# Amicus Therapeutics Announces Second Quarter 2024 Financial Results and Corporate Updates

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***Q2 2024 Total Revenue of $126.7M, a 34% Increase Year-over-Year***

***Galafold® Q2 Revenue of $110.8M, up 17% Year-over-Year***

***Pombiliti® + Opfolda® Q2 Revenue of $15.9M, up 44% from Q1 2024***

***Raising 2024 Total Revenue Growth Guidance to 26%-31% at CER and 2024 Galafold Growth Guidance to 14%-18% at CER***

***Narrowing non-GAAP Operating Expense Guidance to $345M to $360M***

***Non-GAAP Profitability Achieved in Q2 and H1 2024 with Acceleration Expected in H2***

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

PRINCETON, N.J., Aug. 08, 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 second quarter ended June 30, 2024.

"In the first half of 2024 we demonstrated strong commercial execution, leading to robust revenue growth and achieving non-GAAP profitability for the period," said Bradley Campbell, President and Chief Executive Officer of Amicus Therapeutics, Inc. "We are very pleased with the continued global uptake of Galafold and sustained patient demand leading to the increase of our 2024 guidance. The commercial launch of Pombiliti and Opfolda is performing exceptionally well with a steady addition of new patients in each of the approved markets. Looking ahead, we remain confident in our ability to deliver significant revenue growth, accomplish our objective of achieving full-year non-GAAP profitability and continuing to deliver on our mission for people living with rare diseases."

**Financial and Corporate Highlights:**

- **Total revenue in the second quarter 2024** was $126.7 million, a year-over-year increase of 34% from total revenue of $94.5 million in the second quarter 2023. On a constant currency basis (CER)[1], second quarter 2024 total revenue growth was 36%. Given strong performance in the first half 2024, the Company is raising its full year 2024 total revenue growth guidance to 26% to 31% on a constant currency basis (CER)[1].

| (in thousands) | Three Months Ended June 30, | | Year over Year % Growth | | Six Months Ended June 30, | | Year over Year % Growth | |
|---|---|---|---|---|---|---|---|---|
| | 2024 | 2023 | Reported | at CER[1] | 2024 | 2023 | Reported | at CER[1] |
| Galafold® | $110,817 | $94,331 | 17% | 19% | $210,176 | $180,443 | 16% | 17% |
| Pombiliti® + Opfolda® | $15,852 | $172 | n/a | n/a | $26,896 | $330 | n/a | n/a |
| Net Product Revenues | $126,669 | $94,503 | 34% | 36% | $237,072 | $180,773 | 31% | 32% |

- **Galafold (migalastat) net product sales** were $110.8 million in the second quarter 2024, a year-over-year increase of 17%, or 19% at constant exchange rates[1], reflecting continued strong demand. As a result of strong performance in the first half 2024, the company is raising its revenue growth guidance for Galafold to 14% to 18% on a constant currency basis (CER)[1].
- **Pombiliti (cipaglucosidase alfa-atga) + Opfolda (miglustat) net product sales** were $15.9 million in the second quarter 2024, a 44% increase from the first quarter of 2024. As of the end of July, 186 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 well on-track to achieve full year 2024 revenue guidance for Pombiliti + Opfolda of $62 million to $67 million on a constant currency basis (CER)[1].
- **Swissmedic in Switzerland approved Pombiliti + Opfolda on July 4th** as a long-term enzyme replacement therapy and enzyme stabilizer for adults with late-onset Pompe disease. Additional regulatory reviews are ongoing in Australia and Canada.
- **Total GAAP operating expenses** of $100.4 million for the second quarter 2024 decreased by 4% as compared to $104.2

million for the second quarter 2023. **Total non-GAAP operating expenses** of $82.1 million for the second quarter 2024 decreased by 2% as compared to $84.0 million for the second quarter 2023. Given our continued financial discipline in the first half of 2024, the Company enhances its non-GAAP Operating Expense guidance[3] to $345 million to $360 million.

- **GAAP net loss** was $15.7 million, or $0.05 per share, for the second quarter 2024, and was reduced compared to a net loss of $43.2 million, or $0.15 per share, for the second quarter 2023.
- **Non-GAAP net income** was $18.5 million, or $0.06 per share, for the second quarter 2024, compared to a non-GAAP net loss of $20.3 million, or $0.07 per share, for second quarter 2023[2]. Non-GAAP profitability was also achieved in the first half 2024. The Company expects non-GAAP profitability to accelerate in the second half 2024.
- **Cash, cash equivalents, and marketable securities** totaled $260.1 million at June 30, 2024, compared to $286.2 million at December 31, 2023.

**2024 Financial Guidance:**

| | Previous | | Updated |
|---|---|---|---|
| Total Revenue Growth[1] | 25% to 30% | → | 26% to 31% |
| Galafold Revenue Growth[1] | 13% to 17% | → | 14% to 18% |
| Pombiliti + Opfolda Revenue[1] | $62M to $67M | → | $62M to $67M |
| Non-GAAP Operating Expense[3] | $345M to $365M | → | $345M to $360M |

**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, August 8, 2024, at 8:30 a.m. ET to discuss the second 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 June 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.

