UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT PURSUANT TO
SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): **May 10, 2023**

AMICUS THERAPEUTICS, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	001-33497	71-0869350
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

3675 Market Street, Philadelphia, PA 19104
(Address of Principal Executive Offices, and Zip Code)

215-921-7600
Registrant's Telephone Number, Including Area Code

(Former Name or Former Address, if Changed Since Last Report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock Par Value $0.01	FOLD	NASDAQ

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).
Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On May 10, 2023,Amicus Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended March 31, 2023. A copy of this press release is attached hereto as Exhibit 99.1. The Company will host a conference call and webcast on May 10, 2023 to discuss its first quarter results of operations. A copy of the conference call presentation materials is attached hereto as Exhibit 99.2. Both exhibits are incorporated herein by reference.

In accordance with General Instruction B.2. of Form 8-K, the information in this Current Report on Form 8-K and the Exhibits shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No.	Description
99.1	Press Release dated May 10, 2023
99.2	May 10, 2023 Conference Call Presentation Materials
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

Signature Page

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AMICUS THERAPEUTICS, INC.

Date: May 10, 2023

By: /s/ Ellen S. Rosenberg
Name: Ellen S. Rosenberg
Title: Chief Legal Officer and Corporate Secretary

Amicus Therapeutics Announces First Quarter 2023 Financial Results and Corporate Updates

1Q23 Revenue Growth of 14% at CER to $86.3M

On Track to Deliver Full-Year 2023 Galafold Revenue Growth of 12%-17% at CER

U.S. FDA Pre-approval Inspection for AT-GAA Complete; Approval Expected 3Q 2023

European Launch of Pombiliti®+Opfolda® Expected 3Q 2023

Non-GAAP Profitability Projected in 2H 2023

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

PHILADELPHIA, PA, May. 10, 2023 – 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, 2023.

Bradley Campbell, President and Chief Executive Officer of Amicus Therapeutics, Inc., stated, "We had an outstanding start to 2023 across our global business. In Q1, Galafold saw strong operational growth primarily driven by robust patient demand in our major markets. We are pleased with the outcome of the U.S. FDA inspection of the WuXi Biologics manufacturing facility and remain highly confident in the anticipated global approvals of AT-GAA as we move towards launch in the three largest Pompe markets this year. Our strategic focus remains on continuing to grow Galafold, securing regulatory approvals and launching of AT-GAA, and achieving non-GAAP profitability in the second half of 2023. Together, we see these driving value for our stakeholders and advancing our mission of delivering high quality medicines for people living with rare diseases."

Corporate Highlights:

- **Global revenue in the first quarter 2023 was $86.3 million**. First quarter revenue represented a year-over-year increase of 10% from total revenue of $78.7 million in the first quarter of 2022. First quarter operational revenue growth measured at constant exchange rates (CER)[1] was 14%.

(in thousands)	Three Months Ended March 31,		Year over Year % Growth	
	2023	2022	As Reported	at CER[1]
Net Product Revenues	$ 86,270	$ 78,715	10%	14%

- **For the full-year 2023, the Company anticipates double-digit Galafold revenue growth of 12-17% at CER[1].** Growth is expected to be driven by continued underlying demand from both switch and treatment-naïve patients, geographic expansion, label extensions, continued diagnosis of new Fabry patients, and commercial execution across all major markets, including the U.S., EU, U.K., and Japan.

- **The U.S. Food and Drug Administration (FDA) has very recently completed the required pre-approval inspection of the WuXi Biologics manufacturing site in China.** The Company believes the comments and observations received at the close of the FDA inspection are all addressable and continues to expect regulatory approval of AT-GAA in the U.S. in the third quarter of 2023.

- **The EU and U.K. AT-GAA regulatory reviews remain on-track with marketing authorization expected in 3Q 2023.** In the European Union (EU), the European Commission (EC) granted approval for Pombiliti® (cipaglucosidase alfa), used in combination with miglustat for adults with late-onset Pompe disease. In April, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion of Opfolda® (miglustat), the enzyme stabilizer component. Full approval of Pombiliti + Opfolda is anticipated in the third quarter of 2023. In the U.K., the regulatory submission process was initiated in December 2022, with final approval expected in the third quarter of 2023.

- **Strategic expansion of Supply and Manufacturing Services Agreement with WuXi Biologics.** The long-term agreement further strengthens relationship with WuXi and secures long-term capacity at the new state-of-the-art manufacturing facility of WuXi in Dundalk, Ireland.

