BofA SECURITIES

Biotechnology

SMid Biotech FY23 preannouncement: ALNY, ASND, BCRX, FOLD, PHVS and RARE

Price Objective Change

ASND: Raising our PO on GHD launch strength

Ascendis Pharma (ASND, Buy, $145 PO) preannounced preliminary 4Q Skytrofa revenue of €64mn (+33% q/q) well ahead of BofA and street estimates (ours: €57.1mn, cons: €57.6mn). Management expects the strong growth to continue in 2024 guiding to FY24 Skytrofa revenue of €320-340mn. We are encouraged by the company's strong 2024 outlook for Skytrofa and raise our US/EU peak penetration estimates to 30%/25% (prev. 25%/20%) given continued positive feedback from our KOLs (key opinion leaders). We now estimate FY24 and peak risk adjusted Skytrofa sales of €325mn and €829mn, respectively. On Yorvipath (TransCon PTH), management continues to guide to a January launch in Germany utilizing their existing EU Skytrofa salesforce. Additionally, the company cites high focus on May 14th PDUFA (prescription drug user fee act) action date for US approval. If positive, ASND will be ready to go to begin a US commercial launch in 3Q24. We assume an 80% likelihood of US approval and model FY24 risk-adjusted sales of €96.6mn (cons: €81mn). We continue to be encouraged by the company's commercial performance with Skytrofa and think the company is well positioned to capitalize on a relatively untapped hypoparathyroidism market. We reiterate our Buy rating with $145 PO (prev. $129; see model changes below).

Here we highlight other key 2024 catalysts: 1) management expects to submit a sBLA (supplementary Biologics License Application) for Skytrofa usage in adult growth hormone deficient (GHD) patients in 2Q, 2) topline results for the phase 3 ApproaCH trial evaluating TransCon CNP in achondroplasia are expected to readout in 4Q. ASND expects to submit an NDA (New Drug Application) for pediatric achondroplasia patients in 4Q. The company also expects to submit an IND application in 4Q to evaluate TransCon CNP in adult achondroplasia patients, 3) COACH trial (TransCon hGH / TransCon CNP combination) topline results in 4Q, 4) topline results for the phase 3 trial evaluating TransCon hGH in Turner syndrome in 4Q, 5) complete enrollment in 4Q for the phase 2 BelieveIT-202 trial (advanced head and neck squamous cell carcinoma), 6) provide a clinical update in 4Q on the phase 2 IL-Believe trial (solid tumors), and 7) create a spinout ophthalmology focused company in 1Q. We also highlight the company entered in an exclusive licensing agreement with Teijin Limited for TransCon hGH, PTH and CNP in Japan in 4Q23.

In our DCF-based model, we roll the quarter and update for preannounced 4Q23 Skytrofa revenues. We also adjust our 2024 operating expense estimates in-line with management guidance (~€600mn based on 2023 exchange rates).

See inside for details on Alnylam Pharmaceuticals (ALNY), Biocryst Pharmaceuticals (BCRX), Amicus Therapeutics (FOLD), Pharvaris (PHVS) and Ultragenyx Pharmaceuitcals (RARE).

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

Ticker	Previous	Current
ASND	$129	$145
RARE	$84	$85

Source: BofA Global Research
BofA GLOBAL RESEARCH

See Exhibit 2 and 3 on page 4 for estimate changes

ALNY: FY23 ATTR franchise revenues of $913mn

Alnylam (ALNY, Buy, $246 PO) preannounced FY23 revenues for Onpattro of $355mn (-36% y/y, ours: $348mn, cons: $360mn), Amvuttra of $558mn (+595% y/y, ours: $550mn, cons: $551mn), Givlaari of $219mn(+26% y/y, ours: $220mn, cons: $222mn) and Oxlumo of $110mn (+58% y/y, ours: $113mn, cons: $108mn). The company also noted cash and cash equivalents at the end of 2023 were ~$2.4bn. Management highlighted strong commercial execution in 2023 and reiterated the readouts of the phase 3 HELIOS-B trials evaluating vutrisiran in transthyretin amyloidosis (ATTR) cardiomyopathy are expected in early-24. In our DCF-based model, we roll the quarter and adjust our FY23 estimates accordingly. We look for additional commentary on FY24 revenue guidance before adjusting our estimates. We currently model FY24 revenues of $852mn for Amvuttra and $213mn for Onpattro. Recall, management has commented they expect FY24 Onpattro revenues to be $200-225mn. We continue to be encouraged by the strong commercial performance of the ATTR franchise and the rest of the portfolio and highlight focus remains on the highly anticipated HELIOS-B readout.