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 June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | **2024** | **2023** | **2024** | **2023** |
| Net product sales | $ 126,669 | $ 94,503 | $ 237,072 | $ 180,773 |
| Cost of goods sold | 11,261 | 9,114 | 24,828 | 16,056 |
| Gross profit | 115,408 | 85,389 | 212,244 | 164,717 |
| Operating expenses: | | | | |
| Research and development | 24,683 | 35,149 | 53,012 | 76,648 |
| Selling, general, and administrative | 73,576 | 65,423 | 161,605 | 139,380 |
| Changes in fair value of contingent consideration payable | — | 337 | — | 588 |
| Restructuring charges | — | — | 6,045 | — |
| Loss on impairment of assets | — | 1,134 | — | 1,134 |
| Depreciation and amortization | 2,182 | 2,206 | 4,336 | 3,463 |
| Total operating expenses | 100,441 | 104,249 | 224,998 | 221,213 |
| Income (loss) from operations | 14,967 | (18,860) | (12,754) | (56,496) |
| Other expense: | | | | |
| Interest income | 1,370 | 1,737 | 2,910 | 3,936 |
| Interest expense | (12,512) | (12,492) | (24,948) | (24,336) |
| Other expense | (3,717) | (10,902) | (8,683) | (16,840) |
| Income (loss) before income tax | 108 | (40,517) | (43,475) | (93,736) |
| Income tax expense | (15,805) | (2,715) | (20,641) | (2,428) |
| **Net loss attributable to common stockholders** | $ (15,697) | $ (43,232) | $ (64,116) | $ (96,164) |
| Net loss attributable to common stockholders per common share — basic and diluted | $ (0.05) | $ (0.15) | $ (0.21) | $ (0.33) |
| Weighted-average common shares outstanding — basic and diluted | 303,773,922 | 292,797,002 | 303,336,787 | 292,071,201 |

**TABLE 2**

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

| | June 30, 2024 | December 31, 2023 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 209,335 | $ 246,994 |
| Investments in marketable securities | 50,727 | 39,206 |
| Accounts receivable | 85,174 | 87,632 |
| Inventories | 81,320 | 59,696 |
| Prepaid expenses and other current assets | 35,145 | 49,533 |
| Total current assets | 461,701 | 483,061 |
| Operating lease right-of-use assets, net | 22,611 | 26,312 |
| Property and equipment, less accumulated depreciation of $27,844 and $25,429 at June 30, 2024 and December 31, 2023, respectively | 31,161 | 31,667 |
| Intangible assets, less accumulated amortization of $4,147 and $2,510 at June 30, 2024 and December 31, 2023, respectively | 18,853 | 20,490 |
| Goodwill | 197,797 | 197,797 |
| Other non-current assets | 17,361 | 18,553 |
| **Total Assets** | $ 749,484 | $ 777,880 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 32,057 | $ 15,120 |
| Accrued expenses and other current liabilities | 127,897 | 144,245 |
| Operating lease liabilities | 8,112 | 8,324 |
| Total current liabilities | 168,066 | 167,689 |
| Long-term debt | 388,939 | 387,858 |
| Operating lease liabilities | 47,007 | 48,877 |
| Other non-current liabilities | 12,949 | 13,282 |
| Total liabilities | 616,961 | 617,706 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Common stock, $0.01 par value, 500,000,000 shares authorized, 296,428,877 and 293,594,209 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively | 2,923 | 2,918 |
| Additional paid-in capital | 2,868,925 | 2,836,018 |
| Accumulated other comprehensive income (loss): | | |
| Foreign currency translation adjustment | 8,991 | 5,429 |
| Unrealized loss on available-for-sale securities | (197) | (188) |
| Warrants | 71 | 71 |
| Accumulated deficit | (2,748,190) | (2,684,074) |
| Total stockholders' equity | 132,523 | 160,174 |
| **Total Liabilities and Stockholders' Equity** | $ 749,484 | $ 777,880 |

**TABLE 3**

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | **2024** | **2023** | **2024** | **2023** |
| **Total operating expenses - as reported GAAP** | **$ 100,441** | **$ 104,249** | **$ 224,998** | **$ 221,213** |
| **Research and development:** | | | | |
| Stock-based compensation | 3,061 | 4,117 | 7,932 | 12,607 |
| **Selling, general and administrative:** | | | | |
| Stock-based compensation | 13,136 | 12,460 | 39,068 | 38,864 |
| **Loss on impairment of assets** | — | 1,134 | — | 1,134 |
| **Changes in fair value of contingent consideration payable** | — | 337 | — | 588 |
| **Restructuring Charges** | — | — | 6,045 | — |
| **Depreciation and amortization** | 2,182 | 2,206 | 4,336 | 3,463 |
| **Total operating expense adjustments to reported GAAP** | 18,379 | 20,254 | 57,381 | 56,656 |
| **Total operating expenses - as adjusted** | $ 82,062 | $ 83,995 | $ 167,617 | $ 164,557 |

**TABLE 4**

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | **2024** | **2023** | **2024** | **2023** |
| **GAAP net loss** | **$ (15,697)** | **$ (43,232)** | **$ (64,116)** | **$ (96,164)** |
| Share-based compensation | 16,197 | 16,577 | 47,000 | 51,471 |
| Changes in fair value of contingent consideration payable | — | 337 | — | 588 |
| Depreciation and amortization | 2,182 | 2,206 | 4,336 | 3,463 |
| Loss on impairment of assets | — | 1,134 | — | 1,134 |
| Restructuring charges | — | — | 6,045 | — |
| Income tax expense | 15,805 | 2,715 | 20,641 | 2,428 |
| Non-GAAP net income (loss) | $ 18,487 | $ (20,263) | $ 13,906 | $ (37,080) |
| Non-GAAP net income (loss) attributable to common stockholders per common share — basic and diluted | $ 0.06 | $ (0.07) | $ 0.05 | $ (0.13) |
| Weighted-average common shares outstanding — basic and diluted | 303,773,922 | 292,797,002 | 303,336,787 | 292,071,201 |