- **Expanded access programs continue to meet the growing demand for AT-GAA across multiple countries**. In the U.K., under the Early Access to Medicines Scheme (EAMS), multiple physicians have requested access from each of the leading Pompe centers in the country. Many patients with Pompe disease are participating in additional expanded access programs in the U.S., Germany, France, and Japan.

- **Galafold U.S. intellectual property estate strengthened following the issuance of multiple new patents in 2023.** Galafold is protected by orphan drug regulatory exclusivities and a broad U.S. intellectual property portfolio of 49 orange book-listed patents, including 8 composition of matter patents, 33 of which provide protection through at least 2038.

- **Full-year 2023 non-GAAP operating expense guidance of $340 million to $360 million**, driven by prudent expense management while investing in AT-GAA manufacturing and pre-launch activities.

- **Based on the current operating plan, the timing of AT-GAA approvals, and through prudent management of expenses, the Company is on-track to achieve non-GAAP profitability[2] in the second half of 2023.**

First Quarter 2023 Financial Results

- Total revenue in the first quarter 2023 was $86.3 million, a year-over-year increase of 10% from total revenue of $78.7 million in the first quarter 2022. On a constant currency basis, first quarter 2023 total revenue growth was 14%. Compared to the first quarter 2022, reported revenue was offset by a negative currency impact of $3.8 million, or 4%.
- Cash, cash equivalents, and marketable securities totaled $267.1 million at March 31, 2023, compared to $293.6 million at December 31, 2022.
- Total GAAP operating expenses of $117.0 million for the first quarter 2023 decreased as compared to $146.5 million for the first quarter 2022.
- Total non-GAAP operating expenses of $80.6 million for the first quarter 2023 decreased as compared to $109.0 million for the first quarter 2022, primarily reflecting decreased program spend.[3]
- Net loss was $52.9 million, or $0.18 per share in the first quarter 2023, and was reduced compared to a net loss of $85.3 million, or $0.30 per share, for the first quarter 2022.

2023 Financial Guidance

- For the full-year 2023, the Company anticipates total Galafold revenue growth between 12 and 17% at CER[1] driven by continued underlying demand from both switch and treatment-naïve patients, geographic expansion, label extensions, the continued diagnosis of new Fabry patients, and commercial execution across all major markets, including the U.S., EU, U.K., and Japan.
- Non-GAAP operating expense guidance for the full-year 2023 is $340 million to $360 million, driven by prudent expense management offset by continued investment in Galafold, AT-GAA clinical studies and pre-launch activities, in addition to certain non-recurring costs for manufacturing to support the global launch of AT-GAA[4].
- The Company is on-track to achieve non-GAAP profitability[2] in the second half of 2023.

Amicus is focused on the following five key strategic priorities in 2023:

- Sustain double-digit Galafold revenue growth (12-17% at CER[1])
- Secure FDA, EMA, and MHRA approvals for AT-GAA
- Initiate successful global launches of AT-GAA
- Advance next generation pipeline programs (Fabry GTx, Fabry Next-Generation Chaperone, Pompe GTx)
- Maintain strong financial position on path to profitability

[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. Full-year 2023 Galafold revenue guidance utilizes the actual exchange rates at December 31, 2022.

[2] Based on projections of Amicus' non-GAAP Net Income under current operating plans, which includes successful AT-GAA regulatory approvals and continued Galafold growth. Amicus defines non-GAAP Net Income as GAAP Net 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.

[3] 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.

[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 10, 2023, at 8:30 a.m. ET to discuss the first quarter 2023 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 Fabry patients 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.

EU Important Safety Information

Treatment with Galafold should be initiated and supervised by specialists experienced in the diagnosis and treatment of Fabry disease. Galafold is not recommended for use in patients with a nonamenable mutation.

- Galafold is not intended for concomitant use with enzyme replacement therapy.
- Galafold is not recommended for use in patients with Fabry disease who have severe renal impairment (<30 mL/min/1.73 m2). The safety and efficacy of Galafold in children less than 12 years of age have not yet been established. No data are available.
- No dosage adjustments are required in patients with hepatic impairment or in the elderly population.
- There is very limited experience with the use of this medicine in pregnant women. If you are pregnant, think you may be pregnant, or are planning to have a baby, do not take this medicine until you have checked with your doctor, pharmacist, or nurse.
- While taking Galafold, effective birth control should be used. It is not known whether Galafold is excreted in human milk.

