Amicus Therapeutics Announces First Quarter 2024 Financial Results and Corporate Updates

May 9, 2024 at 7:00 AM EDT

1Q 2024 Total Revenue of $110.4M, a 28% Increase Year-over-Year

Guiding to Full-Year 2024 Total Revenue Growth of 25%-30% at CER

Raising Full-Year 2024 Galafold® Guidance on Continued Strong Demand

Strong Pombiliti® + Opfolda® Launch with Increasing Rate of Commercial Patient Starts

Reiterating Full-Year Non-GAAP Profitability Projected in 2024

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

PRINCETON, N.J., May 09, 2024 (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, 2024.

“Amicus delivered a great start to the year across our global business,” said Bradley Campbell, President and Chief Executive Officer of Amicus Therapeutics, Inc. “In the first quarter, we continued to deliver excellent commercial performance. Once again, we have delivered mid-teen growth in global sales of Galafold, leading us to raise our product guidance for the year. We are also very pleased with the strong commercial launch of Pombiliti and Opfolda, which continues to build momentum with an increasing rate of commercial patient starts in the first months of the year. In 2024, we look to deliver significant total revenue growth of 25% to 30% coupled with continued expense management to deliver full year non-GAAP profitability. With these two therapies, we believe Amicus continues to make a profound difference in the lives of many individuals affected by rare diseases across the globe.”

First Quarter 2024 Financial Highlights:

- **Total revenue in the first quarter 2024** was $110.4 million, a year-over-year increase of 28% from total revenue of $86.3 million in the first quarter 2023. On a constant currency basis (CER)[1], first-quarter 2024 total revenue growth was 28%.

(in thousands)	Three Months Ended March 31,		Year-over-Year % Growth	
	2024	2023	Reported	at CER[1]
Galafold®	99,359	86,112	15%	16%
Pombiliti® + Opfolda®	11,044	158	n/a	n/a
Net Product Revenues	$110,403	$86,270	28%	28%

- **Galafold (migalastat) net product sales** were $99.4 million in the first quarter 2024, a year-over-year increase of 15%, or 16% at constant exchange rates[1].
- **Pombiliti (cipaglucosidase alfa-atga) + Opfolda (miglustat) net product sales** were $11.0 million in the first quarter 2024, a 30% increase from the fourth quarter of 2023. As of the end of April, over 155 patients are on treatment with commercial product or scheduled to be treated.
- **Total GAAP operating expenses** of $124.6 million for the first quarter 2024 increased by 6% as compared to $117.0 million for the first quarter 2023. **Total non-GAAP operating expenses** of $85.6 million for the first quarter 2024 increased by 6% as compared to $80.6 million for the first quarter 2023.
- **GAAP net loss** was $48.4 million, or $0.16 per share, for the first quarter 2024, and was reduced compared to a net loss of $52.9 million, or $0.18 per share, for the first quarter 2023. **Non-GAAP net loss** was $4.6 million, or $0.02 per share, for the first quarter 2024, and was reduced compared to a net loss of $16.8 million, or $0.06 per share, for first quarter 2023[2].
- **Cash, cash equivalents, and marketable securities** totaled $239.6 million at March 31, 2024, compared to $286.2 million at December 31, 2023.

2024 Financial Guidance:

	Updated	Previous
Total Revenue Growth[1]	25% to 30%	n/a
Galafold Revenue Growth[1]	13% to 17%	11% to 16%
Pombiliti + Opfolda Revenue[1]	$62M to $67M	n/a
Non-GAAP Operating Expense[3]	$345M to $365M	$345M to $365M

Amicus is focused on the following key strategic priorities in 2024:

- Delivering double-digit Galafold revenue growth
- Executing multiple successful launches of Pombiliti + Opfolda
- Advancing ongoing studies to support medical and scientific leadership in Fabry and Pompe diseases
- Achieving full-year non-GAAP profitability[4]

[1] At constant exchange rates (CER). 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. Full-year revenue guidance utilizes actual exchange rate as of December 31, 2023.

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

[3] 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.

[4] Based on projections of Amicus' non-GAAP Net (Loss) Income under current operating plans, which includes successful Pombiliti + Opfolda launch and continued Galafold growth. 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.

Conference Call and Webcast

Amicus Therapeutics will host a conference call and audio webcast today, May 9, 2024, at 8:30 a.m. ET to discuss the first quarter 2024 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 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 preclinical and clinical development of our product candidates, the timing and reporting of results from preclinical studies and clinical trials, the prospects and timing of the potential regulatory approval of our product candidates, commercialization plans, manufacturing and supply plans, financing plans, 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, with respect to 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 results of clinical or preclinical studies indicate that the product candidates are unsafe or ineffective; the potential that it may be difficult to enroll patients in our clinical trials; 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 preclinical and clinical studies could be delayed because we identify serious side effects or other safety issues; the potential that we may not be able to manufacture or supply sufficient clinical or commercial products; and the potential that we will need additional funding to complete all of our studies, 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, 2023, and on Form 10-Q for the quarter ended March 31, 2024, 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.

