BofA SECURITIES

Biotechnology

Takeaways from Day 1 of the SF Healthcare Conference

Price Objective Change

SRPT: Elevidys FY23 revs beat expectations

Sarepta (SRPT, Buy, $164 PO) reported preliminary 4Q Elevidys revenues of $131.3mn (+90% q/q, ours: $31mn, cons: $101mn) beating all expectations. Additionally, the company reported preliminary FY23 revenues for the exon skipping franchise of $945mn ahead of guidance of $925mn. Management highlighted the strong launch trajectory so far and reiterated their plans for a potential Elevidys label expansion in 2024. Recall, the efficacy supplement was submitted in December (see our Dec 22 note) requesting a label without age or ambulatory status restrictions and conversion of the accelerated approval to traditional approval. Management noted that under normal regulatory timelines they would expect acceptance of the filing in early March and an action date in August. However, they noted they anticipate a more expedited review is possible given the large unmet need. Management reiterated they do not expect an additional advisory committee, however we think FDA could require one. The company also highlighted their focus on transitioning the manufacturing process to suspension manufacturing, which would expand the manufacturing capabilities and supply additional global demand, developing a new capsid and explore strategies to clear pre-existing antibodies to expand the address patient population. As 2024 priorities, management noted they plan to continue expanding the rest of the pipeline with plans to report data for SRP-5051 (next generation exon skipping therapy) and focus on advancing the ongoing pivotal trial for SRP-9003 in limb-girdle muscular dystrophy type 2E. We are encouraged by the strong momentum of the Elevidys launch despite the initial restricted label and reiterate our view that a label expansion is likely based on the totality of data, which could provide additional upside to our estimates. We currently model $2.4bn in risk-adjusted peak sales for Elevidys assuming 35% peak penetration and 75%/60% US/EU likelihood of success. We continue to look for color on the feedback from FDA on the label expansion review and the dynamics between the exon skipping franchise and Elevidys in 2024. We reiterate SRPT as one of our 2024 top picks. We reiterate our Buy with $164 PO.

In our DCF-based model, we roll the quarter and adjust our FY23 estimates for Elevidys and the exon skipping franchise based on the preliminary results.

See inside for details on Incyte Corporation (INCY) PTC Therapeutics (PTCT) and SAGE Therapeutics (SAGE).

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Exhibit 1: Summary of PO changes
PO changes from our covered names

Ticker	Previous	Current
SAGE	$22	$26

Source: BofA Global Research

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Refer to important disclosures on page 6 to 10. Analyst Certification on page 5. Price Objective Basis/Risk on page 4.

INCY: Management highlights pipeline outlook

Incyte (INCY, Neutral, $69 PO) highlighted key achievements in 2023 and provided a strategic outlook for 2024. The company noted the commercial performance of Jakafi in the first 9 months of 2023 and several readouts across the pipeline. Management highlighted their focus on expanding the opportunity in myeloproliferative neoplasms and chronic graft vs host disease (cGVHD). They noted the biologics license application for axatilimab in 3L+ cGVHD was submitted and they expect approval in 2024. Additionally, the company plans to: 1) initiate a phase 3 trial in combination with steroids and a phase 2 in combination with ruxolitinib both in 1L cGVHD in 2024, 2) initiate a phase 3 trial for BET inhibitor in combination with rux' in 2H, 3) provide proof of concept data for zilurgisertib in combination with rux' by mid-24 and 4) initiate a phase 1 study for the next generation JAK inhibitor, JAK2V617F, in 1Q.

On the dermatology pipeline, management noted the potential to expand the commercial opportunity for Opzelura into pediatric atopic dermatitis (2-3mn patients) with a supplemental new drug application expected by mid-24. Additionally, the company reported positive phase 2 data for rux' cream in hidradenitis suppurativa (HS). The company expect to present the data at a medical conference in 2024 and is evaluating next steps for a phase 3 trial. INCY is also evaluating povorcitinib in phase 3 trials in HS and extensive vitiligo, and has plans to initiate phase 3 trials in prurigo nodularis. On the commercial side, management commented they continue to see different dynamics in AD and vitiligo. Management noted the opportunity in vitiligo could eventually be the larger opportunity, but they continue to work on increasing uptake and compliance. On the oncology pipeline, the company highlighted initial clinical activity observed with a CDK2 (cyclin dependent kinase 2) in patients with amplified CCNE1 (cyclin E) with data expected in 2024. We are encouraged by several shots on goal from the pipeline but continue to look for clarity on the market opportunity in these different indications and reiterate that the Jakafi loss of exclusivity in 2028 continues to be an overhang on the stock. We look for guidance on the commercial outlook in 2024 including gross-to-net dynamics for Opzelura and the evolving competitive dynamics for Jakafi following the approval of Ojjaara before adjusting our estimates. We maintain our Neutral with $69 PO.