- Contraindications to Galafold include hypersensitivity to the active substance or to any of the excipients listed in the PRESCRIBING INFORMATION.
- Galafold 123 mg capsules are not for children (≥12 years) weighing less than 45 kg.
- It is advised to periodically monitor renal function, echocardiographic parameters and biochemical markers (every 6 months) in patients initiated on Galafold or switched to Galafold.
- OVERDOSE: General medical care is recommended in the case of Galafold overdose.
- The most common adverse reaction reported was headache, which was experienced by approximately 10% of patients who received Galafold. For a complete list of adverse reactions, please review the SUMMARY OF PRODUCT CHARACTERISTICS.
- Call your doctor for medical advice about side effects.

For further important safety information for Galafold, including posology and method of administration, special warnings, drug interactions and adverse drug reactions, please see the European SmPC for Galafold available from the EMA website at www.ema.europa.eu.

About Fabry Disease

Fabry disease is an inherited lysosomal disorder caused by deficiency of an enzyme called alpha-galactosidase A (alpha-Gal A), which results from mutations in the GLA gene. The primary biological function of alpha-Gal A is to degrade specific lipids in lysosomes, including globotriaosylceramide (referred to here as GL-3 and also known as Gb3). Lipids that can be degraded by the action of alpha-Gal A are called "substrates" of the enzyme. Reduced or absent levels of alpha-Gal A activity lead to the accumulation of GL-3 in the affected tissues, including heart, kidneys, and skin. Accumulation of GL-3 and progressive deterioration of organ function is believed to lead to the morbidity and mortality of Fabry disease. The symptoms can be severe, differ from person to person, and begin at an early age.

About Pompe Disease

Pompe disease is an inherited lysosomal disorder caused by deficiency of the enzyme acid alpha-glucosidase (GAA). Reduced or absent levels of GAA lead to accumulation of glycogen in cells, which is believed to result in the clinical manifestations of Pompe disease. Pompe disease ranges from a rapidly fatal infantile form with significant impacts to heart function, to a more slowly progressive, late-onset form primarily affecting skeletal muscle and progressive respiratory involvement. Late-onset Pompe disease can be severe and debilitating, including progressive muscle weakness throughout the body, particularly the skeletal muscles and muscles controlling breathing, that worsens over time.

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 Twitter 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 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 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, including as they are impacted by COVID-19 related disruption, are based on current information. The potential impact on operations from the COVID-19 pandemic is inherently unknown and cannot be predicted with confidence and may cause actual results and performance to differ materially from the statements in this release, including without limitation, because of the impact on general political and economic conditions, including as a result of efforts by governmental authorities to mitigate COVID-19, such as travel bans, shelter in place orders and third-party business closures and resource allocations, manufacturing and supply chain disruptions and limitations on patient access to commercial or clinical product. In addition to the impact of the COVID-19 pandemic, 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, including the FDA, EMA, MHRA, and PMDA, 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 commercializing Galafold in Europe, Japan, the US and other geographies or AT-GAA if and when approved; 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 and manufacturing. Further, the results of earlier preclinical studies and/or clinical trials may not be predictive of future results. Statements regarding corporate financial guidance and financial goals and the attainment of such goals. With respect to statements regarding projections of the Company's revenue 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, 2022, and on Form 10-Q for the quarter ended March 31, 2023, 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,	
	2023	**2022**
Net product sales	$ 86,270	$ 78,715
Cost of goods sold	6,942	7,582
Gross profit	79,328	71,133
Operating expenses:		
Research and development	41,499	81,517
Selling, general, and administrative	73,957	58,116
Changes in fair value of contingent consideration payable	251	(1,188)
Loss on impairment of assets	—	6,616
Depreciation and amortization	1,257	1,411
Total operating expenses	116,964	146,472
Loss from operations	(37,636)	(75,339)
Other (expense) income:		
Interest income	2,199	133
Interest expense	(11,844)	(8,147)
Other (expense) income	(5,938)	1,902
Loss before income tax	(53,219)	(81,451)
Income tax benefit (expense)	287	(3,809)
Net loss attributable to common stockholders	$ (52,932)	$ (85,260)
Net loss attributable to common stockholders per common share — basic and diluted	$ (0.18)	$ (0.30)
Weighted-average common shares outstanding — basic and diluted	291,336,750	288,481,741

