

Amicus Therapeutics

2024 focus on maximizing Pompe patients on Pombiliti+Opfolda; Reiterate Buy

Reiterate Rating: BUY | PO: 16.00 USD | Price: 12.88 USD

FOLD reiterates Galafold growth guidance of 11-16%

Amicus (FOLD) reported 4Q revenues of \$106.6mn for Galafold and \$8.5mn for Pombiliti+Opfolda (P&O) in-line with preannouncement. The company reiterated their 2024 Galafold revenue growth guidance of 11-16% at constant exchange rate. Management highlighted they expect continued increased diagnosis and treatment rates will continue to drive growth of Galafold. The company highlighted they currently have 60-65% market share of amenable patients but noted in mature markets they have been able to capture 80-90%. They continue to see high compliance rates of >90% and highlighted strong uptake in treatment-naïve patients. Additionally, FOLD highlighted they expect to reach full year non-GAAP profitability in 2024. We are encouraged by the strong commercial performance of Galafold and positive early metrics for the P&O launch in late-onset Pompe disease (LOPD). We reiterate our Buy with \$16 PO.

Positive early metrics for the P&O launch in LOPD

On the P&O launch, management reiterated ~120 patients were being treated or awaiting treatment in early January and they continue to see strong demand in the US, UK and Germany. Recall, 105 were clinical trial and early access patients with the remainder being treatment-naïve or switches. The company highlighted they continue to see positive dynamics in terms of patients switching from all existing treatments as well as treatment-naïve patients. They noted they estimate ~50% of patients are stable and 25% of patients are declining on current treatment, which represents a large commercial opportunity for P&O. The company expects to continue expanding the commercial opportunity for P&O with >10 regulatory submissions expected in 2024. In terms of reimbursement, management commented P&O has already been added to formulary by large payors and they continue to see expanded coverage including Medicare and Medicaid. We see these early metrics positively and await further color on the cadence of new patients added in 2024.

Model changes

In our DCF-based model, we update for FY23 results, cash and share count. We also adjust our 2024 quarterly revenue estimates and adjust the ex-US price for P&O to \$380K (prev. \$455K) and 20% gross-to-net in the US based on management commentary. We also lower our operating expense estimates based on company guidance and lower our peak Galafold estimates based on cadence of the launch. These changes result in our new \$16 PO (prev. \$19). We currently model 2024 Galafold sales of \$440mn (+13% y/y) and 2024 P&O sales of \$99mn.

Estimates (Dec) (US\$)	2022A	2023A	2024E	2025E	2026E
EPS	(0.82)	(0.51)	(0.09)	0.31	0.78
EPS Change (YoY)	10.9%	37.8%	82.4%	NM	151.6%
Consensus EPS (Bloomberg)			0.15	0.69	1.23
DPS	0	0	0	0	0
Valuation (Dec)					
P/E	NM	NM	NM	41.5x	16.5x
EV / EBITDA*	NM	NM	106.5x	23.3x	12.0x
Free Cash Flow Yield*	-4.5%	-1.7%	1.7%	5.0%	8.9%

* For full definitions of *IQmethod*SM measures, see page 4.

28 February 2024

Equity

Key Changes

(US\$)	Previous	Current
Price Obj.	19.00	16.00
2024E Rev (m)	552.0	538.4
2025E Rev (m)	758.9	679.5
2026E Rev (m)	NA	842.5
2024E EPS	0.10	-0.09
2025E EPS	0.74	0.31
2026E EPS	NA	0.78

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Stock Data

Price	12.88 USD
Price Objective	16.00 USD
Date Established	28-Feb-2024
Investment Opinion	C-1-9
52-Week Range	9.70 USD - 14.57 USD
Mkt Val (mn) / Shares Out (mn)	3,802 USD / 295.2
Free Float	98.7%
Average Daily Value (mn)	38.18 USD
BofA Ticker / Exchange	FOLD / NAS
Bloomberg / Reuters	FOLD US / FOLD.OQ
ROE (2024E)	-5.7%
Net Dbt to Eqty (Dec-2023A)	-38.1%
ESGMeter TM	Medium

