Amicus Therapeutics Announces First Quarter 2025 Financial Results and Corporate Updates

May 1, 2025 at 7:00 AM EDT

1Q 2025 Total Revenue of $125.2M, a 15% Increase Year-over-Year at CER

Expanding Portfolio through In-Licensing of DMX-200 Phase 3 Program for Rare Kidney Disease with Significant Market Potential in the U.S.

Maintaining 2025 Guidance for Galafold, Reflecting Strong Underlying Demand

Updating 2025 Pombiliti + Opfolda Guidance with New Patient Starts Accelerating in 2H

Adjusting 2025 Total Revenue Growth Guidance to 15-22% at CER

Reiterating GAAP Profitability During H2 2025

Conference Call and Webcast Today at 8:30 a.m. ET

PRINCETON, N.J., May 01, 2025 (GLOBE NEWSWIRE) -- Amicus Therapeutics (Nasdaq: FOLD), a patient-dedicated global biotechnology company focused on developing and commercializing novel medicines for rare diseases, today announced financial results for the first quarter ended March 31, 2025.

“Amicus delivered another consecutive quarter of significant double-digit revenue growth. Looking forward, the underlying patient demand we observed in Q1 will drive robust growth for Galafold, and we continue to expect accelerating Pombiliti + Opfolda sales as the year progresses, driven by patient starts from new launch markets as well as anticipated acceleration in U.S. switches. While some unexpected factors impacted revenue in the quarter, the key performance indicators for both products are very strong and we remain on-track to achieve GAAP profitability during the second half of 2025 and to deliver double-digit revenue growth this year and beyond,” said Bradley Campbell, President and Chief Executive Officer of Amicus Therapeutics, Inc.

Mr. Campbell continued “We are also thrilled to have announced the in-licensing of the U.S. commercial rights to Dimerix’ DMX-200, a first-in-class treatment in Phase 3 development for people living with FSGS, a rare and potentially fatal kidney disease. This aligns perfectly with our strategy to leverage our rare disease commercial infrastructure and brings a third program with blockbuster market potential to our portfolio. Amicus is well positioned to create substantial value for shareholders and to deliver on our mission for patients, and we very much look forward to working with Dimerix to bring this much needed therapy to people living with FSGS in the United States.”

First Quarter 2025 Financial Highlights:

- **Total revenues for the first quarter 2025 were $125.2 million**, reflecting operational growth measured at constant exchange rates (CER)[1] of 15% and a currency headwind of $1.4 million or 1%.

(in thousands)	Three Months Ended March 31,		Year over Year % Growth	
	2025	2024	Reported	at CER[1]
Galafold®	104,244	99,359	5%	6%
Pombiliti® + Opfolda®	21,005	11,044	90%	92%
Net Product Revenues	$125,249	$110,403	13%	15%

- **Galafold® (migalastat) net product sales for the first quarter 2025 were $104.2 million**, representing a year-over-year increase of 5%, or 6% at CER[1]. Strong patient demand of 14% in the quarter was partially offset by order timing and the ongoing impact of the higher than anticipated VPAG (Voluntary Scheme for Branded Medicines Pricing and Access) rebate in the U.K. Given the significant underlying demand, the Company anticipates Galafold revenue to accelerate in the second quarter and is reiterating its full year 2025 revenue growth guidance of +10-15% at CER.
- **Pombiliti (cipaglucosidase alfa-atga) + Opfolda (miglustat) net product sales for the first quarter 2025 were $21.0 million**, representing a year-over-year increase of 90%, or 92% at CER[1]. First quarter sales reflected the timing of patient starts in new launch countries and the ongoing impact of the higher than anticipated VPAG rebate in the U.K. The Company now expects the benefit of patient starts in new launch markets to be more weighted towards the second half of the year. Taken together with an anticipated acceleration in U.S. switches, the Company is therefore adjusting its 2025 revenue growth guidance range for Pombiliti + Opfolda to +50-65% at CER.
- **Total GAAP operating expenses** of $121.5 million for the first quarter 2025 decreased by 2.5% as compared to $124.6

million for the first quarter 2024. **Total non-GAAP operating expenses[2]** were up 10.4% to $94.5 million for the first quarter 2025 as compared to $85.6 million for the first quarter 2024.