TABLE 2

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

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 160,602	$ 148,813
Investments in marketable securities	106,507	144,782
Accounts receivable	68,178	66,196
Inventories	27,004	23,816
Prepaid expenses and other current assets	37,406	40,209
Total current assets	399,697	423,816
Operating lease right-of-use assets, net	28,483	29,534
Property and equipment, less accumulated depreciation of $22,901 and $22,281 at March 31, 2023 and December 31, 2022, respectively	31,406	30,778
Intangible asset, less accumulated depreciation of $36 and $0 at March 31, 2023 and December 31, 2022, respectively	22,964	23,000
Goodwill	197,797	197,797
Other non-current assets	20,172	19,242
Total Assets	$ 700,519	$ 724,167
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 24,965	$ 15,413
Accrued expenses and other current liabilities	92,747	93,636
Contingent consideration payable	12,668	21,417
Operating lease liabilities	8,005	8,552
Total current liabilities	138,385	139,018
Long-term debt	392,658	391,990
Operating lease liabilities	51,349	51,578
Deferred reimbursements	5,906	4,656
Deferred income taxes	—	4,939
Other non-current liabilities	9,648	8,939
Total liabilities	597,946	601,120
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.01 par value, 500,000,000 shares authorized, 283,300,585 and 281,108,273 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	2,820	2,815
Additional paid-in capital	2,691,836	2,664,744
Accumulated other comprehensive loss:		
Foreign currency translation adjustment	(6,543)	(11,989)
Unrealized loss on available-for-sale securities	(201)	(116)
Warrants	83	83
Accumulated deficit	(2,585,422)	(2,532,490)
Total stockholders' equity	102,573	123,047
Total Liabilities and Stockholders' Equity	$ 700,519	$ 724,167

TABLE 3

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

	Three Months Ended March 31,	
	2023	**2022**
Total operating expenses - as reported GAAP	**$ 116,964**	**$ 146,472**
Research and development:		
Stock-based compensation	8,490	9,365
Selling, general and administrative:		
Stock-based compensation	26,404	21,286
Loss on impairment of assets	—	6,616
Changes in fair value of contingent consideration payable	251	(1,188)
Depreciation and amortization	1,257	1,411
Total operating expense adjustments to reported GAAP	36,402	37,490
Total operating expenses - as adjusted	$ 80,562	$ 108,982


AT THE FOREFRONT OF
THERAPIES FOR RARE DISEASES
1Q23 Results
Conference Call &
Webcast
May 10, 2023
Amicus
Therapeutics

Forward-Looking Statements

This presentation contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 relating to preclinical and clinical development of our prod 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 candida commercialization plans, manufacturing and supply plans, financing plans, and the projected revenues and cash position for the Company. The inclusion of forward-looking statements sho 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 presentation may turn out to be wrong and can be affec 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 discussions with regulatory authorities, including as they are impacted by COVID-19 related disruption, are based on current information. The potential impact on operations from the COV 19 pandemic is inherently unknown and cannot be predicted with confidence and may cause actual results and performance to differ materially from the statements in this release, includ without limitation, because of the impact on general political and economic conditions, including as a result of efforts by governmental authorities to mitigate COVID-19, such as travel ba shelter in place orders and third-party business closures and resource allocations, manufacturing and supply chain disruptions and limitations on patient access to commercial or clini product. In addition to the impact of the COVID-19 pandemic, actual results may differ materially from those set forth in this release due to the risks and uncertainties inherent in our busine 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 en patients in our clinical trials; the potential that regulatory authorities, including the FDA, EMA, MHRA, and PMDA, may not grant or may delay approval for our product candidates; the poten 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 commercializing Galafol Europe, Japan, the US and other geographies or AT-GAA if and when approved; the potential that preclinical and clinical studies could be delayed because we identify serious side effects 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 compl all of our studies and manufacturing. Further, the results of earlier preclinical studies and/or clinical trials may not be predictive of future results. Statements regarding corporate financ guidance and financial goals and the attainment of such goals. With respect to statements regarding projections of the Company's revenue and cash position, actual results may differ based 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 Form 10-K for the year ended December 31, 2022, and on Form 10-Q for the quarter ended March 31, 2023, to be filed today. You are cautioned not to place undue reliance on these forwa 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 rev or update this news release to reflect events or circumstances after the date hereof.