BCRX: 2024 Orladeyo guide indicates $690mn peak sales could be low

Biocryst Pharmaceuticals (BCRX, Buy, $11 PO) preannounced 4Q and FY23 Orladeyo revenues of $89.9mn (+5% q/q, ours: $86.2mn, cons: $86.6mn) and $325mn (+29% y/y, ours: $321.3mn, cons: $315.3mn), respectively. Management continues to target $1bn in peak sales for Orladeyo by the turn of the decade and expects to turn cash flow positive by 2026. BCRX provided FY24 revenue guidance of $380-400mn; as such, we now model FY24 Orladeyo revenues of $390mn. We highlight BCRX expects seasonal impacts for 1Q24 revenues similar to years past due to prescription reauthorizations and Inflation Reduction Act impacts. We continue to view the Orladeyo launch positively but think the $1bn peak sales number still needs additional valuation from future sales trends. We currently model peak sales of $692mn in 2029. We reiterate our Buy with $11 PO given our continued view that our peak sales estimate does not require outsized future growth.

In our DCF-based model we roll the quarter and adjust our 4Q23 Orladeyo estimates in-line with preannounced numbers. On 2024 operating expense expectations, management guides to $20mn less spend for R&D and $20mn more spend for SG&A relative to 2023 resulting in a flat y/y total operating expense spend. We adjust our 2024 operating expense estimates in-line with management guidance.

FOLD: FY24 Galafold growth of 11-16%

Amicus Therapeutics (FOLD, Buy, $19 PO) preannounced FY23 revenues for Galafold of ~$387.8mn (+21% y/y, ours: $3852mn, cons: $386mn) and Pombiliti+Opfolda (P&O) of ~$11.6mn (ours: $10.1mn, cons: $10mn). The company also provided FY24 guidance for Galafold of 11-16% growth at constant exchange rate and highlighted their focus on the ongoing launch of P&O and achieving non-GAAP profitability in 2024. We will look for additional color on key growth drivers for Galafold in 2024 and expectations for the launch of P&O in Pompe disease. In our DCF-based model, we roll the quarter and adjust our 4Q23 estimates. We now model FY24 Galafold revenues of $439mn (+13% y/y) in-line with guidance and FY24 P&O revenues of $112.8mn. We remain encouraged by the continued growth of Galafold and initial positive metrics for the P&O launch in Pompe disease. We reiterate our Buy with $19 PO.

PHVS: Focus on US prophy clinical hold resolution

Pharvaris (PHVS, Underperform, $11 PO) provided an updated 2024 strategic outlook. Recall, the company presented phase 2 topline results in December for the CHAPER-1 study evaluating deucrictibant (instant release formulation) as a prophylactic treatment for hereditary angioedema (HAE; see our initial take). While we were encouraged by the trial achieving its primary endpoint showing a placebo-adjusted monthly HAE attack reduction of 84.5% (p-val=0.0008), we continue to view the ongoing US clinical hold for the prophy program as a significant stock overhang. PHVS reports

the 26-week nonclinical study was submitted to the FDA but the timing for potential resolution remains unclear. For the on-demand program, PHVS expects to initiate the phase 3 RAPIDe-3 study in 1H24. We note the on-demand market is smaller than the prophylaxis market, and as such, our investment thesis largely focuses on the prophylaxis program. Management also announced the $300mn underwritten offering closed, extending the company's cash runway for at least 2 years. We maintain our Underperform rating with $11 PO as we await updates regarding the US prophy clinical hold.