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iQprofileSM Amicus Therapeutics

iQmethodSM – Bus Performance*

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Return on Capital Employed	-28.0%	-12.0%	5.8%	21.4%	29.3%
Return on Equity	-109.9%	-55.5%	-5.7%	15.7%	27.5%
Operating Margin	-64.4%	-19.3%	4.7%	21.3%	34.4%
Free Cash Flow	(170)	(64)	66	190	340

iQmethodSM – Quality of Earnings*

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Cash Realization Ratio	NM	NM	NM	2.1x	1.4x
Asset Replacement Ratio	0.7x	0.6x	0.6x	0.6x	0.6x
Tax Rate	2.3%	NM	8.5%	NM	NM
Net Debt-to-Equity Ratio	-120.9%	-38.1%	-54.0%	-69.3%	-80.1%
Interest Cover	-5.7x	-1.5x	0.5x	3.0x	5.9x

Income Statement Data (Dec)

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Sales	329	399	538	679	843
% Change	7.8%	21.3%	34.8%	26.2%	24.0%
Gross Profit	291	362	468	593	739
% Change	7.2%	24.6%	29.3%	26.6%	24.6%
EBITDA	(207)	(69)	34	154	299
% Change	-3.3%	66.5%	NM	357.6%	94.6%
Net Interest & Other Income	(30)	(73)	(54)	(54)	(55)
Net Income (Adjusted)	(237)	(152)	(26)	93	238
% Change	5.5%	35.9%	82.8%	NM	155.1%

Free Cash Flow Data (Dec)

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Net Income from Cont Operations (GAAP)	(237)	(152)	(26)	93	238
Depreciation & Amortization	5	8	8	9	9
Change in Working Capital	(40)	(3)	(4)	(4)	(5)
Deferred Taxation Charge	NA	NA	NA	NA	NA
Other Adjustments, Net	105	88	93	98	103
Capital Expenditure	(4)	(5)	(5)	(5)	(5)
Free Cash Flow	-170	-64	66	190	340
% Change	17.5%	62.4%	NM	187.2%	78.4%
Share / Issue Repurchase	(11)	0	0	0	0
Cost of Dividends Paid	0	0	0	0	0
Change in Debt	4	14	14	14	14

Balance Sheet Data (Dec)

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Cash & Equivalents	149	161	268	480	833
Trade Receivables	66	73	80	88	97
Other Current Assets	209	138	103	86	78
Property, Plant & Equipment	31	10	10	10	10
Other Non-Current Assets	270	222	222	222	222
Total Assets	724	603	682	885	1,239
Short-Term Debt	0	0	0	0	0
Other Current Liabilities	139	136	141	147	152
Long-Term Debt	0	0	0	0	0
Other Non-Current Liabilities	462	44	45	46	47
Total Liabilities	601	180	186	193	199
Total Equity	123	423	495	692	1,040
Total Equity & Liabilities	724	603	682	885	1,239

* For full definitions of iQmethodSM measures, see page 4.

Company Sector

Biotechnology

Company Description

Amicus is an orphan disease focused biotechnology company based in Cranbury, New Jersey, with assets in late stages of development. Lead assets are Galafold, an oral small molecule for the treatment of Fabry disease, and Pombiliti+Opfoda, an enzyme replacement therapy, for the treatment of late-onset Pompe disease.

Investment Rationale

We rate FOLD shares Buy. The company's lead asset migalastat is the first oral small molecule for the treatment of Fabry disease where standard of care intravenous (IV) enzyme replacement therapy (ERT) represents a >\$1bn market. Migalastat is currently marketed in the US and EU. Pombiliti+Opfoda was also approved for the treatment of late-onset Pompe disease representing another potential \$1bn opportunity.

Stock Data

Average Daily Volume 2,964,595

Quarterly Earnings Estimates

	2023	2024
Q1	-0.18A	-0.07E
Q2	-0.15A	-0.04E
Q3	-0.07A	0E
Q4	-0.11A	0.03E

Price objective basis & risk

Amicus Therapeutics (FOLD)

We use a sum of the parts DCF valuation to arrive at our \$16 price objective (PO) for Amicus Therapeutics (FOLD). We value lead asset migalastat Galafold at \$8/share using a WACC of 9%, similar to how we value other assets in similar stages of development. Pombiliti in Pompe contributes \$8/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.