Non-GAAP Financial Measures

In addition to financial information prepared in accordance with U.S. GAAP, this presentation also contains adjusted financial measures that we believe provide investors and management w supplemental information relating to operating performance and trends that facilitate comparisons between periods and with respect to projected information. These adjusted financ 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 typically exclude cert 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 th measures in different ways. When we provide our expectation for non-GAAP operating expenses on a forward-looking basis, a reconciliation of the differences between the non-GA 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 t 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 potentia unpredictable, impact on our future GAAP results.

A Rare Company

Patient-dedicated, rare disease biotechnology company with sustained double-digit revenue growth, a global commercial infrastructure, and late-stage development capabilities

Galafold® (migalastat)

First Oral Precision Medicine for Fabry Disease

GLOBAL COMMERCIAL ORGANIZATION

World-class Clinical Development Capabilities

Gene Therapy Platform

Leveraging Experience in Protein Engineering & Glycobiology

Non-GAAP PROFITABILITY expected in **2H 2023**

EMPLOYEES in 20 Countries

AT-GAA

Under Global Regulatory Reviews for Pompe Disease

12-17%

FY23 Galafold Revenue Growth at CER

GALAFOLD & **POMBILITI + OPFOLDA**

Cumulative $1.5B-$2B Peak Potential

$267M

Cash as of 3/31/23

2023 Strategic Priorities

1. Sustain double-digit Galafold revenue growth of 12-17% at CE
2. Secure FDA, EMA, and MHRA approvals for AT-GAA
3. Initiate successful global launches of AT-GAA
4. Advance best-in-class, next-generation Fabry and Pompe pipeli programs and capabilities
5. Maintain strong financial position on path to profitability

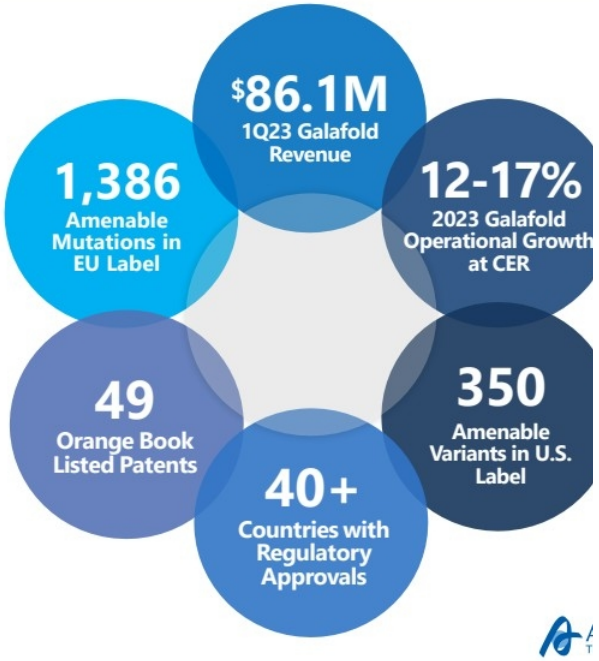
[1]CER: Constant Exchange Rates; 2023 Galafold revenue guidance utilizes actual exchange rate as of December 31, 2022

Amicus Therapeutics®

2023 Galafold Success (as of March 31, 2023)

Building on Galafold's success and leveraging leadership position to drive continued growth

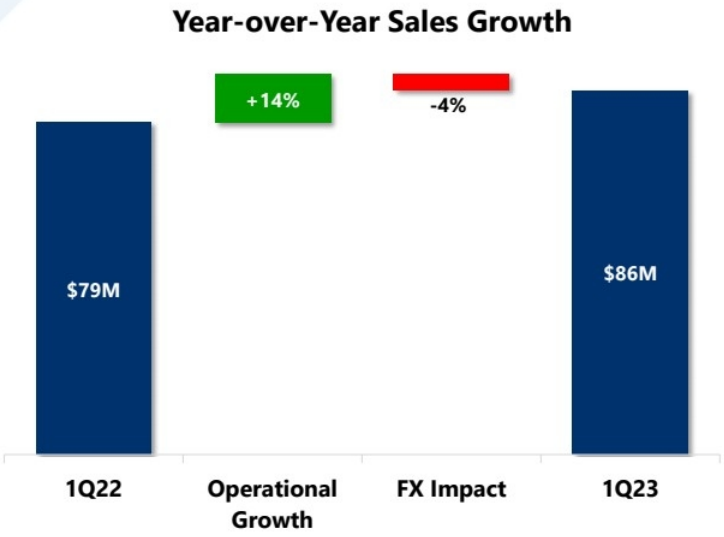
Galafold is the first and only approved oral treatment option with a unique mechanism of action for Fabry patients with amenable variants



Galafold is indicated for adults with a confirmed diagnosis of Fabry disease and an amenable variant. The most common adverse reactions reported with Galafold (≥10%) were headache, nasopharyngitis, urinary tract infection, nausea, and pyrexia. For additional information about Galafold, including the full U.S. Prescribing Information, please visit https://www.amicusrx.com/pi/Galafold.pdf. For further important safety information for Galafold, including posology and method of administration, special warnings, drug interactions, and adverse drug reactions, please see the European SmPC for Galafold available from the EMA website at www.ema.europa.eu.