PTCT: Translarna CHMP final decision expected late-Jan

PTC Therapeutics (PTCT, Underperform, $20 PO) preannounced FY23 Translarna and Emflaza revenues of $355mn (ours: $353mn, cons: $345mn) and $255mn (ours: $254mn, cons: $246mn), respectively, as well as Evrysdi collaboration and royalty revenues of $278mn (ours: $312mn, cons: $181mn). We highlight the near-term focus for the company continues to be the Translarna EU CHMP (Committee for Medicinal Products for Human Use) re-examination for conditional marketing authorization renewal. The final decision is expected later this month with EC ratification 67-days later (likely in April). On a potential Translarna US approval, PTCT will meet with the FDA in 1Q as a last attempt to determine a potential NDA (new drug application) submission path. In addition to future EU Translarna revenues being uncertain, we note the upcoming Emflaza loss of exclusivity (LOE) in February is another major risk factor for 2024 revenues especially given Catalyst Pharmaceutical's (ticker: CPRX) Agamree was recently approved by the FDA. As such, management has provided a broad range for FY24 total revenue guidance of $600-850mn representing a negative CHMP opinion on the low end and a positive opinion on the high end. On pipeline, we highlight the company's portfolio still needs derisking with several upcoming regulatory meetings that will likely determine each program's next steps (see below for timing). We reiterate our Underperform rating with same $20 PO given our view that the numerous regulatory pressures for PTCT's commercial and pipeline franchises presents a bleak outlook with the lack of limited near-term upside.

Here we highlight key 2024 catalysts: **1) sepiapterin in phenylketonuria:** submit MAA (marketing authorization application) to the EMA (European Medicines Agency) in 1Q.

Management expects to submit an NDA to the FDA by no later than 3Q, **2) vatiquinone in Friedrich ataxia:** PTCT guides to a meeting with FDA in 1Q to determine a potential NDA submission path. On EU, the company seeks EMA feedback on a potential conditional marketing authorization submission in 1Q, **3)** interim 12-month data for the PIVOT-HD trial evaluating PTC518 in Huntington's disease in 2Q, **4)** submit BLA (biologics license application) to FDA in 1Q for Upstaza for the treatment of aromatic l-amino acid decarboxylase deficiency, and **5)** topline results for the phase 2 CardinALS trial evaluating utreloxastat in amyotrophic lateral sclerosis expected in 4Q.

In our DCF-based model, we roll the quarter and update for preannounced FY23 revenue numbers. We note we currently risk-adjust Translarna 2024+ EU revenues assigning a likelihood of success of 70% to the program. Additionally, we anticipate significant revenue impact for Emflaza LOE given recent competitor approval. Therefore, we now model FY24 total revenue of $574mn (Translarna: $265mn; Emflaza: $170mn) slightly below the low end of management guidance. We look for additional color on company revenue expectations on the official 4Q/FY23 earnings call. Lastly, we tweak our FY24 operating expenses in-line with management guidance of $740-835mn.

SAGE: Looking for initial launch metrics on Zurzuvae

Sage Therapeutics (SAGE, Neutral, $26 PO) highlighted progress in the launch of Zurzuvae in post-partum depression (PPD) and several readouts from the pipeline in 2024. Management highlighted Zurzuvae became commercially available in mid-December 2023 and they have achieved the first commercial sale, which entitled them to a $75mn milestone payment. The company continues to work with payors to optimize access to Zurzuvae. Management highlighted these conversations are going well as payors understand the unmet need in PPD and the value proposition for Zurzuvae. The company noted they are working on securing Zurzuvae access without the need for prior authorizations or step edits, and noted payors are focused on ensuring access is given to patients diagnosed with PPD. The company is also focused on improving treatment and diagnosis rates as <50% of patients are diagnosed and less are treated. We think positive commentary on payor negotiations are a step in the right direction, but we continue to look for initial launch metrics and more color on access and treatment rates in the real world to understand the long-term potential to expand the addressable patient population. We reiterate our Neutral with new $26 PO.