Analyst Certification

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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
	Ocular Therapeutix	OCUL	OCUL US	Tazeen Ahmad
	PepGen Inc	PEPG	PEPG 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
	Prothena Corporation	PRTA	PRTA US	Tazeen Ahmad
	SAGE Therapeutics	SAGE	SAGE US	Tazeen Ahmad



US - Biotechnology Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
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

iQ^{method}™ Measures Definitions**Business Performance**

Return On Capital Employed

Return On Equity
Operating Margin
Earnings Growth
Free Cash Flow

Quality of Earnings

Cash Realization Ratio
Asset Replacement Ratio
Tax Rate
Net Debt-To-Equity Ratio
Interest Cover

Valuation Toolkit

Price / Earnings Ratio
Price / Book Value
Dividend Yield
Free Cash Flow Yield
Enterprise Value / Sales

EV / EBITDA

Numerator

NOPAT = (EBIT + Interest Income) × (1 – Tax Rate) + Goodwill Amortization

Net Income
Operating Profit
Expected 5 Year CAGR From Latest Actual
Cash Flow From Operations – Total Capex

Numerator

Cash Flow From Operations
Capex
Tax Charge
Net Debt = Total Debt – Cash & Equivalents
EBIT

Numerator

Current Share Price
Current Share Price
Annualised Declared Cash Dividend
Cash Flow From Operations – Total Capex
EV = Current Share Price × Current Shares + Minority Equity + Net Debt + Other LT Liabilities
Enterprise Value

Denominator

Total Assets – Current Liabilities + ST Debt + Accumulated Goodwill
Amortization
Shareholders' Equity
Sales
N/A
N/A

Denominator

Net Income
Depreciation
Pre-Tax Income
Total Equity
Interest Expense

Denominator

Diluted Earnings Per Share (Basis As Specified)
Shareholders' Equity / Current Basic Shares
Current Share Price
Market Cap = Current Share Price × Current Basic Shares
Sales
Basic EBIT + Depreciation + Amortization

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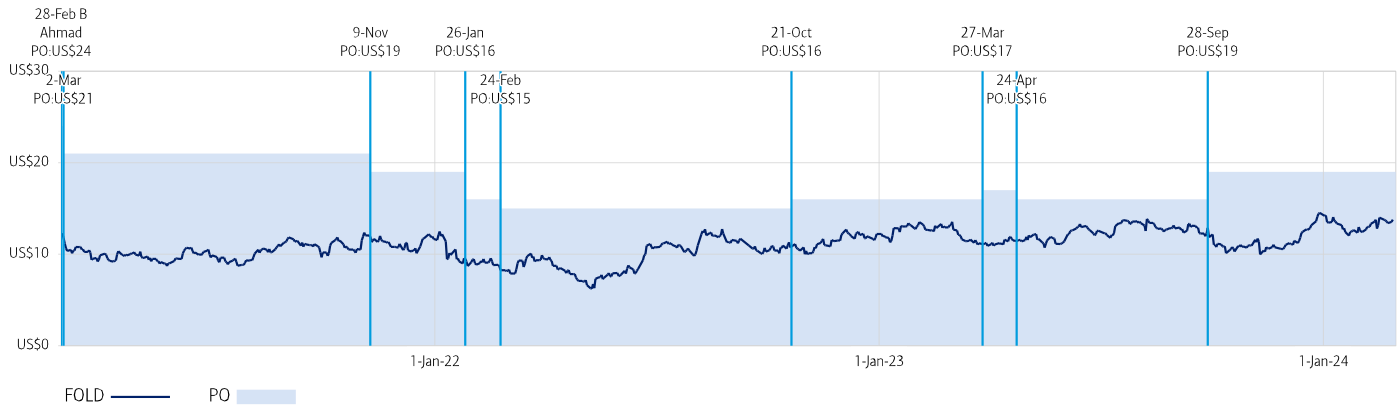
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Amicus Therapeutics (FOLD) Price Chart



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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}
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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