Galafold Performance

Year-over-year reported revenue growth of +10% to $86.1M – Strong operational growth of +14% at CER

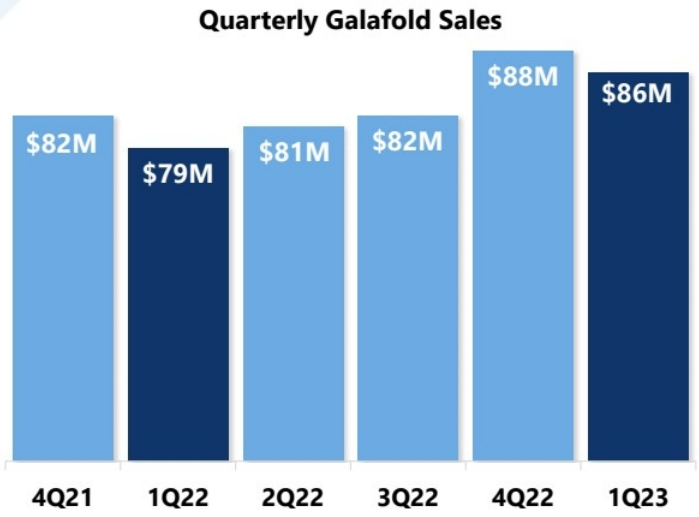


- >55% share of treated amenable patients
- Global mix of switch (~45%) and previously untreated patients (~55%)[1]
- Compliance and adherence over 90%+

[1]Data on file

Galafold Quarterly Trends

Galafold quarterly growth remains strong with Q1 revenue of $86.1M



- Expect non-linear quarterly growth to continue d
to uneven ordering patterns and FX fluctuations

Distribution of Galafold Revenue by Quarter in Past 5 years:

	Q1	Q2	Q3	Q4
5 Year Avg.	22%	24%	26%	28%

Galafold Global Commercial Momentum (as of March 31, 2023)

Strong patient demand and performance against key metrics lay the foundation for continued double-digit growth in 2023

Pombiliti + Opfolda Launch Preparations

Experienced and passionate rare disease commercial and medical organization ready to support second successful product launch

Team	Training and launch readiness established across commercial and medical teams Tier 1 countries trained and prepared for launch
KOLs	Existing relationships with HCPs at key treatment centers and hospitals to leverage upon launch
Marketing	Educational and promotional materials developed to help facilitate outreach at launch
Supply Chain	International distribution system with product moving through the channel
Scientific Exchange	Robust clinical data and continued disease education through publications and medical congresses
Access	Commitment to patient access Expansion of Amicus Assist in U.S.
Initial Focus	Focus within the first 90 days on converting clinical trial and expanded access patients
Payors	Engaging with payors to demonstrate value

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AT-GAA
(cipaglucosidase alfa) + (miglustat)

Potential to establish a new standard of care
for people living with Pompe disease

Pompe Disease Overview

Pompe is a severe and fatal neuromuscular disease caused by the deficiency of lysosomal enzyme GA

- Estimated incidence of ~1:28,000; Significant underdiagnosis
- Age of onset ranges from infancy to adulthood
- Majority of patients on current standard of care decline after ~2 years
- Respiratory and cardiac failure are leading causes of morbidity and mortality
- Deficiency of GAA leading to lysosomal glycogen accumulation and cellular dysfunction
- Symptoms include muscle weakness, respiratory failure, and cardiomyopathy
- ~$1.2B+ global Pompe ERT sales[1]