- **GAAP net loss** was $21.7 million, or $0.07 loss per share basic and diluted, for the first quarter 2025, compared to a net loss of $48.4 million, or $0.16 per share basic and diluted, for the first quarter 2024. **Non-GAAP net income[2,3]** was $9.0 million, or $0.03 per share basic and diluted, for the first quarter 2025, compared to a non-GAAP net loss of $4.6 million, or $0.02 per share basic and diluted, for the first quarter 2024.
- **Cash, cash equivalents, and marketable securities** totaled $250.6 million at March 31, 2025, representing a slight increase as compared to $249.9 million at December 31, 2024.

Corporate Updates:

- **Pombiliti + Opfolda selected as preferred treatment for adults living with late-onset Pompe disease in the Netherlands**. The five-year agreement will enable broad and sustained access to Pombiliti + Opfolda for adults living with late-onset Pompe disease in the Netherlands currently receiving enzyme replacement therapy or naïve to treatment. First commercial patients are expected to begin treatment in 2Q 2025. The Netherlands has the highest prevalence of Pompe disease in Europe with over 150 individuals living with the condition.
- **Pombiliti + Opfolda regulatory approval granted in Canada and Australia for adult LOPD patients**. The Company continues to anticipate a regulatory decision in Japan this year as well as additional reimbursement agreements throughout the year. The Company also remains on track for up to 10 new launch countries in 2025, which include more than 650 individuals living with LOPD.
- **Commercial manufacturing and supply services agreement reached with Sharp Sterile to manufacture Pombiliti drug product in the U.S.** This agreement is another important step in further diversifying the supply chain for Pombiliti.
- **Entered into exclusive U.S. licensing agreement with Dimerix**. As announced separately, Amicus has licensed exclusive rights for the U.S. commercialization of Dimerix' Phase 3 program, DMX-200, a first in class treatment for FSGS, a rare and fatal kidney disease with no approved therapies and significant market potential.
- **Amicus is focused on delivering significant long-term revenue growth and anticipates surpassing $1 billion in total sales in 2028**. The Company anticipates continuing to grow its current commercial business with Galafold and Pombiliti + Opfolda resulting in strong total revenue growth.

2025 Financial Guidance

Amicus' updated financial guidance for 2025, which includes the upfront license payment and all other anticipated operating expenses of the licensing of DMX-200 in the U.S., is as follows:

	Previous		Updated	
Total Revenue Growth[1]	17% to 24%	→	15% to 22%	
Galafold Revenue Growth[1]	10% to 15%	→	10% to 15%	
Pombiliti + Opfolda Growth[1]	65% to 85%	→	50% to 65%	
Gross Margin	Mid 80%	→	Mid 80%	
Non-GAAP Operating Expenses[4]	$350M to $370M	→	$380M to $400M	(Incl. $30M Upfront License Payment)
GAAP Net Income	Positive during 2H 2025	→	Positive during 2H 2025	

[1] In order to illustrate underlying performance, Amicus discusses its results in terms of constant exchange rate (CER) growth. This represents growth calculated as if the exchange rates had remained unchanged from those used in the comparative period.

[2] Full reconciliation of GAAP results to the Company's non-GAAP adjusted measures for all reporting periods appear in the tables to this press release.

[3] Amicus defines non-GAAP Net (Loss) Income as GAAP Net (Loss) Income excluding the impact of share-based compensation expense, changes in fair value of contingent consideration, loss on impairment of assets, depreciation and amortization, acquisition related income (expense), loss on extinguishment of debt, restructuring charges and income taxes.

[4] A reconciliation of the differences between the non-GAAP expectation and the corresponding GAAP measure is not available without unreasonable effort due to high variability, complexity, and low visibility as to the items that would be excluded from the GAAP measure.

