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): **August 3, 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 August 8, 2023, Amicus Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended June 30, 2023. A copy of this press release is attached hereto as Exhibit 99.1. The Company will host a conference call and webcast on August 8, 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 Item 2.02 of 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 5.02. – Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officer.

The Company announced today that Daphne Quimi, the Company's Chief Financial Officer, notified the Company on August 3, 2023 that she intends to retire before the end of 2023. Both the Company and Ms. Quimi expect that she will remain employed by the Company as Chief Financial Officer until a successor Chief Financial Officer is appointed. The Company and Ms. Quimi also expect that Ms. Quimi will remain employed by the Company for a transition period following the appointment of such successor to ensure an orderly transition of duties and responsibilities.

The Company is conducting an external search for its next Chief Financial Officer, and through this search the Company has already identified a number of highly qualified candidates.

Forward Looking Statements

This Current Report on Form 8-K contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. 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. All forward-looking statements are subject to risks detailed in our Annual Report on Form 10-K for the year ended December 31, 2022 and the Quarterly Report filed on Form 10-Q for the quarter ended March 31, 2023. 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.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits:

Exhibit No.	Description
99.1	Press Release dated August 8, 2023
99.2	August 8, 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: August 8, 2023

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

Amicus Therapeutics Announces Second Quarter 2023 Financial Results and Corporate Updates

1H 2023 Revenue Growth of 16% at CER to $180.8M

Raising FY 2023 Galafold® Revenue Growth Guidance to 14%-18% at CER

EU Launch of Pombiliti® + Opfolda® Underway; U.S. and U.K. Approvals Expected 3Q 2023

Reducing 2023 Non-GAAP Operating Expense Guidance to $330M-$350M

Non-GAAP Profitability Projected in 2H 2023

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

PHILADELPHIA, PA, Aug. 8, 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 second quarter ended June 30, 2023.

Bradley Campbell, President and Chief Executive Officer of Amicus Therapeutics, Inc., stated, "Amicus has made tremendous progress through the first half of 2023, highlighted by the strong growth of Galafold and the regulatory approval of Pombiliti and Opfolda in the EU. We are confident in our trajectory towards delivering on our core objectives this year, including the continued growth of Galafold and the anticipated approvals of Pombiliti and Opfolda in the U.S. and U.K. this quarter. I am also very pleased to share we have revised our revenue guidance upwards and are reducing operating expense guidance for the year further supporting our path to non-GAAP profitability. Amicus is well positioned to deliver sustainable value for our shareholders while advancing our mission to deliver great medicines for people living with rare diseases."

Corporate Highlights:

- **Global revenue in the second quarter 2023 was $94.5 million.** Second quarter revenue represented a year-over-year increase of 17% from total revenue of $80.7 million in the second quarter 2022. Second quarter performance reflected a strong operational revenue growth of 17% measured at constant exchange rates (CER)[1] and a negligible currency impact of $0.2 million, or 0%.

- **Global revenue in the first half 2023 was $180.8 million.** First half revenue represented a year-over-year increase of 13% from total revenue of $159.4 million in the first half 2022. First half performance reflected strong operational revenue growth of 16% measured at constant exchange rates (CER)[1] and a negative currency impact of $4.1 million, or 3%.

	Three Months Ended June 30,		Year over Year % Growth		Six Months Ended June 30,		Year over Year % Growth	
(in thousands)	2023	2022	As Reported	at CER[1]	2023	2022	As Reported	at CER[1]
Net Product Revenues	$ 94,503	$ 80,731	17%	17%	$ 180,773	$ 159,446	13%	16%

- **Given strong operational performance in the first half of 2023, the Company now anticipates Galafold® revenue growth of 14-18% at CER[1] for the full-year 2023.** 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.