CONTACT:

Investors:
Amicus Therapeutics
Andrew Faughnan
Vice President, Investor Relations
afaughnan@amicusrx.com
(609) 662-3809

Media:

Amicus Therapeutics
Diana Moore
Head of Global Corporate Affairs and Communications
dmoore@amicusrx.com
(609) 662-5079

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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,	
	2024	**2023**
Net product sales	$ 110,403	$ 86,270
Cost of goods sold	13,567	6,942
Gross profit	96,836	79,328
Operating expenses:		
Research and development	28,329	41,499
Selling, general, and administrative	88,029	73,957
Changes in fair value of contingent consideration payable	—	251
Restructuring charges	6,045	—
Depreciation and amortization	2,154	1,257
Total operating expenses	124,557	116,964
Loss from operations	(27,721)	(37,636)
Other expense:		
Interest income	1,540	2,199
Interest expense	(12,436)	(11,844)
Other expense	(4,966)	(5,938)
Loss before income tax	(43,583)	(53,219)
Income tax (expense) benefit	(4,836)	287
Net loss attributable to common stockholders	$ (48,419)	$ (52,932)
Net loss attributable to common stockholders per common share — basic and diluted	$ (0.16)	$ (0.18)
Weighted-average common shares outstanding — basic and diluted	302,903,009	291,336,750

TABLE 2

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

	March 31, 2024	**December 31, 2023**
Assets		
Current assets:		
Cash and cash equivalents	$ 209,761	$ 246,994
Investments in marketable securities	29,842	39,206
Accounts receivable	76,433	87,632
Inventories	60,759	59,696
Prepaid expenses and other current assets	54,444	49,533
Total current assets	431,239	483,061
Operating lease right-of-use assets, net	23,003	26,312
Property and equipment, less accumulated depreciation of $26,563 and $25,429 at March 31, 2024 and December 31, 2023, respectively	32,421	31,667
Intangible assets, less accumulated amortization of $3,328 and $2,510 at March 31, 2024 and December 31, 2023, respectively	19,672	20,490
Goodwill	197,797	197,797
Other non-current assets	17,657	18,553

Total Assets	$ 721,789	$ 777,880
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 9,210	$ 15,120
Accrued expenses and other current liabilities	124,622	144,245
Operating lease liabilities	8,270	8,324
Total current liabilities	142,102	167,689
Long-term debt	388,391	387,858
Operating lease liabilities	47,831	48,877
Other non-current liabilities	12,771	13,282
Total liabilities	591,095	617,706
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.01 par value, 500,000,000 shares authorized, 296,159,417 and 293,594,209 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	2,922	2,918
Additional paid-in capital	2,853,550	2,836,018
Accumulated other comprehensive loss:		
Foreign currency translation adjustment	6,847	5,429
Unrealized loss on available-for-sale securities	(203)	(188)
Warrants	71	71
Accumulated deficit	(2,732,493)	(2,684,074)
Total stockholders' equity	130,694	160,174
Total Liabilities and Stockholders' Equity	$ 721,789	$ 777,880

TABLE 3

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

	Three Months Ended March 31,	
	2024	**2023**
Total operating expenses - as reported GAAP	**$ 124,557**	**$ 116,964**
Research and development:		
Stock-based compensation	4,871	8,490
Selling, general and administrative:		
Stock-based compensation	25,932	26,404
Restructuring charges	6,045	—
Changes in fair value of contingent consideration payable	—	251
Depreciation and amortization	2,154	1,257
Total operating expense adjustments to reported GAAP	39,002	36,402
Total operating expenses - as adjusted	$ **85,555**	$ **80,562**

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,	
	2024	**2023**
GAAP net loss	**$ (48,419)**	**$ (52,932)**
Share-based compensation	30,803	34,894
Changes in fair value of contingent consideration payable	—	251
Depreciation and amortization	2,154	1,257
Restructuring charges	6,045	—

Income tax expense (benefit)	4,836	(287)
Non-GAAP net loss	$ (4,581)	$ (16,817)
Non-GAAP net loss attributable to common stockholders per common share — basic and diluted	$ (0.02)	$ (0.06)
Weighted-average common shares outstanding — basic and diluted	302,903,009	291,336,750