Conference Call and Webcast

Amicus Therapeutics will host a conference call and audio webcast today, May 1, 2025, at 8:30 a.m. ET to discuss the first quarter 2025 financial results and corporate updates. Participants and investors interested in accessing the call by phone will need to register using the online registration form. After registering, all phone participants will receive a dial-in number along with a personal PIN number to access the event.

A live audio webcast and related presentation materials can also be accessed via the Investors section of the Amicus Therapeutics corporate website at ir.amicusrx.com. Web participants are encouraged to register on the website 15 minutes prior to the start of the call. An archived webcast and accompanying slides will be available on the Company's website shortly after the conclusion of the live event.

About Galafold

Galafold® (migalastat) 123 mg capsules is an oral pharmacological chaperone of alpha-Galactosidase A (alpha-Gal A) for the treatment of Fabry disease in adults who have amenable galactosidase alpha gene *(GLA)* variants. In these patients, Galafold works by stabilizing the body's own dysfunctional enzyme so that it can clear the accumulation of disease substrate. Globally, Amicus Therapeutics estimates that approximately 35 to 50 percent of people living with Fabry disease may have amenable *GLA* variants, though amenability rates within this range vary by geography. Galafold is approved in more than 40 countries around the world, including the U.S., EU, U.K., and Japan.

U.S. INDICATIONS AND USAGE

Galafold is indicated for the treatment of adults with a confirmed diagnosis of Fabry disease and an amenable galactosidase alpha gene (*GLA*) variant based on *in vitro* assay data.

This indication is approved under accelerated approval based on reduction in kidney interstitial capillary cell globotriaosylceramide (KIC GL-3) substrate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

U.S. IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS: The most common adverse reactions reported with Galafold (≥10%) were headache, nasopharyngitis, urinary tract infection, nausea and pyrexia. **USE IN SPECIFIC POPULATIONS:** There is insufficient clinical data on Galafold use in pregnant women to inform a drug-associated risk for major birth defects and miscarriage. Advise women of the potential risk to a fetus. It is not known if Galafold is present in human milk. Therefore, the developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Galafold and any potential adverse effects on the breastfed child from Galafold or from the underlying maternal condition. Galafold is not recommended for use in patients with severe renal impairment or end-stage renal disease requiring dialysis. The safety and effectiveness of Galafold have not been established in pediatric patients. To report Suspected Adverse Reactions, contact Amicus Therapeutics at 1-877-4AMICUS or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. **For additional information about Galafold, including the full U.S. Prescribing Information, please visit https://www.amicusrx.com/pi/Galafold.pdf.**

About Pombiliti + Opfolda

Pombiliti + Opfolda, is a two-component therapy that consists of cipaglucosidase alfa-atga, a bis-M6P-enriched rhGAA that facilitates high-affinity uptake through the M6P receptor while retaining its capacity for processing into the most active form of the enzyme, and the oral enzyme stabilizer, miglustat, that's designed to reduce loss of enzyme activity in the blood.

U.S. INDICATIONS AND USAGE

POMBILITI in combination with OPFOLDA is indicated for the treatment of adult patients with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) weighing ≥40 kg and who are not improving on their current enzyme replacement therapy (ERT).

SAFETY INFORMATION

HYPERSENSITIVITY REACTIONS INCLUDING ANAPHYLAXIS: Appropriate medical support measures, including cardiopulmonary resuscitation equipment, should be readily available. If a severe hypersensitivity reaction occurs, POMBILITI should be discontinued immediately and appropriate medical treatment should be initiated. INFUSION-ASSOCIATED REACTIONS (IARs): If severe IARs occur, immediately discontinue POMBILITI and initiate appropriate medical treatment. RISK OF ACUTE CARDIORESPIRATORY FAILURE IN SUSCEPTIBLE PATIENTS: Patients susceptible to fluid volume overload, or those with acute underlying respiratory illness or compromised cardiac or respiratory function, may be at risk of serious exacerbation of their cardiac or respiratory status during POMBILITI infusion. See PI for complete Boxed Warning. CONTRAINDICATION: POMBILITI in combination with Opfolda is contraindicated in pregnancy. **EMBRYO-FETAL TOXICITY:** May cause embryo-fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception during treatment and for at least 60 days after the last dose. **Adverse Reactions:** Most common adverse reactions ≥ 5% are headache, diarrhea, fatigue, nausea, abdominal pain, and pyrexia. **Please see full PRESCRIBING INFORMATION, including BOXED WARNING, for POMBILITI (cipaglucosidase alfa-atga) LINK and full PRESCRIBING INFORMATION for OPFOLDA (miglustat) LINK.**