- **Commercial Launch of Pombiliti® (cipaglucosidase alfa) + Opfolda® (miglustat) underway in the EU.** In the EU, the European Commission granted full approval of Pombiliti + Opfolda for the treatment of adults with late-onset Pompe disease (LOPD). The Company has initiated the commercial launch of Pombiliti + Opfolda in Germany and reimbursement discussions with healthcare authorities in additional European countries are underway.

- **U.S. and U.K. regulatory reviews of AT-GAA remain on-track.** The Company continues to expect regulatory approvals of AT-GAA in both the U.S. and U.K. in the third quarter of 2023.
- **Galafold U.S. intellectual property estate further 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 53 orange book-listed patents, including 9 composition of matter patents, 37 of which provide protection through 2038 and beyond.
- **Full-year 2023 non-GAAP operating expense guidance reduced to $330 million to $350 million**, driven by prudent expense management while investing in AT-GAA manufacturing and launch activities.
- **Based on the current operating plan and the timing of AT-GAA approvals, the Company is on-track to achieve non-GAAP profitability[2] in the second half of 2023.**
- **Amicus announces retirement of Chief Financial Officer, Daphne Quimi.** After 15 years of distinguished leadership at Amicus, Daphne Quimi has decided to retire. Ms. Quimi will remain in her role as CFO until her successor is appointed and will remain with Amicus through the end of the year in order to support a smooth transition.

Second Quarter 2023 Financial Results

- Total revenue in the second quarter 2023 was $94.5 million, a year-over-year increase of 17% from total revenue of $80.7 million in the second quarter 2022. On a constant currency basis, second quarter 2023 total revenue growth was 17%. Currency impact on reported revenue in the second quarter of 2023 represented a negligible amount of $0.2 million, or 0%.
- Total GAAP operating expenses of $104.2 million for the second quarter 2023 decreased as compared to $133.1 million for the second quarter 2022.
- Total non-GAAP operating expenses of $84.0 million for the second quarter 2023 decreased as compared to $119.2 million for the second quarter 2022, primarily reflecting decreased program spend.[3]
- Net loss was $43.2 million, or $0.15 per share in the second quarter 2023, and was reduced compared to a net loss of $62.2 million, or $0.21 per share, for the second quarter 2022.
- Cash, cash equivalents, and marketable securities totaled $265.6 million at June 30, 2023, compared to $293.6 million at December 31, 2022.

2023 Financial Guidance

- For the full-year 2023, the Company now anticipates total Galafold revenue growth between 14 and 18% at CER[1] driven by several factors including continued strong underlying demand from both switch and treatment-naïve patients further geographic expansion and 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.
- Amicus is reducing its non-GAAP operating expense guidance for the full-year 2023 to $330 million to $350 million, driven by prudent expense management offset by continued investment in Galafold, AT-GAA clinical studies, non-recurring costs for manufacturing as well as global launch activities[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 (14-18% at CER[1])
- Secure EMA, MHRA and FDA approvals for Pombiliti + Opfolda
- Initiate successful global launches of Pombiliti + Opfolda
- 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, August 8, 2023, at 8:30 a.m. ET to discuss the second 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 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 Therapeutic Indication

Galafold® (migalastat) is indicated for long-term treatment of adults and adolescents aged 12 years and older with a confirmed diagnosis of Fabry disease (α-galactosidase A deficiency) and who have an amenable mutation.

EU Important Safety Information

Treatment with Galafold should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of Fabry disease. Galafold is not intended for concomitant use with enzyme replacement therapy.

The safety and efficacy of Galafold in children aged less than 12 years have not been established. No data are available.

Galafold is contraindicated in patients with hypersensitivity to the active substance or to any of the excipients listed in the Summary of Product Characteristics (SmPC).

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 or switched to Galafold. In case of meaningful clinical deterioration, further clinical evaluation or discontinuation of treatment with Galafold should be considered.

Galafold is not indicated for use in patients with non-amenable mutations.

Galafold is not recommended for use in patients with severe renal insufficiency, defined as estimated GRF less than 30 mL/min/1.73m^2.

