



Amicus Therapeutics

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Agenda

- Company Overview
- Product and Disease Overview
- Highlights & Pipeline Strategy
- Market Projections
- 2024 Financial Overview
- SWOT Analysis
- Ratio Analysis
- Price-to-Sales Multiple
- DCF Valuation
- Portfolio Analysis
- Recommendation

Executive Summary

- Recommending Seger Fund buys ~\$15k worth of shares of FOLD to make a position of ~4.5% of portfolio using funds currently in benchmark (Russell 2000)
- We believe Amicus Therapeutics (FOLD) has significant potential upside considering growth factors of industry, consistent and continued revenue growth of products, and undervaluation of FOLD based on DCF Model and Price-to-Sales multiple

Company Overview

A biotech-pharmaceutical company focused on the creation of medicines for rare diseases, delivering therapies that have potential to obsolete current treatments, provide significant benefits to patients, and be best-in-class.

- **Galafold**[®] (migalastat) is approved in over 40 countries around the world, including the US, EU, UK, and Japan, and has also been granted orphan drug designation. It's the first oral monotherapy for people living with **Fabry disease**.
- **Pombiliti**[™] + **Opfolda**[™] is a treatment for adults living with **Pompe disease** and was approved in 2023 in the US, EU, and the UK. Multiple regulatory submissions and reimbursement processes with global health authorities are currently underway. And, like Galafold, it has been granted orphan drug designation in the US, EU, UK, Japan and several other countries.

Offices Located in...
US – Australia – Canada
France – Germany
Switzerland
Ireland – Italy – Japan
Netherlands
Spain – Portugal

Galafold Treating Fabry Disease

Galafold® (migalastat HCl) for Fabry Disease

- ▶ Galafold was granted accelerated approval by the FDA in August 2018 for the treatment of adults with a confirmed diagnosis of Fabry disease and an amenable galacto-alpha gene variant based on in-vitro data. Galafold was approved in the E.U. and U.K. in May 2016 as a first-line therapy for long-term treatment of adults and adolescents. Marketing authorization approvals as well as approvals for adolescents within range have been granted in over 40 countries around the world.
- ▶ They plan to continue to launch Galafold® in additional countries, including for adolescents. Galafold is designed to bind to and stabilize an endogenous alpha-Gal A enzyme in those patients with genetic variants identified as amenable in a Good Laboratory Practice cell-based amenability assay.

Pombiliti + Opfolda Treating Pompe Disease

Pombiliti™ + Opfolda™ for Pompe Disease

- ▶ New using these drugs treatments received regulatory approval from the European Commission in June 2023, the UK's MHRA in August 2023, and the FDA in September 2023, with additional submissions for reimbursement underway.
- ▶ Pombiliti + Opfolda includes a specially engineered enzyme designed for better uptake in the lysosomes, combined with miglustat, which binds to and stabilizes enzymes reducing inactivation of the glyco-protein in the bloodstream to improve the uptake of the active enzyme into the diseased tissues.
- ▶ In addition, clinical studies are ongoing in pediatric patients for both the late-onset Pompe disease and infantile-onset Pompe disease populations.

Ongoing Clinical Patents

Amicus holds rights to patents and numerous global applications related to Galafold, Opfolda + Pombiliti, and their clinical programs.

- ▶ They hold patents for migalastat, the main ingredient in Galafold, used to treat Fabry disease. These patents will expire between 2027 and 2042 and are listed in the FDA Orange Book.
- ▶ They also have several U.S. patents for Opfolda + Pombiliti, a combo treatment for Pompe, which will expire between 2033 and 2037.
- ▶ They have patent applications and extensions on various aspects, which, if granted, will expire between 2033 and 2043.

Highlights & Pipeline Strategy

- ▶ **Fabry Success:** In 2023, Galafold generated \$387.8 million in revenue, an increase of \$58.7 million from the previous year, reflecting strong commercial momentum and expansion into new markets.
- ▶ **Pompe Milestones:** Pombiliti+Opfolda generated \$11.6 million in revenue for 2023. These treatments received regulatory approvals from the European Commission, UK's MHRA, and the FDA in mid-2023.
- ▶ **Pipeline Growth:** The company is focusing on advancing its research and development in Fabry and Pompe diseases, working on next-generation therapies and innovative technologies to enhance its product offerings.
- ▶ **Financial strength:** Total cash, cash equivalents, and marketable securities as of December 31, 2023 was \$286.2 million.