[1]Based on 12 months ended December 31, 2022. Source: Sanofi Press Release

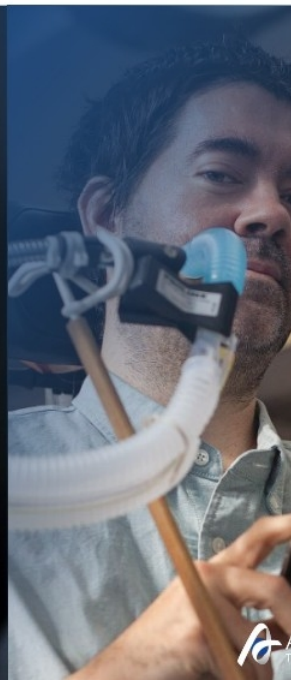
AT-GAA: Global Regulatory Status

Expect regulatory approvals and launch into the three largest Pompe markets in 2023

- Pombiliti® (cipaglucosidase alfa) EC approval granted in March 2023
- Opfolda® (miglustat) positive CHMP opinion in April 2023
  EC approval expected in 3Q 2023

- U.S. FDA pre-approval inspection complete
- FDA approval expected 3Q 2023

- U.K. MAA submitted via recognition procedure based on CHMP opinion
- Anticipating 3Q 2023 MHRA approval



AT-GAA: Ongoing Clinical Studies and Expanded Access Mechanisms

Advancing science though ongoing clinical studies and providing expanded access through multiple mechanisms

- Ongoing clinical studies in children and adolescents[1] with LOPD as well as in Infantile-Onset Pompe Disease (IOPD)
- Multiple expanded access mechanisms in place, including in the U.S., U.K., Germany, France, Japan, and others
- ~200 people living with Pompe disease are now on AT-GAA across extension studies and expanded access programs
- ~75 centers worldwide currently participating in clinical trials and access programs

[1] Children and adolescents aged 0 to <18 years old

Corporate Outlook

Delivering on our mission for patients and shareholders

2023 Select Financial Results

2023 revenue of $86.3M and growth rate of 14% at CER from global sales

(in thousands, except per share data)	Mar. 31, 2023	Mar. 31, 2022
Product Revenue	$86,270	$78,715
Cost of Goods Sold	6,942	7,582
R&D Expense	41,499	81,517
SG&A Expense	73,957	58,116
Changes in Fair Value of Contingent Consideration	251	(1,188)
Loss on Impairment of Assets	—	6,616
Depreciation and Amortization	1,257	1,411
Loss from Operations	(37,636)	(75,339)
Income Tax Benefit (Expense)	287	(3,809)
Net Loss	(52,932)	(85,260)
Net Loss Per Share	(0.18)	(0.30)

Financial Outlook and Path to Profitability

Clear strategy to build our business, advance our portfolio, and achieve profitability

Sustain Revenue Growth

$86.3M 1Q 2023 revenue, +14% YoY operational growth

2023 Galafold revenue growth guidance of **+12-17%** YoY ***at CER***

Secure Approvals of AT-GAA

Galafold and AT-GAA expected to drive strong double-digit growth long term

Deliver on Financial Goals

Focused on prudent expense management

2023 non-GAAP operating expense guidance of **$340M-$360M**

Achieve profitability[1] in 2H 2023

[1]Based on projections of Amicus non-GAAP Net Income under current operating plans, which includes successful AT-GAA regulatory approvals and continued Galafold growth. We define non-GAAP Net Income as GAAP Net Income excluding the impact of share-based compensation expense, changes in fair value of contingent consideration, depreciation and amortization, acquisition related income (expense), loss on extinguishment of debt, loss on impairment of assets, restructuring charges, and income taxes.

Positioned for Significant Value Growth

Focused on execution and driving sustainable double-digit revenue growth on path to profitabili

- Continue to bring Galafold® to as many patients as possible, sustain double-digit operational revenue growth
- Successful launch of AT-GAA for people living with Pompe disease
- Advance next-generation gene therapies in Fabry and Pompe diseases
- Fully leverage global capabilities and infrastructure as a leader in rare diseases
- Achieve non-GAAP profitability in 2H 2023[1]

[1] Based on projections of Amicus non-GAAP Net Income under current operating plans, which includes successful AT-GAA regulatory approvals and continued Galafold growth. Non-GAAP Net Income defined as GAAP Net 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.