Management also highlighted several expected readouts for the pipeline in 2024. For dalzanemdor (SAGE-718), the company expected to present topline phase 2 data from: 1) PRECEDENT study in mild cognitive impairment associated (MCI) with Parkinson's disease in early-24 (Q1/Q2), 2) SURVEYOR study in Huntington's disease (HD) cognitive impairment in mid-24 (Q2/Q3), 3) LIGHTWAVE study in MCI and mild dementia due to Alzheimer's disease in late/24 (Q3/Q4) and 4) DIMENTION study in HD cognitive impairment in late-24. Additionally, management highlighted they expect to report topline data for the phase 2b KINECT2 study evaluating SAGE-324 in essential tremor in mid-24. The company commented that results from KINECT2 will inform the dose for a potential phase 3 trial. Management also highlighted the early-stage pipeline with SAGE 319 with potential in neurodevelopmental/motor disorders and SAGE-421 with potential in cognitive impairment and schizophrenia. In our DCF-based model, we roll the quarter and increase our pipeline value to $400mn (prev. $200mn) given several pipeline readouts with potential in large indications expected in 2024. These changes result in our new $26 PO (prev. $22).

Exhibit 2: Estimate changes in this report
Summary of estimate changes in this report

Ticker	PTCT		SAGE		SRPT	
Rating	C39		C29		C19	
Price	$29.99		$25.10		$102.61	
Estimates	Prev.	Current	Prev.	Current	Prev.	Current
Price Obj.	$20	$20	$22	$26	$164	$164
2023E EPS	-2.92	-3.08	-9.35	-9.23	-8.80	-7.58
2024E EPS	-6.17	-5.79	-6.71	-4.84	0.66	0.67
2025E EPS	-5.61	-5.61	-2.35	-0.71	13.43	13.37

Exhibit 3: Companies mentioned in this report
Summary of tickers mentioned in this report

Ticker	Company name	Rating	Price	Price Obj.
INCY	Incyte Corporation	B29	$65.82	$69
PTCT	PTC Therapeutics	C39	$29.99	$20
SAGE	SAGE Therapeutics	C29	$25.10	$26
SRPT	Sarepta Therapeutics	C19	$102.61	$164

Source: BofA Global Research, Bloomberg

BofA GLOBAL RESEARCH

Price objective basis & risk

Incyte Corporation (INCY)

Our PO of $69 for INCY consists of $43/share for Jakafi/Jakavi, $18/share for Ruxolitinib cream, $3/share for Pemazyre, -$2/share for Monjuvi, $4/share for Olumiant royalty, $0.2/share for Iclusig, $1/share for Tabrecta royalty, -$14/share for pipeline, and the remainder in net cash. We apply a weighted-average cost of capital (WACC) of 9% for commercial-stage assets, 10% for late-stage clinical pipeline, and 11% for earlier-stage clinical pipeline with no terminal value.

Upside risks to our PO are 1) positive data from clinical trials in the pipeline, 2) better than expected results from its marketed assets, 3) additional updates from early-stage assets.

Downside risks to our PO are 1) failure of Jakafi or Opzelura to meet our estimates, 2) business development events that investors view negatively, or 3) negative data in clinical trials.

PTC Therapeutics (PTCT)

Our $20 price objective for PTC reflects $8 for Translarna in DMD, $7 for Evrysdi in SMA, $3 for Emflaza, $8 for GT-AADC, $5 for PKU, and the remainder of our valuation is cash and pipeline spend. We use an 10% WACC for Translarna, a 9% WACC for Emflaza and Evrysdi, and an 10% WACC for Upstaza (PCT-AADC) and sepiapterin, consistent with how we model drugs in similar stage of development. We attach a 14% WACC to the early-stage pipeline pending presentation of data. We assume zero terminal value for all products, also consistent with our valuation of other covered companies.

Downside risks to our price objective are removal of the EU approval for Translarna in DMD, failure to receive approval for Translarna in the US, and slower than expected uptake for Evrysdi in SMA and Upstaza in AADC deficiency.

Upside risks to our price objective are faster-than-expected uptake of Evrysdi in SMA, higher Emflaza or Translarna sales than expected, US approval for DMD, and a successful AADC launch.