Food and caffeine should not be consumed at least 2 hours before and 2 hours after taking Galafold to give a minimum 4 hours fast.

Galafold is not recommended in women of childbearing potential not using contraception. Galafold is not recommended during pregnancy. It is not known whether Galafold is secreted in human milk.

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 SmPC.

OVERDOSE: General medical care is recommended in the case of Galafold overdose.

For complete information please see the EU SmPC available at https://www.ema.europa.eu/en/medicines/human/EPAR/galafold

About Pombiliti® + Opfolda®

Pombiliti + Opfolda, is a two-component therapy that consists of cipaglucosidase alfa, 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. In clinical studies, Pombiliti + Opfolda was associated with demonstrated improvements in both musculoskeletal and respiratory measures.

Important Safety Information

Pombiliti (cipaglucosidase alfa) Important Safety Information

Posology and Method of Administration: Pombiliti must be used in combination with miglustat 65 mg hard capsules. The recommended dose of Pombiliti is 20 mg/kg of body weight every other week. The Pombiliti infusion should start 1 hour after taking miglustat capsules. ***Paediatric population:*** The safety and efficacy of Pombiliti in combination with miglustat therapy in paediatric patients less than 18 years old have not yet been established. No data are available. ***Contraindications*:** Life-threatening hypersensitivity to the active substance, or to any of the excipients. Contraindication to miglustat. ***Anaphylaxis and infusion-associated reactions (IARs):*** Serious anaphylaxis and IARs have occurred in some patients during infusion and following infusion with Pombiliti. Premedication with oral antihistamine, antipyretics, and/or corticosteroids may be administered to assist with signs and symptoms related to IARs experienced with prior enzyme replacement therapy (ERT) treatment. Reduction of the infusion rate, temporary interruption of the infusion, symptomatic treatment with oral antihistamine, or antipyretics, and appropriate resuscitation measures should be considered to manage serious IARs. If anaphylaxis or severe allergic reactions occur, infusion should be immediately paused, and appropriate medical treatment should be initiated. The current medical standards for emergency treatment of anaphylactic reactions are to be observed and cardiopulmonary resuscitation equipment should be readily available. The risks and benefits of re-administering Pombiliti following anaphylaxis or severe allergic reaction should be carefully considered, and appropriate resuscitation measures made available. ***Risk of acute cardiorespiratory failure in susceptible patients:*** Patients with acute underlying respiratory illness or compromised cardiac and/or respiratory function may be at risk of serious exacerbation of their cardiac or respiratory compromise during infusions. Appropriate medical support and monitoring measures should be readily available during Pombiliti infusion. ***Immune complex-related reactions:*** Immune complex-related reactions have been reported with other ERTs in patients who had high IgG antibody titres, including severe cutaneous reactions and nephrotic syndrome. If immune complex-related reactions occur, discontinuation of the administration of Pombiliti should be considered and appropriate medical treatment should be initiated. The risks and benefits of re-administering Pombiliti following an immune complex-related reaction should be reconsidered for each individual patient. ***Contraception in females:*** Reliable contraceptive measures must be used by women of childbearing potential during treatment with Pombiliti in combination with miglustat, and for 4 weeks after discontinuing treatment. ***Pregnancy:*** Pombiliti in combination with miglustat therapy is not recommended during pregnancy. ***Breast feeding:*** It is not known if Pombiliti and miglustat are secreted in human breast milk. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Pombiliti in combination with miglustat therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman. ***Summary of the safety profile:*** The most commonly reported adverse reactions only attributable to Pombiliti were chills (4.0%), dizziness (2.6%), flushing (2.0%), somnolence (2.0%), chest discomfort (1.3%), cough, (1.3%), infusion site swelling (1.3%), and pain (1.3%). Reported serious adverse reactions only attributable to Pombiliti were urticaria (2.0%), anaphylaxis (1.3%), pyrexia (0.7%), presyncope (0.7%), dyspnoea (0.7%), pharyngeal oedema (0.7%), wheezing (0.7%), and hypotension (0.7%). Refer to SmPC for full list.