Market Projections: Galafold for Fabry

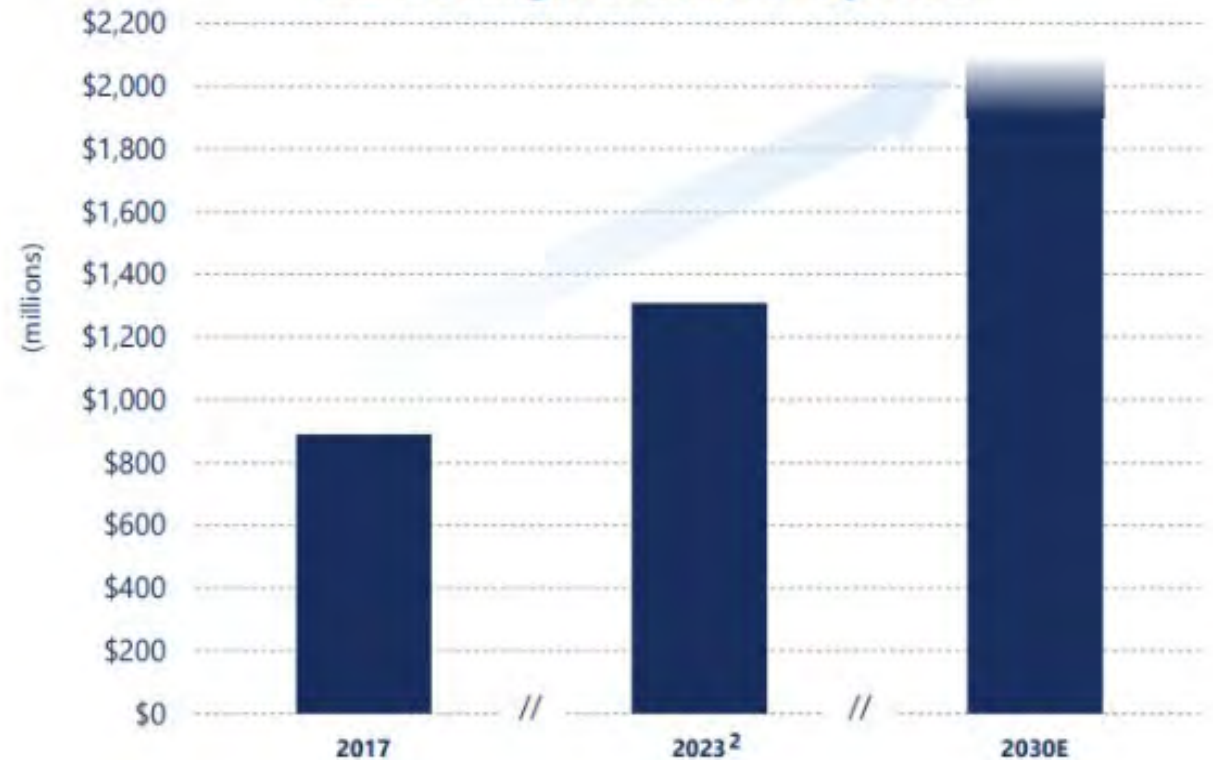
- ▶ Patient diagnoses has significantly increased since 2015 to around 17,000 with double the amount being treated.
- ▶ Global Fabry market of ~\$2B in 2023 and tracks toward ~3B+ end of 2030
 - Significantly underdiagnosed (~1:1000 to ~1:4000)
 - Fasted growing Fabry treatment and greatest contributor to market growth



Market Projections: Pom.+Op. for Pompe

- ▶ Global Pompe disease growth of ~\$1.3B in 2023, pushing towards ~\$2B by 2030
- ▶ Market Sales Split
 - US = 43%, EU = 36%, Other = 21%
 - 3,500-4,000 patients are being treated by ERT

Global Pompe Market of ~\$1.3B in 2023 and Tracking toward \$2B+ by 2030¹



2024 Financial Overview

- ▶ Corporate Guidance has Total Revenue Growth at 26% to 31% for fiscal year 2024 compared to 2023
- ▶ Galafold Revenue is projected to grow by 14% to 18% totaling \$442M - \$458M compared to \$388M in fiscal year 2023
- ▶ With Pombiliti + Opfolda being FDA approved in September 2023 it sold \$11M total in 2023
- ▶ Pombiliti + Opfolda met 2023 sales in Q1 of 2024 and the product is projected to sell \$62M to \$67M for fiscal year 2024