RARE: Focus on 2024 late-stage pipeline readouts

Ultragenyx Pharmaceuticals (RARE, Buy, $85 PO) reported preliminary FY23 total revenue of $430-435mn including Crysvita revenue of $325-330mn (+17% y/y, ours: $328.7mn, cons: $305.9mn) and Dojolvi revenue of $70-71mn (+27% y/y, ours: $70.9mn, cons: $20.2mn). The company also noted cash and cash equivalents at the end of 2023 were ~$776mn. For FY24, management provided total revenue guidance of $500-530mn, Crysvita guidance of $375-400mn and Dojolvi guidance of $75-80mn. We continue to be encouraged by the company's commercial performance and view RARE as a market leader in the rare disease space. We highlight RARE as one of our top picks of 2024 with high potential for future upside given several late-stage pipeline readouts expected within the next 12-months: **1) Angelman syndrome:** management expects to provide a phase 2 data update for at least 20 expansion cohort patients in 1H. We also look for color on ongoing regulatory discussions regarding a pivotal phase 3 trial design. **2) osteogenesis imperfecta:** the company expects to complete phase 3 enrollment in 1Q and will also provide additional phase 2 data later in 2024, **3) gene therapy franchise:** RARE guides to interim Stage 1 data evaluating UX701 in Wilson disease in 1H, phase 3 data evaluating DTX401 in glycogen storage disease type Ia in 1H and updated Transfer A data evaluating UX111 in Sanfilippo syndrome at WORLDSymposium in February. The company also expects to complete enrollment for the phase 3 trial evaluating DTX301 in ornithine transcarbamylase deficiency in 1H. We reiterate our Buy with $85 PO (prev. $84) ahead of a catalyst rich 2024.

In our DCF-based model, we roll the quarter, adjust our 4Q23 revenue estimates in-line with preannounced ranges and update cash. We currently model FY24 Crysvita and Dojolvi revenue of $380mn and $77mn, respectively, in-line with company guidance. We also tweak operating expenses in line with trend.

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

Ticker	ALNY		ASND		BCRX		FOLD	
Rating	B19		C19		C19		C19	
Price	$189.38		$129.72		$6.09		$13.52	
Estimates	Prev.	Current	Prev.	Current	Prev.	Current	Prev.	Current
Price Obj.	$246	$246	$129	$145	$11	$11	$19	$19
2023E EPS	-4.13	-4.06	-9.35	-9.23	-1.03	-1.01	-0.42	-0.41
2024E EPS	-6.07	-6.08	-6.71	-4.84	-0.77	-0.68	0.16	0.10
2025E EPS	-0.63	-0.63	-2.35	-0.71	-0.45	-0.42	0.77	0.74

Ticker	RARE	
Rating	C19	
Price	$47.60	
Estimates	Prev.	Current
Price Obj.	$84	$85
2023E EPS	-9.24	-9.22
2024E EPS	-8.55	-8.95
2025E EPS	-7.59	-8.00

Source: BofA Global Research estimates, Bloomberg

BofA GLOBAL RESEARCH

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

Ticker	Company name	Rating	Price	Price Obj.
ALNY	Alnylam Pharmaceuticals Inc	B19	$189.38	$246
ASND	Ascendis Pharma A/S	C19	$129.72	$145
BCRX	BioCryst Pharmaceuticals Inc	C19	$6.09	$11
FOLD	Amicus Therapeutics Inc	C19	$13.52	$19
PHVS	Pharvaris NV	C39	$25.00	$11
RARE	Ultragenyx Pharmaceutical Inc	C19	$47.60	$85

Source: BofA Global Research, Bloomberg

BofA GLOBAL RESEARCH

Price objective basis & risk

Alnylam Pharmaceuticals (ALNY)

Our PO of $246 for ALNY consists of $4/share for Onpattro, $120/share for Vutrisiran, $25/share for Givlaari and Lumasiran, $6/share for Leqvio, $7/share for Fitusiran, $20/share for ALN-AGT, $52/sh for other pipeline and partnered assets and $11/sh for net cash. We apply a WACC of 9% for commercial-stage assets, 10% for Vutrisiran in ATTR-CM, 10% for other late stage pipeline, and 11% for ALN-AGT.

Upside risks to our PO are 1) better-than-expected uptake of its marketed stage assets, 2) approval of Onpattro and Vutrisiran in ATTR cardiomyopathy, 3) early-stage pipeline advancing into late-stage development, and 4) positive results from partnered programs.