Opfolda (miglustat) 65 mg hard capsules Important Safety Information

Posology and Method of Administration: Opfolda must be used in combination with Pombiliti. The recommended dose is to be taken orally every other week and is based on body weight. Opfolda should be taken approximately 1 hour but no more than 3 hours before the start of the Pombiliti infusion. **Paediatric population:** The safety and efficacy of Opfolda in combination with Pombiliti therapy in paediatric patients less than 18 years old have not yet been established. No data are available. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. Contraindication to cipaglucosidase alfa. **Food Interaction:** Patients should fast for 2 hours before and 2 hours after taking Opfolda. **Contraception in females:** Reliable contraceptive measures must be used by women of childbearing potential during treatment with Opfolda in combination with Pombiliti, and for 4 weeks after discontinuing treatment. **Pregnancy:** Opfolda crosses the placenta. Opfolda in combination with Pombiliti therapy is not recommended during pregnancy. **Breast feeding:** It is not known if Opfolda and Pombiliti are secreted in human breast milk. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Opfolda in combination with Pombiliti therapy taking into account the benefit of breastfeeding for the child and the benefit of therapy for the woman. **Summary of the safety profile:** The most commonly reported adverse reaction only attributable to Opfolda 65 mg was constipation (1.3%). Refer to SmPC for full list.

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 June 30, 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.

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 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,	
	2023	**2022**	**2023**	**2022**
Net product sales	$ 94,503	$ 80,731	$ 180,773	$ 159,446
Cost of goods sold	9,114	8,197	16,056	15,779
Gross profit	85,389	72,534	164,717	143,667
Operating expenses:				
Research and development	35,149	78,319	76,648	159,836
Selling, general, and administrative	65,423	53,379	139,380	111,495
Changes in fair value of contingent consideration payable	337	115	588	(1,073)
Loss on impairment of assets	1,134	—	1,134	6,616
Depreciation and amortization	2,206	1,334	3,463	2,745
Total operating expenses	104,249	133,147	221,213	279,619
Loss from operations	(18,860)	(60,613)	(56,496)	(135,952)
Other (expense) income:				
Interest income	1,737	356	3,936	489
Interest expense	(12,492)	(8,257)	(24,336)	(16,404)
Other (expense) income	(10,902)	7,268	(16,840)	9,170
Loss before income tax	(40,517)	(61,246)	(93,736)	(142,697)
Income tax expense	(2,715)	(911)	(2,428)	(4,720)
Net loss attributable to common stockholders	$ (43,232)	$ (62,157)	$ (96,164)	$ (147,417)
Net loss attributable to common stockholders per common share — basic and diluted	$ (0.15)	$ (0.21)	$ (0.33)	$ (0.51)
Weighted-average common shares outstanding — basic and diluted	292,797,002	291,970,562	292,071,201	288,646,587

TABLE 2

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

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 211,307	$ 148,813
Investments in marketable securities	54,319	144,782
Accounts receivable	63,716	66,196
Inventories	51,381	23,816
Prepaid expenses and other current assets	52,099	40,209
Total current assets	432,822	423,816
Operating lease right-of-use assets, net	28,042	29,534
Property and equipment, less accumulated depreciation of $24,060 and $22,281 at June 30, 2023 and December 31, 2022, respectively	30,238	30,778
Intangible asset, less accumulated depreciation of $855 and $0 at June 30, 2023 and December 31, 2022, respectively	22,145	23,000
Goodwill	197,797	197,797
Other non-current assets	19,049	19,242
Total Assets	$ 730,093	$ 724,167
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 13,522	$ 15,413
Accrued expenses and other current liabilities	124,868	93,636
Contingent consideration payable	13,005	21,417
Operating lease liabilities	7,840	8,552
Total current liabilities	159,235	139,018
Long-term debt	393,350	391,990
Operating lease liabilities	50,976	51,578
Deferred reimbursements	5,906	4,656
Deferred income taxes	—	4,939
Other non-current liabilities	9,045	8,939
Total liabilities	618,512	601,120
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.01 par value, 500,000,000 shares authorized, 286,992,923 and 281,108,273 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	2,856	2,815
Additional paid-in capital	2,733,148	2,664,744
Accumulated other comprehensive gain (loss):		
Foreign currency translation adjustment	4,337	(11,989)
Unrealized loss on available-for-sale securities	(177)	(116)
Warrants	71	83
Accumulated deficit	(2,628,654)	(2,532,490)
Total stockholders' equity	111,581	123,047
Total Liabilities and Stockholders' Equity	$ 730,093	$ 724,167