	Updated Guidance	Previous Guidance
Total Revenue Growth¹	26% to 31%	25% to 30%
Galafold Revenue Growth¹	14% to 18%	13% to 17%
Pombiliti + Opfolda Revenue¹	\$62M to \$67M	\$62M to \$67M
Non-GAAP Operating Expense	\$345M to \$360M	\$345M to \$365M

SWOT Analysis

Strengths

- **Innovative Portfolio:** Strong pipeline of approved and promising therapies for rare diseases.
- **Intellectual Property:** Solid foundation of patents supporting market exclusivity.
- **Expertise:** Advanced knowledge in pharmacological chaperones and enzyme replacement therapies.

Opportunities

- **Growing Market:** Increased awareness and diagnosis of rare diseases.
- **New Market Expansion:** Potential to enter emerging markets.
- **Strategic Partnerships:** Opportunities for collaborations to enhance research and product offerings.
- **Technological Advancements:** Leveraging new drug development technologies

Weaknesses

- **Product Dependency:** Reliance on a few key therapies for revenue.
 - **High R&D Costs:** Significant investment needed for research could strain finances.
 - **Market Challenges:** Difficulty reaching target patient populations.

Threats

- **Competition:** Intense rivalry from other biotech companies.
- **Regulatory Challenges:** Complex approval processes that may delay product launches.
- **Reimbursement Issues:** Potential difficulties securing coverage for treatments.
 - **Economic Uncertainties:** Fluctuating economies and changing healthcare policies affecting funding and access.

Ratio Analysis

- ▶ FOLD has strong liquidity with leading in Current and Quick Ratios compared to competitors
- ▶ Even with operating in a high margin industry, FOLD is in the upper bound of Gross Margin
- ▶ High Incremental Operating Margin is indicator of expansion of operations margin and improved efficiencies
- ▶ Concerned with Working Capital Management with a Cash Conversion Cycle that significantly increase in 2023 and high DIO
- ▶ FOLD's high DPO is positive indicator for possible working capital improvement if sustainable

Ratio Analysis				
2023	FOLD	NBIX	BMRN	TEVA
Current Ratio	2.88	2.45	2.51	1.02
Quick Ratio	2.23	2.25	1.45	0.54
Cash Conversion Cycle	402.50	-739.96	492.92	158.95
DPO	76.12	1,153.71	299.07	97.67
DIO	408.32	337.42	709.39	174.80
Gross Margin	90.65%	97.90%	78.72%	48.25%
Incremental Operating Margin	192.39%	0.48%	2.64%	274.92%

Price-to-Sales Multiple

FWD Price-to-Sales Multiple Valuation

Price- to-Sales Target Price	\$	12.80
FOLD Market Price	\$	11.50
Undervalued		11.29%

- ▶ Used Price-to-Sales Multiple to value FOLD because lack of positive earnings and EBITDA
- ▶ Found the Implied Share Price using P/S Multiple of 10 different competitors
- ▶ Removed the two biggest outliers and averaged the remaining to reach a P/S Implied Share Price of \$12.80
- ▶ P/S Multiple Valuation shows FOLD undervalued by ~11%

DCF Valuation: WACC & Beta

Cost of Equity

Risk Free Rate (per Fed 10/31/2024)	4.50%
Market Risk Premium	5%
ASO Cost of Equity	7.88%

Cost of Debt

Effective Interest Rate	12.80%
Tax Rate	21.00%
After-Tax Cost of Debt	10.11%

Beta

Calculated Beta	0.64
Yahoo Finance Beta	0.68

WACC Calculation

Categories of Capital	Value of Capital	Weights	Costs	WACC
Equity	\$3,394,391,922.50	89.745310%	7.88%	7.072%
Debt	\$387,858,000.00	10.254690%	10.11%	1.037%
Total Capital	\$3,782,249,922.50	100.000000%		8.109%

DCF Valuation: Forecasts and Growth Assumptions

- ▶ DCF Valuation is heavily reliant on meeting or exceeding Sales and SG&A projections
- ▶ Sales projection is built off corporate guidance and slowly working down to projected industry growth rate of 10.5%
- ▶ SG&A Margin is based off 2024 guidance and assuming management can reduce margins to industry standards

