Amicus Therapeutics Announces Third Quarter 2024 Financial Results and Corporate Updates

November 6, 2024 at 7:00 AM EST

Q3 2024 Total Revenue of $141.5M, a 37% Increase Year-over-Year

Galafold® Q3 Revenue of $120.4M, up 20% Year-over-Year

Pombiliti® + Opfolda® Q3 Revenue of $21.1M, up 33% from Q2 2024

Raising 2024 Total Revenue Growth Guidance to 30%-32% at CER

Reducing non-GAAP Operating Expense Guidance to $340M to $350M

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

PRINCETON, N.J., Nov. 06, 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 third quarter ended September 30, 2024.

"The third quarter of the year was marked by the excellent commercial performance of our two approved therapies and continued financial discipline," said Bradley Campbell, President and Chief Executive Officer of Amicus Therapeutics, Inc. "Strong patient demand for Galafold drove double digit revenue growth, while the commercial launch of Pombiliti and Opfolda continues to build momentum. We also announced a settlement of the Galafold (migalastat) patent litigation with Teva, which is a major step forward in ensuring Amicus can continue to support the Fabry community with Galafold for many years to come. Importantly, throughout the first nine months of the year, we've exceeded expectations, which resulted in the achievement of non-GAAP profitability for the full year 2024 as we closed the third quarter. Amicus continues to be well positioned to drive sustainable shareholder value and further our mission of delivering great medicines for people living with rare diseases."

Financial and Corporate Highlights:

- **Total revenue in the third quarter 2024** was $141.5 million, a year-over-year increase of 37% from total revenue of $103.5 million in the third quarter 2023. On a constant currency basis (CER)[1], third quarter 2024 total revenue growth was 36%.

(in thousands)	Three Months Ended September 30,		Year over Year % Growth		Nine Months Ended September 30,		Year over Year % Growth	
	2024	2023	Reported	at CER[1]	2024	2023	Reported	at CER[1]
Galafold®	$120,381	$100,733	20%	19%	$330,557	$281,177	18%	18%
Pombiliti® + Opfolda®	$21,136	$2,768	664%	658%	$48,032	$3,097	1451%	1442%
Net Product Revenues	$141,517	$103,501	37%	36%	$378,589	$284,274	33%	33%

- **Galafold (migalastat) net product sales** were $120.4 million in the third quarter 2024, a year-over-year increase of 20%, or 19% at constant exchange rates[1], reflecting continued strong demand. Given strong performance in the first nine months of 2024, the Company is raising its full year 2024 revenue growth guidance for Galafold to +16% to +18% on a constant currency basis (CER)[1].
- **Pombiliti (cipaglucosidase alfa-atga) + Opfolda (miglustat) net product sales** were $21.1 million in the third quarter 2024, a 33% increase from the second quarter of 2024. As of the end of October, 203 patients have been treated or are scheduled to be treated with commercial product in five markets (USA, Germany, UK, Spain, and Austria). Given strong launch momentum, the Company is raising its full year 2024 revenue guidance for Pombiliti + Opfolda to $69 million to $71 million on a constant currency basis (CER)[1].
- **Total GAAP operating expenses** of $106.6 million for the third quarter 2024 decreased by 4% as compared to $110.6 million for the third quarter 2023. **Total non-GAAP operating expenses** of $82.6 million for the third quarter 2024 decreased by 8% as compared to $89.8 million for the third quarter 2023. Given continued financial discipline in the first nine months of 2024, the Company is reducing its non-GAAP Operating Expense guidance[3] to $340 million to $350 million.
- **GAAP net loss** was $6.7 million, or $0.02 per share, for the third quarter 2024, and was reduced compared to a net loss of $21.6 million, or $0.07 per share, for the third quarter 2023.
- **Non-GAAP net income** was $30.8 million, or $0.10 per share, for the third quarter 2024, compared to a non-GAAP net

loss of $4.0 million, or $0.01 per share, for the third quarter 2023[2]. Non-GAAP profitability was also achieved in the first nine months of 2024.

- **Cash, cash equivalents, and marketable securities** totaled $249.8 million at September 30, 2024, compared to $286.2 million at December 31, 2023.
- In October 2024, the Company announced that it has entered into a License Agreement with Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals, Inc. allowing Teva to market a generic version of Galafold® in the United States beginning on January 30, 2037, if approved by the U.S. Food and Drug Administration (FDA) and unless certain limited circumstances customarily included in these types of agreements occur. Similar patent litigation previously disclosed by the Company will continue against Aurobindo (Aurobindo Pharma LTD and Aurobindo Pharma USA, Inc.) as the remaining active party and the litigation stay remains in place for Lupin (Lupin LTD and Lupin Pharmaceuticals, Inc.).

2024 Financial Guidance:

	Previous		Updated
Total Revenue Growth[1]	26% to 31%	→	30% to 32%
Galafold Revenue Growth[1]	14% to 18%	→	16% to 18%
Pombiliti + Opfolda Revenue[1]	$62M to $67M	→	$69M to $71M
Non-GAAP Operating Expense[3]	$345M to $360M	→	$340M to $350M

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 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, November 6, 2024, at 8:30 a.m. ET to discuss the third 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 September 30, 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.