TABLE 3

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Total operating expenses - as reported GAAP	**$ 104,249**	**$ 133,147**	**$ 221,213**	**$ 279,619**
Research and development:				
Stock-based compensation	4,117	4,379	12,607	13,744
Selling, general and administrative:				
Stock-based compensation	12,460	8,084	38,864	29,370
Loss on impairment of assets	1,134	-	1,134	6,616
Changes in fair value of contingent consideration payable	337	115	588	(1,073)
Depreciation and amortization	2,206	1,334	3,463	2,745
Total operating expense adjustments to reported GAAP	20,254	13,912	56,656	51,402
Total operating expenses - as adjusted	$ 83,995	$ 119,235	$ 164,557	$ 228,217


AT THE FOREFRONT OF
THERAPIES FOR RARE DISEASES
2Q23 Results
Conference Call &
Webcast
August 8, 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 candidat 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 COVI 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, includi 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 potent 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 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 June 30, 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 certa 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 the 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 th 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

14-18%

FY23 Galafold Revenue Growth at CER

GALAFOLD & POMBILITI + OPFOLDA

Cumulative $1.5B-$2B Peak Potential

$266M

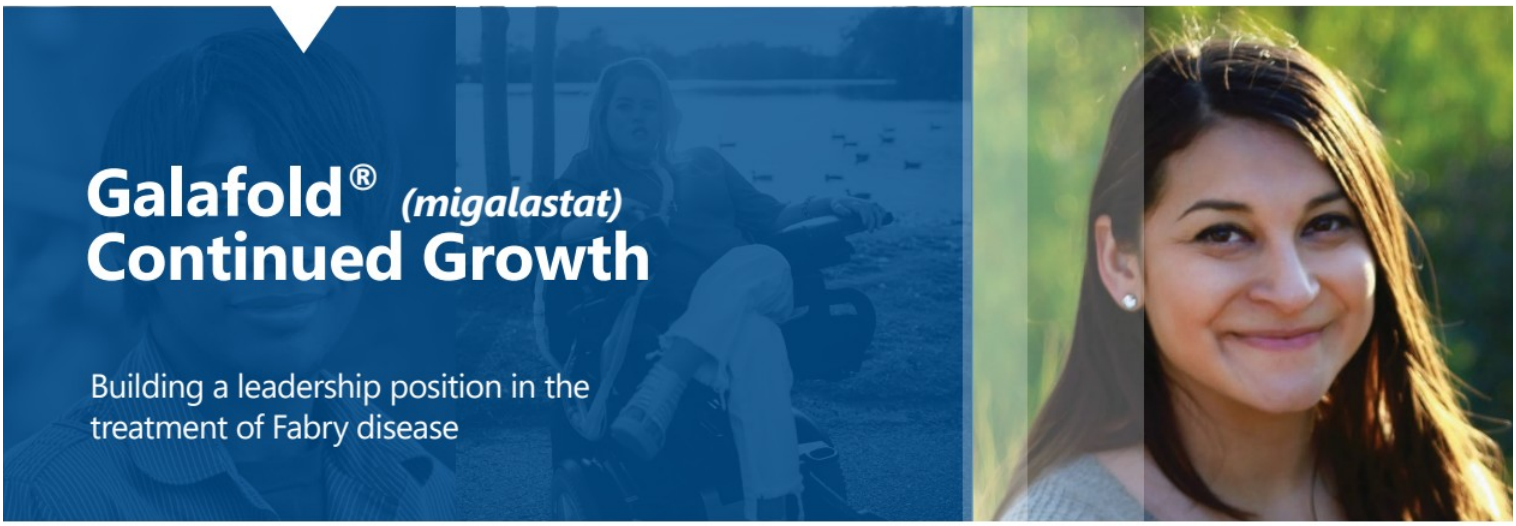
Cash as of 6/30/23

2023 Strategic Priorities

1. Sustain double-digit Galafold revenue growth of 14-18% at CER
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 pipeline 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

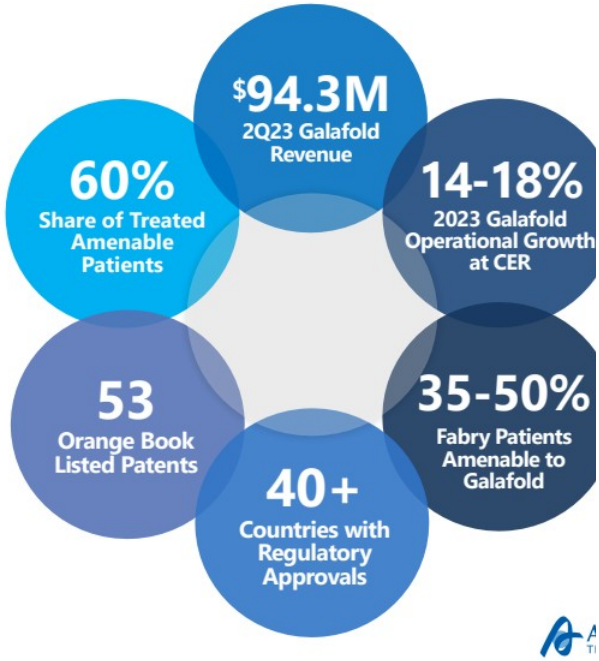
Amicus Therapeutics®



2023 Galafold Success (as of June 30, 2023)

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

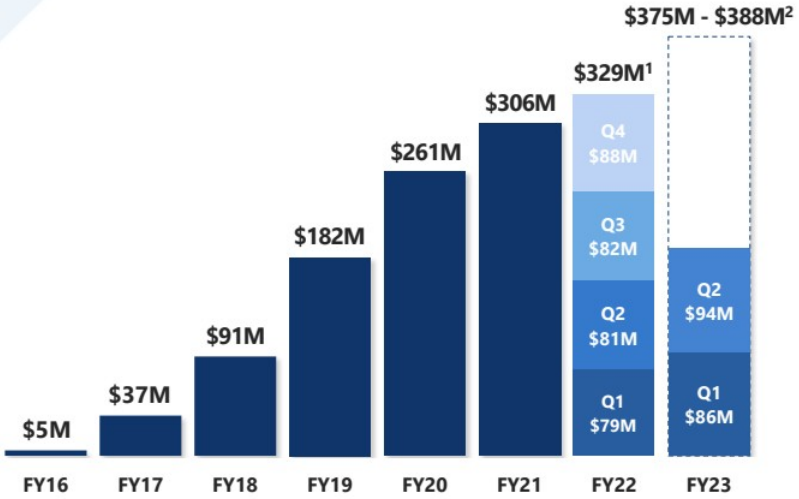
Galafold is the first and only approved oral treatment option with a unique mechanism of action for Fabry patients with amenable variants



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

Raising FY23 revenue growth guidance to 14% to 18% at CER



- Global mix of switch (~45%) and previously untreated patients (~55%)[3]
- Compliance and adherence over 90%+
- Expect non-linear quarterly growth to continue due to uneven ordering patterns and FX fluctuations