SAGE Therapeutics (SAGE)
Our discounted cash flow (DCF)-derived PO of $26 for SAGE consists of $2/share for Zulresso in PPD. Zuranolone contributes $7/share to our PO for PPD and $4/share in MDD. The remaining value in our PO comes from cash ($14/sh), corporate expenses (-$11/sh) and milestones ($2/sh). We use a 9% weighted-average cost of capital (WACC) for Zulresso, a 9% WACC for Zuranolone in PPD, and 11% WACC in MDD, and assume no terminal value for SAGE.

Upside risks to our price objective are 1) approval of zuranolone in MDD, 2) higher-than-expected penetration of zuranolone in PPD and MDD, and 3) positive data from early stage assets.

Downside risks are 1) failure of Zuranolone in MDD, 2) failure of other clinical programs, and 3) lower-than-expected penetration of zuranolone and Zulresso

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.

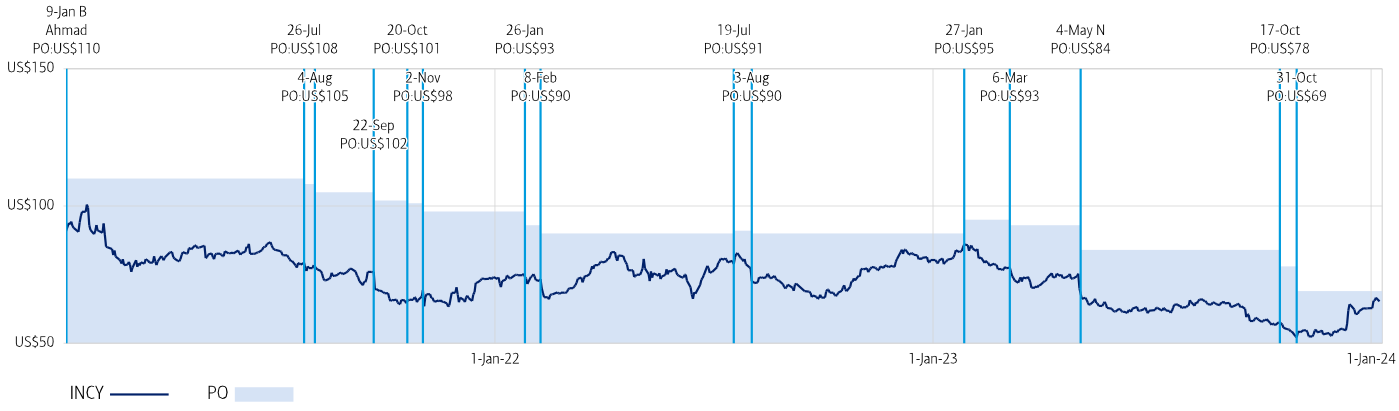
US - Biotechnology Coverage Cluster

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

Disclosures

Important Disclosures

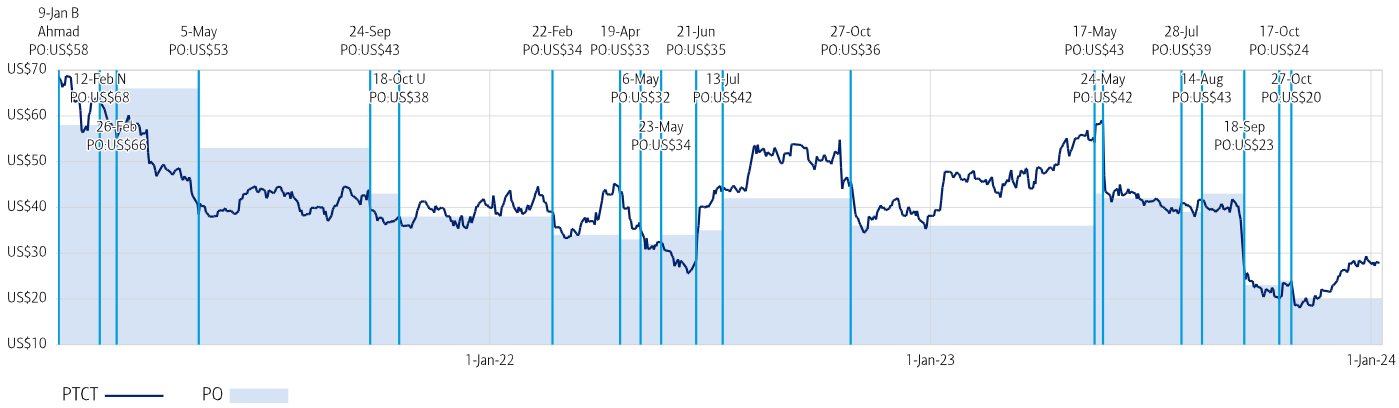
Incyte (INCY) Price Chart



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.