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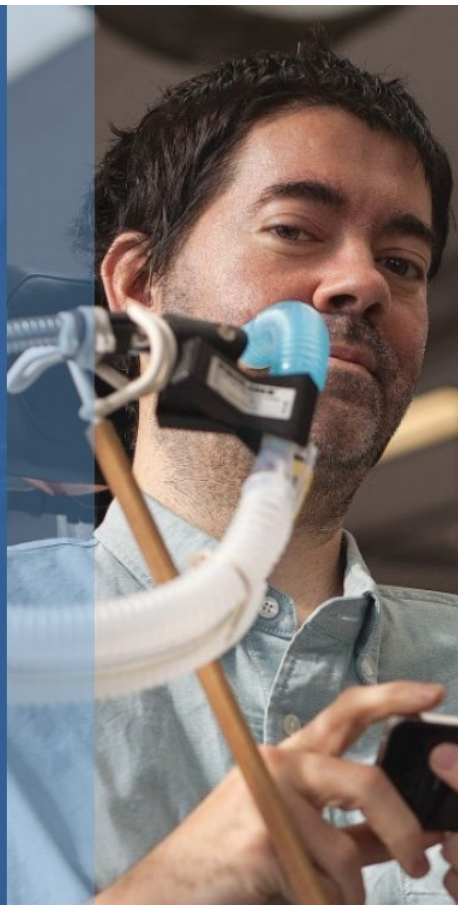
Appendix



Appendix

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

	Three Months Ended March 31,	
	2023	**2022**
Total operating expenses - as reported GAAP	**$ 116,964**	**$ 146,472**
Research and development:		
Stock-based compensation	8,490	9,365
Selling, general and administrative:		
Stock-based compensation	26,404	21,286
Loss on impairment of assets	—	6,616
Changes in fair value of contingent consideration payable	251	(1,188)
Depreciation and amortization	1,257	1,411
Total operating expense adjustments to reported GAAP	36,402	37,490
Total operating expenses - as adjusted	$ **80,562**	$ **108,982**

2022 Environmental, Social, & Governance (ESG) Snapshot

Who We Serve

Programs we invest in have 3 key characteristics

- **Address a rare genetic disease**
- **First-in-class or best-in-class**
- **Impart meaningful benefit for patients**

Pledge for a Cure

Designate a portion of product revenue back into R&D for that specific disease until there is a cure.

Pricing PROMISE

Committed to never raising the annual price of our products more than consumer inflation.

Charitable Giving

Contributions allocated:

$2,288,998 U.S.

$954,349 Intl.

Expanded Access through Feb 2023:
79 patients / **19** countries

Amicus supported community programs:
22

Volunteer hours (U.S.):
580

Environmental Management

Committed to producing transformative medicines for patients while practicing environmental responsibility and adhering to sustainability best practices in our operations.

*Our mission is to drive **sustainability with our partners** by incorporating environmental and sustainability principles into all our commercial relationships*

0% **Amicus Owned Direct Manufacturing and Related GHG Emissions**

Global Employees
484

% Female Employees
57%

% Hiring Slate Diversity **97%**

Board of Directors

Committed to ongoing Board refreshment and diversity of background, gender, skills, and experience:

Director Diversity
3 Female
2 Veteran Status
1 African American

80% **Board Independence**

60% **Overall Board Diversity**

Diversity, Equity, & Inclusion (DEI)

Pledge to support a more inclusive culture to im our employees, our communities, and society.

Goal of maintaining gender dive increasing overall diversity thr our global w

Employee Recruitment, Engagement, & Retention

Leverage employee capabilities and expertise to pr culture that drives performance and ultimately attra energizes, and retains critical talent.

*Pulse surveys reveal employees feel **high perso satisfaction** in their job, are **proud of their w** and what they contribute to the community*

Career Developr

Reimagined performance management pr measure the what and the how, rewarding th role-model our **Mission-Focused Be**

FX Sensitivity and Galafold Distribution of Quarterly Sales

Impact from Foreign Currency Q1 2023

Currency Variances: USD/	Q1 2022	Q1 2023	YoY Variance
EUR	1.122	1.073	(4.4%)
GBP	1.342	1.215	(9.5%)
JPY	0.009	0.008	(12.2%)

Full Year 2023 Revenue Sensitivity

Given the high proportion of Amicus revenue Ex-US, a change in exchange rates of +/- 5% compared to year end 2022 rates could lead to a $11M-$12M change in global reported revenues in 2023.

Distribution of Galafold Revenue by Quarter in Past 5 years:

	Q1	Q2	Q3	Q4
5 Year Avg.	22%	24%	26%	28%

Amicus Pipeline

Streamlined rare disease pipeline with focus on Fabry disease and Pompe disease franchises

Amicus Therapeutics®

Thank you