Downside risks to our PO are 1) slower-than-expected uptake of commercial assets, 2) unexpected safety in its siRNA-based assets, and 3) higher-than-expected expenses.

Amicus Therapeutics (FOLD)

We use a sum of the parts DCF valuation to arrive at our $19 price objective (PO) for Amicus Therapeutics (FOLD). We value lead asset migalastat Galafold at $10/share using a WACC of 9%, similar to how we value other assets in similar stages of development. Pombiliti in Pompe contributes $11/sh to our DCF derived PO. We value Pombiliti using a 9% WACC. The remainder of our valuation comes from the pipeline and cash,

contributing -$2 to our PO. Our DCF goes out to 2035 and we use a zero terminal value, consistent with how we value other companies.

Upside risks to our PO are 1) stronger than expected sales of migalastat in the US, 2) identification of additional amenable mutations treatable by migalastat, 3) stronger than expected launch for Pombiliti, and 5) durability and efficacy data from the early stage gene therapy programs.

Downside risks to our PO are 1) failure of one or more of FOLD's products to reach the market, 2) slower than expected uptake for migalastat, 3) better than expected success for competing marketed and development stage drugs.

Ascendis Pharma (ASND)
Our $145 price objective for ASND includes $51 for TransCon GH, $82 for TransCon PTH, $9 for oncology assets, and the remainder of value coming from net cash and pipeline. We use a 9% weighted-average cost of capital (WACC) for GH and 10% WACC for PTH, consistent with how we model other drugs in a similar development stage. We assume zero terminal value for all products, also consistent with our valuation of other covered companies.

Risks to our price objective are slower TransCon GH sales, higher-than-expected competition from other long-acting therapies, failure of PTH to advance to commercialization and pushback on pricing from payors.

Biocryst Pharmaceuticals Inc (BCRX)
Our DCF-derived PO of $11 is comprised of $12/share for Orladeyo in preventing HAE attacks, pipeline/corporate expenses, and net cash. We assume a 9% WACC for Orladeyo and 14% WACC for pipeline expenses. We assume no terminal value.

Upside risks to our price objective are 1) Orladeyo uptake faster than we expect, 2) failure of competitor products in development for HAE, 3) increased government funding, and 4) positive outcome from BCX10013 in PNH, C3G and other complement-mediated diseases.

Downside risks to our price objective are 1) slower-than-expected Orladeyo market penetration, 2) high discontinuation rate of Orladeyo, 3) unexpected long term safety concerns, 4) stronger preference for competing products including Takhzyro, and 5) failure of pipeline products, such as BCX10013 in PNH.

Pharvaris (PHVS)
Our $11 PO is based on our DCF-based valuation with $8/sh assigned to HAE programs in both prophylaxis and acute on-demand settings. The remainder of our valuation comes from pipeline and corporate expenses, and cash. Our assumptions are based on 12% WACC for the acute on-demand program and prophylaxis program, 6% COGS, 15-20% GTN, and 10%-20% peak penetrations in target indications.

Upside risks to our price objective are: 1) positive data and additional validation in HAE, 2) superior efficacy or safety profile compared to standard of care or other competitors in the pipeline, 3) pipeline expansion to other indications outside of HAE.

Downside risks are: 1) failure to show efficacy in HAE, 2) unexpected side effect, 3) inferior efficacy or safety profile compared to standard of care or other competitors, and 4) competitors entry in HAE.

Ultragenyx Pharmaceuticals (RARE)
Our DCF-derived PO of $85 for RARE consists of $10/share for Dojolvi in LC-FAOD, $20/share for Crysvita in XLH and TIO, $0.5/share for Mepsevii in MPS7, $16/share for

Angelman, $43/share for gene therapy assets and the remainder for cash and RARE's pipeline. We use a 9% WACC for approved products, 11-12% for clinical-stage products, such as gene therapy programs.

Upside risks to our price objective are: 1) better than expected uptake for its approved products, 2) positive data for clinical stage assets, and 3) accelerated approval for its drug candidates.

Downside risks are: 1) low penetration into rare disease populations, 2) negative data for clinical stage assets, 3) unexpected safety risks associated with clinical stage drug candidates, 4) unexpected generic competition.

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

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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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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