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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 September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Net product sales	$ 141,517	$ 103,501	$ 378,589	$ 284,274
Cost of goods sold	13,279	9,946	38,107	26,002
Gross profit	128,238	93,555	340,482	258,272
Operating expenses:				
Research and development	26,160	40,704	79,172	117,352
Selling, general, and administrative	75,106	65,651	236,711	205,031
Changes in fair value of contingent consideration payable	—	1,995	—	2,583
Restructuring charges	3,143	—	9,188	—
Loss on impairment of assets	—	—	—	1,134
Depreciation and amortization	2,170	2,228	6,506	5,691
Total operating expenses	106,579	110,578	331,577	331,791
Income (loss) from operations	21,659	(17,023)	8,905	(73,519)
Other expense:				
Interest income	1,081	1,471	3,991	5,407
Interest expense	(12,692)	(12,986)	(37,640)	(37,322)
Other (expense) income	(3,263)	3,833	(11,946)	(13,007)
Income (loss) before income tax	6,785	(24,705)	(36,690)	(118,441)
Income tax (expense) benefit	(13,514)	3,128	(34,155)	700
Net loss attributable to common stockholders	$ (6,729)	$ (21,577)	$ (70,845)	$ (117,741)
Net loss attributable to common stockholders per common share — basic and diluted	$ (0.02)	$ (0.07)	$ (0.23)	$ (0.40)
Weighted-average common shares outstanding — basic and diluted	304,690,596	295,759,435	303,792,479	293,314,167

TABLE 2

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

	September 30, 2024	December 31, 2023
Assets		
Current assets:		

Cash and cash equivalents	$ 233,647	$ 246,994
Investments in marketable securities	16,110	39,206
Accounts receivable	98,073	87,632
Inventories	115,338	59,696
Prepaid expenses and other current assets	35,306	49,533
Total current assets	498,474	483,061
Operating lease right-of-use assets, net	23,144	26,312
Property and equipment, less accumulated depreciation of $29,324 and $25,429 at September 30, 2024 and December 31, 2023, respectively	30,438	31,667
Intangible assets, less accumulated amortization of $4,974 and $2,510 at September 30, 2024 and December 31, 2023, respectively	18,026	20,490
Goodwill	197,797	197,797
Other non-current assets	18,678	18,553
Total Assets	$ 786,557	$ 777,880
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 13,481	$ 15,120
Accrued expenses and other current liabilities	136,116	144,245
Operating lease liabilities	8,541	8,324
Total current liabilities	158,138	167,689
Long-term debt	389,494	387,858
Operating lease liabilities	46,623	48,877
Other non-current liabilities	13,477	13,282
Total liabilities	607,732	617,706
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.01 par value, 500,000,000 shares authorized, 298,691,094 and 293,594,209 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	2,942	2,918
Additional paid-in capital	2,905,760	2,836,018
Accumulated other comprehensive income (loss):		
Foreign currency translation adjustment	25,159	5,429
Unrealized loss on available-for-sale securities	(188)	(188)
Warrants	71	71
Accumulated deficit	(2,754,919)	(2,684,074)
Total stockholders' equity	178,825	160,174
Total Liabilities and Stockholders' Equity	$ 786,557	$ 777,880

TABLE 3

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Total operating expenses - as reported GAAP	**$ 106,579**	**$ 110,578**	**$ 331,577**	**$ 331,791**
Research and development:				
Stock-based compensation	4,397	4,380	12,329	16,987
Selling, general and administrative:				
Stock-based compensation	14,291	12,131	53,359	50,995
Loss on impairment of assets	—	—	—	1,134
Changes in fair value of contingent consideration payable	—	1,995	—	2,583
Restructuring Charges	3,143	—	9,188	—
Depreciation and amortization	2,170	2,228	6,506	5,691
Total operating expense adjustments to reported GAAP	24,001	20,734	81,382	77,390
Total operating expenses - as adjusted	$ 82,578	$ 89,844	$ 250,195	$ 254,401

TABLE 4

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
GAAP net loss	**$ (6,729)**	**$ (21,577)**	**$ (70,845)**	**$ (117,741)**
Share-based compensation	18,688	16,511	65,688	67,982
Changes in fair value of contingent consideration payable	—	1,995	—	2,583
Depreciation and amortization	2,170	2,228	6,506	5,691
Loss on impairment of assets	—	—	—	1,134
Restructuring charges	3,143	—	9,188	—
Income tax expense (benefit)	13,514	(3,128)	34,155	(700)
Non-GAAP net income (loss)	$ 30,786	$ (3,971)	$ 44,692	$ (41,051)
Non-GAAP net income (loss) attributable to common stockholders per common share — basic and diluted	$ 0.10	$ (0.01)	$ 0.15	$ (0.14)
Weighted-average common shares outstanding — basic and diluted	304,690,596	295,759,435	303,792,479	293,314,167