About Amicus Therapeutics

Amicus Therapeutics (Nasdaq: FOLD) is a global, patient-dedicated biotechnology company focused on discovering, developing and delivering novel high-quality medicines for people living with rare diseases. With extraordinary patient focus, Amicus Therapeutics is committed to advancing and expanding a pipeline of cutting-edge, first- or best-in-class medicines for rare diseases. For more information please visit the company's website at www.amicusrx.com, and follow on X and LinkedIn.

Non-GAAP Financial Measures

In addition to financial information prepared in accordance with U.S. GAAP, this press release also contains adjusted financial measures that we believe provide investors and management with supplemental information relating to operating performance and trends that facilitate comparisons between periods and with respect to projected information. These adjusted financial measures are non-GAAP measures and should be considered in addition to, but not as a substitute for, the information prepared in accordance with U.S. GAAP. We use these non-GAAP measures as key performance measures for the purpose of evaluating operational performance and cash requirements internally. We typically exclude certain GAAP items that management does not believe affect our basic operations and that do not meet the GAAP definition of unusual or non-recurring items. Other companies may define these measures in different ways. When we provide our expectation for non-GAAP operating expenses and profitability on a forward-looking basis, a reconciliation of the differences between the non-GAAP expectation and the corresponding GAAP measure generally is not available without unreasonable effort due to potentially high variability, complexity and low visibility as to the items that would be excluded from the GAAP measure in the relevant future period, such as unusual gains or losses. The variability of the excluded items may have a significant, and potentially unpredictable, impact on our future GAAP results.

Forward Looking Statement

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 relating to the

prospects and timing of the potential regulatory and pricing approval of our products, commercialization plans, manufacturing and supply plans, financing plans, the collaboration with Dimerix, and the projected revenues and cash position for the Company. The inclusion of forward-looking statements should not be regarded as a representation by us that any of our plans will be achieved. Any or all of the forward-looking statements in this press release may turn out to be wrong and can be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. For example, statements regarding the goals, progress, timing, and outcomes of discussions with regulatory authorities and pricing and reimbursement authorities, are based on current information. Actual results may differ materially from those set forth in this release due to the risks and uncertainties inherent in our business, including, without limitation: the potential that regulatory authorities may not grant or may delay approval for our product candidates; the potential that required regulatory inspections may be delayed or not be successful and delay or prevent product approval; the potential that we may not be successful in negotiations with pricing and reimbursement authorities; the potential that we may not be successful in commercializing Galafold and/or Pombiliti and Opfolda in Europe, the UK, the US and other geographies; the potential that the Dimerix collaboration and license agreement for of DMX-200 may not be successful, including without limitation expectations of the timing of Phase 3 clinical trial evaluating DMX-200; the likelihood of success of such clinical trial; the prospects for FDA approval of DMX-200 for FSGS or other indications; the estimated prevalence of FSGS; the achievement of any milestone and timing of any payments associated with milestones and the success of any efforts to commercialize DMX-200, including any projections of future financial performance or payments; ; the potential that we may not be able to manufacture or supply sufficient commercial products; and the potential that we will need additional funding to complete the manufacturing and commercialization of our products. With respect to statements regarding corporate financial guidance and financial goals and the expected attainment of such goals and projections of the Company's revenue, non-GAAP profitability and cash position, actual results may differ based on market factors and the Company's ability to execute its operational and budget plans. In addition, all forward-looking statements are subject to other risks detailed in our Annual Report on Form 10-K for the year ended December 31, 2024 and our Quarterly Report on Form 10-Q to be filed today. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, and we undertake no obligation to revise or update this news release to reflect events or circumstances after the date hereof.