PTC Therapeutics (PTCT) Price Chart



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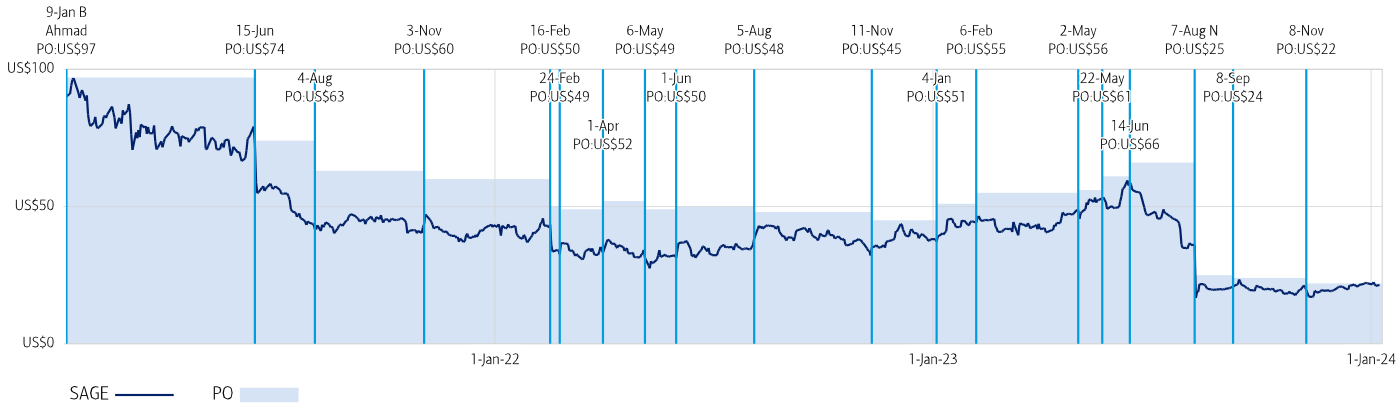
SAGE Therapeutics (SAGE) Price Chart



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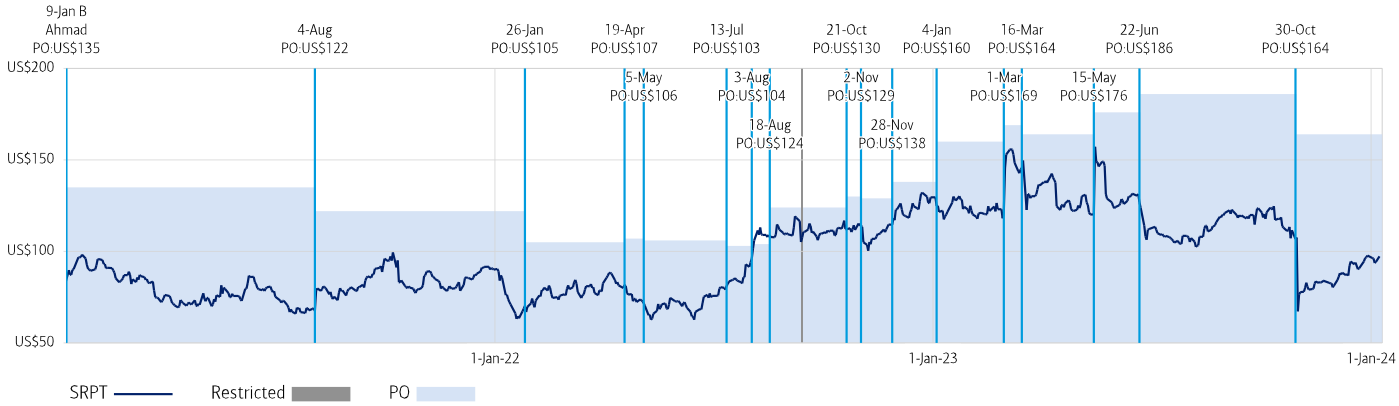
Sarepta (SRPT) Price Chart



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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%

[R1] Issuers that were investment banking clients of BofA Securities or one of its affiliates within the past 12 months. For purposes of this Investment Rating Distribution, the coverage universe includes only stocks. A stock rated Neutral is included as a Hold, and a stock rated Underperform is included as a Sell.

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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]
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Neutral	≥ 0%	≤ 30%
Underperform	N/A	≥ 20%

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