Income Statement Assumptions					
Sales Projections	2024 based off the average of the Companies Guidance and then used IBIS World projections from there per annum				
	2024	2025	2026	2027	2028
	29.0%	24.4%	20.0%	17.5%	10.5%
COGS	Based off Fixed/Variable Spilt 2023 per annum				
SG&A Margin	Based off Projected SG&A Margin Rate of 2024 Company Guidance by FOLD per annum				
	2024	2025	2026	2027	2028
	68.2%	54.1%	40.1%	37.5%	35.0%
R&D Margin	Based off Projected SG&A Margin Rate of 2024 Company Guidance by FOLD per annum				
	2024	2025	2026	2027	2028
	22.0%	21.0%	20.0%	19.0%	18.0%
D&A Margin	Based off Projected D&A Margin Rate of 2023 Company Guidance by ASO per annum				
	2.0%				
Interest Expense	Based off of Interest Rate of Debt from 2023 10k notes				
	12.8%				
Income Tax Expense	Based off of Income Tax Rate from 23 10k notes				
	1.0%				

DCF Valuation

- ▶ DCF gives FOLD an Implied Share Price of \$16.15
- ▶ This gives FOLD an undervaluation of ~40% with current market price
- ▶ Would consider this valuation as semi-conservative given moderate long-term growth rate and below Bloomberg target price
- ▶ Valuation is heavily reliant on improvement in managing SGA cost and sales growth

DCF Model	
WACC	8.11%
NPV First 5 Years	\$ 500,705,593
Smoothed TY	\$ 296,680,440
Net Reinvested Rate	8.78%
ROIC	41.39%
LT Growth Rate	3.64%
Terminal Value	\$ 6,874,151,168
PV of TV	\$ 4,654,931,723
Enterprise Value	\$ 5,155,637,316
Less Net Debt	\$ (387,858,000)
Equity Value	\$ 4,767,779,316
Shares Outstanding	295,164,515
Implied Share Price	\$16.15
Market Price	\$11.50
Undervalued	40.46%

DCF Valuation: Sensitivity Analysis

- ▶ Implied Share Price gathered from DCF model is ~9% lower than Bloomberg Target Price
- ▶ Sensitivity Analysis shows that FOLD has more value creation opportunities with improvements in WACC and Long-Term Growth Rate than downside potential
- ▶ Implied Share Price is resistant to moderate increases in WACC and decreases in Long-Term Growth Rate with still maintain price above current market price

Sensitivity Analysis						
		WACC				
		6%	7%	8.11%	9%	10%
Long-Term Growth Rate	\$16.15					
	5%	79.3906	38.0798	23.3609	17.4744	13.3721
	4.00%	39.5825	25.2996	17.6044	13.9141	11.0837
	3.64%	33.5101	22.5609	16.1625	12.9576	10.4361
	2.50%	22.5219	16.7794	12.8176	10.6277	8.79532
	1%	15.6977	12.5193	10.0505	8.57362	7.26971

Sensitivity Analysis Variance		
	Share Price	% Variance from Base
Best Case	\$79.39	391.49%
Base Case	\$16.15	0.00%
Worst Case	\$7.27	-54.99%
Bloomberg Target Price	\$17.64	9.21%

Portfolio Analysis

- ▶ Decreases in ratios due to FOLD's poor performance YTD
- ▶ Devaluation due to misses on fiscal year 2023 earnings and Q1 2024 earnings
- ▶ FOLD beat Q2 2024 earnings and still maintains consistent buy and hold analyst recommendations
- ▶ Portfolio Analysis gives insight into the past performance of position but does not give indication of future effects of FOLD or portfolio

Portfolio Stats Analysis		
	Seger Fund	Seger Fund w/ FOLD
Sharpe Ratio	1.11	0.99
Jensen Alpha	13.17	10.96
Treynor Measure	0.22	0.2
Beta	0.96	0.96
Standard Deviation (Annualized)	19.58	19.65
Total Return	20.28	18.49

Recommendation

- ▶ Recommending Seger Fund buys ~\$15k worth of shares of FOLD to make a position of ~4.5% of portfolio using funds currently in benchmark (Russell 2000)
- ▶ Exit Strategy: High-end sell at \$18 per share based on giving ~10% upside to Implied Share Price from DCF model giving Seger Fund a gain of ~\$8,500
- ▶ Exit Strategy: Stop-loss at \$7.70 which would be FOLD losing ~1/3 of current value giving Seger Fund a loss of ~\$5,000
- ▶ Alternative Recommendation: Buy ~\$11.7k worth of shares of FOLD to make a position of ~3.5% of portfolio and maintain same Exit Strategy

Buy FOLD into Seger Fund?