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TABLE 1

Amicus Therapeutics, Inc.
Consolidated Statements of Operations
(Unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2025	**2024**
Net product sales	$125,249	$110,403
Cost of goods sold	11,698	13,567
Gross profit	113,551	96,836
Operating expenses:		
Research and development	27,839	28,329
Selling, general, and administrative	91,827	88,029
Restructuring charges	—	6,045
Depreciation and amortization	1,837	2,154
Total operating expenses	121,503	124,557
Loss from operations	(7,952)	(27,721)
Other expense:		
Interest income	812	1,540
Interest expense	(11,455)	(12,436)
Other income (expense)	550	(4,966)
Loss before income tax	(18,045)	(43,583)
Income tax expense	(3,641)	(4,836)

Net loss attributable to common stockholders	$(21,686)	$(48,419)
Net loss attributable to common stockholders per common share — basic and diluted	$(0.07)	$(0.16)
Weighted-average common shares outstanding — basic and diluted	307,689,207	302,903,009

TABLE 2

Amicus Therapeutics, Inc.
Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	March 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$181,657	$213,752
Investments in marketable securities	68,916	36,194
Accounts receivable	88,323	101,099
Inventories	132,412	118,782
Prepaid expenses and other current assets	39,491	34,909
Total current assets	510,799	504,736
Operating lease right-of-use assets, net	22,138	22,278
Property and equipment, less accumulated depreciation of $29,842 and $28,775 at March 31, 2025 and December 31, 2024, respectively	28,718	29,383
Intangible assets, less accumulated amortization of $6,611 and $5,802 at March 31, 2025 and December 31, 2024, respectively	16,389	17,198
Goodwill	197,797	197,797
Other non-current assets	13,998	13,641
Total Assets	$789,839	$785,033
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$14,451	$12,947
Accrued expenses and other current liabilities	129,877	127,300
Operating lease liabilities	8,562	8,455
Total current liabilities	152,890	148,702
Long-term debt	390,708	390,111
Operating lease liabilities	44,196	45,078
Other non-current liabilities	8,487	7,097
Total liabilities	596,281	590,988
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.01 par value, 500,000,000 shares authorized, 307,923,069 and 299,041,653 shares issued and outstanding at March 31, 2025 and December 31, 2024, respectively	3,016	2,944
Common stock in treasury, at cost; 7,390 shares as of March 31, 2025	(71)	—
Additional paid-in capital	2,939,673	2,926,115
Accumulated other comprehensive income (loss):		
Foreign currency translation adjustment	12,941	5,302
Unrealized loss on available-for-sale securities	(135)	(207)
Warrants	—	71
Accumulated deficit	(2,761,866)	(2,740,180)
Total stockholders' equity	193,558	194,045
Total Liabilities and Stockholders' Equity	$789,839	$785,033

TABLE 3

Amicus Therapeutics, Inc.
Reconciliation of Non-GAAP Financial Measures
(in thousands)

(Unaudited)

	Three Months Ended March 31,	
	2025	**2024**
Total GAAP operating expenses	**$ 121,503**	**$ 124,557**
Research and development:		
Share-based compensation	4,004	4,871
Selling, general and administrative:		
Share-based compensation	21,168	25,932
Restructuring charge	—	6,045
Depreciation and amortization	1,837	2,154
Total Non-GAAP operating expense adjustments	27,009	39,002
Total Non-GAAP operating expenses	**$94,494**	**$85,555**

TABLE 4

Amicus Therapeutics, Inc.
Reconciliation of Non-GAAP Financial Measures
(in thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2025	**2024**
GAAP net loss	**$ (21,686)**	**$(48,419)**
Share-based compensation	25,172	30,803
Depreciation and amortization	1,837	2,154
Restructuring charges	—	6,045
Income tax expense	3,641	4,836
Non-GAAP net income (loss)	$8,963	$(4,581)
Non-GAAP net income (loss) attributable to common stockholders per common share — basic and diluted	$0.03	$(0.02)
Weighted-average common shares outstanding — basic	307,689,207	302,903,009
Weighted-average common shares outstanding — diluted	309,654,136	302,903,009