets. The remainder of our valuation comes from pipeline and cash. Our discounted cash flow (DCF) analysis assumes sales out to 2035, with weighted average cost of capital (WACC) of 9-13%.

Upside risks to our PO are 1) better-than-expected market uptake from its exon skipping assets, 2) SRP-9001 US label expansion, and 3) EU approval of SRP-9001 and other assets.

Downside risks to our PO are 1) failure and delay in approval for exon skipping assets, 2) unexpected safety or durability findings in gene therapy programs, 3) other micro dystrophin competitors, and 4) higher-than-expected royalty payments.

Analyst Certification

I, Tazeen Ahmad, hereby certify that the views expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the specific recommendations or view expressed in this research report.

US - Biotechnology Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
BUY				
	4D Molecular Therapeutics, Inc.	FDMT	FDMT US	Tazeen Ahmad
	Alnylam Pharmaceuticals	ALNY	ALNY US	Tazeen Ahmad
	Amicus Therapeutics	FOLD	FOLD US	Tazeen Ahmad
	Annexon Biosciences	ANNX	ANNX US	Tazeen Ahmad
	Apellis Pharmaceuticals	APLS	APLS US	Tazeen Ahmad
	Argenx SE	ARGX	ARGX US	Tazeen Ahmad
	Arvinas	ARVN	ARVN US	Tazeen Ahmad
	Ascendis Pharma	ASND	ASND US	Tazeen Ahmad
	Biocryst Pharmaceuticals Inc	BCRX	BCRX US	Tazeen Ahmad
	BioNTech	BNTX	BNTX US	Tazeen Ahmad
	Denali Therapeutics	DNLI	DNLI US	Tazeen Ahmad
	Inozyme Pharma, Inc.	INZY	INZY US	Tazeen Ahmad
	Merus	MRUS	MRUS US	Tazeen Ahmad
	Neurocrine Biosciences	NBIX	NBIX US	Tazeen Ahmad
	PepGen Inc	PEPG	PEPG US	Tazeen Ahmad
	Prothena Corporation	PRTA	PRTA US	Tazeen Ahmad
	Rhythm Pharmaceuticals	RYTM	RYTM US	Tazeen Ahmad
	Sarepta Therapeutics	SRPT	SRPT US	Tazeen Ahmad
	Ultragenyx Pharmaceuticals	RARE	RARE US	Tazeen Ahmad
NEUTRAL				
	Acadia Pharmaceuticals	ACAD	ACAD US	Tazeen Ahmad
	Incyte Corporation	INCY	INCY US	Tazeen Ahmad
	SAGE Therapeutics	SAGE	SAGE US	Tazeen Ahmad
UNDERPERFORM				
	Achilles Therapeutics	ACHL	ACHL US	Tazeen Ahmad
	Fate Therapeutics	FATE	FATE US	Tazeen Ahmad
	Fulcrum Therapeutics	FULC	FULC US	Tazeen Ahmad
	Pharvaris	PHVS	PHVS US	Tazeen Ahmad
	PTC Therapeutics	PTCT	PTCT US	Tazeen Ahmad



Qmethod ^{su} Measures Definitions

Business Performance	Numerator	Denominator
Return On Capital Employed	NOPAT = (EBIT + Interest Income) × (1 — Tax Rate) + Goodwill Amortization	Total Assets – Current Liabilities + ST Debt + Accumulated Goodwill Amortization
Return On Equity	Net Income	Shareholders' Equity
Operating Margin	Operating Profit	Sales
Earnings Growth	Expected 5 Year CAGR From Latest Actual	N/A
Free Cash Flow	Cash Flow From Operations — Total Capex	N/A
Quality of Earnings	Numerator	Denominator
Cash Realization Ratio	Cash Flow From Operations	Net Income
Asset Replacement Ratio	Capex	Depreciation
Tax Rate	Tax Charge	Pre-Tax Income
Net Debt-To-Equity Ratio	Net Debt = Total Debt – Cash & Equivalents	Total Equity
Interest Cover	EBIT	Interest Expense
Valuation Toolkit	Numerator	Denominator
Price / Earnings Ratio	Current Share Price	Diluted Earnings Per Share (Basis As Specified)
Price / Book Value	Current Share Price	Shareholders' Equity / Current Basic Shares
Dividend Yield	Annualised Declared Cash Dividend	Current Share Price
Free Cash Flow Yield	Cash Flow From Operations – Total Capex	Market Cap = Current Share Price × Current Basic Shares
Enterprise Value / Sales	EV = Current Share Price × Current Shares + Minority Equity + Net Debt + Other LT Liabilities	Sales

EV/EBITDA Enterprise Value Basic EBIT + Depreciation + Amortization

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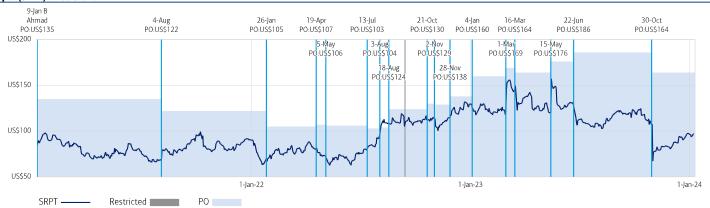
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Disclosures

Important Disclosures

Sarepta (SRPT) Price Chart



B: Buy, N: Neutral, U: Underperform, PO: Price Objective, NA: No longer valid, NR: No Rating

The Investment Opinion System is contained at the end of the report under the heading "Fundamental Equity Opinion Key". Dark grey shading indicates the security is restricted with the opinion suspended. Medium grey shading indicates the security is under review with the opinion withdrawn. Light grey shading indicates the security is not covered. Chart is current as of a date no more than one trading day prior to the date of the report.

Equity Investment Rating Distribution: Health Care Group (as of 31 Dec 2023)

Coverage Universe	Count	Percent	Inv. Banking Relationships R1	Count	Percent
Buy	234	60.94%	Buy	115	49.15%
Hold	80	20.83%	Hold	36	45.00%
Sell	70	18 23%	Sell	29	41 43%

Equity Investment Rating Distribution: Global Group (as of 31 Dec 2023)

Coverage Universe	Count	Percent	Inv. Banking Relationships R1	Count	Percent
Buy	1895	53.62%	Buy	1083	57.15%
Hold	832	23.54%	Hold	454	54.57%
Sell	807	22.84%	Sell	383	47.46%

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Investment rating Total return expectation (within 12-month period of date of initial rating) Ratings dispersion guidelines for coverage cluster^{R2}

Buy	≥ 10%	≤ 70%
Neutral	≥ 0%	≤ 30%
Underperform	N/A	≥ 20%

 $^{^{}R2} Ratings\ dispersions\ may\ vary\ from\ time\ to\ time\ where\ BofA\ Global\ Research\ believes\ it\ better\ reflects\ the\ investment\ prospects\ of\ stocks\ in\ a\ Coverage\ Cluster.$

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