1H23 reported revenue growth of +13% to $180M with strong operational growth of +16%

[1] FY22 reported revenue growth of +8% to $329M with strong operational growth of +16% at CER – FY22 negative currency impact YoY of ~$26M
[2] At constant exchange rate (CER)
[3] Data on file

Galafold Global Commercial Momentum (as of June 30, 2023)

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

Amicus Therapeutics®

Pombiliti® *(cipaglucosidase alfa)* + Opfolda® *(miglustat)*

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

Late-Onset Pompe Disease (LOPD) Overview

Late-onset Pompe disease is a rare, debilitating, and life-threatening lysosomal disorder caused b a deficiency of the enzyme acid alpha-glucosidase (GAA)



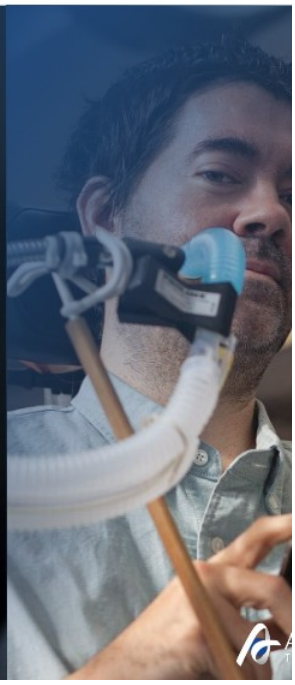
- ~5,000-10,000 people diagnosed globally; Significant underdiagnosis
- Diagnosed at different stages of life, from childhood to adulthood
- Majority of patients on current standard of care decline after ~2 years
- Respiratory failure is a maj cause of mortality
- Deficiency of GAA leading to lysosomal glycogen accumulation and cellular dysfunction
- Symptoms include progressive muscle weakness, particularly skeletal and respiratory muscles, that worsens over time
- ~$1.2B+ global Pompe ERT sales[1]

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

Global Regulatory Status

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

- Pombiliti® + Opfolda® now approved in the EU
- U.S. FDA approval expected 3Q 2023
- U.K. MAA submitted via recognition procedure based on CHMP opinion
- MHRA approval expected 3Q 2023



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 and infantile-onset Pompe disease (IOPD)
- Multiple expanded access mechanisms in place, including in the U.S., U.K., Germany, France, Japan, and others
- At time of first regulatory approval, ~200 people living with Pompe disease 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

Pombiliti + Opfolda EU Opportunity

EU Pompe market currently represents a sizeable market opportunity of $450M+

- Strong indication statement:
  - *Pombiliti® (cipaglucosidase alfa) is a long-term enzyme replacement therapy used in combination with the enzyme stabiliser Opfolda® (miglustat) for the treatment of adults with late-onset Pompe disease (acid α glucosidase [GAA] deficiency)*
- >1,300 patients are estimated to be treated in Europe[1]
  - ~60 Patients throughout EU currently on Pombiliti + Opfolda, including ~20 in Germany and Austria
- Launch underway in Germany
  - 6 month "free pricing" period and AMNOG reimbursement process
  - First patients dosed and additional patients scheduled to start infusions

[1] Amicus data on file from market mapping

Launch of Pombiliti + Opfolda Underway in the EU

Experienced and passionate rare disease commercial and medical organization supporting early days of launch

Pombiliti™ (cipaglucosidase alfa) + Opfolda™ (miglustat) capsules

Performance

Patient Demand

Initial focus on clinical trial and expanded access patients

First patients dosed; Multiple scheduled for infusion

On-track to transition all trial and expanded access patients in Germany within 90 days

KOL and Patient Outreach

Promotion and Education Efforts

Existing relationships with HCPs at key treatment centers

Engaging top prescribers within first 30 days

Ongoing disease education

Access and Reimbursemer

Positive Interactions with Payors

Focus on broad patient acc

Country-by-country reimbursement process

Active discussions to demonstrate value

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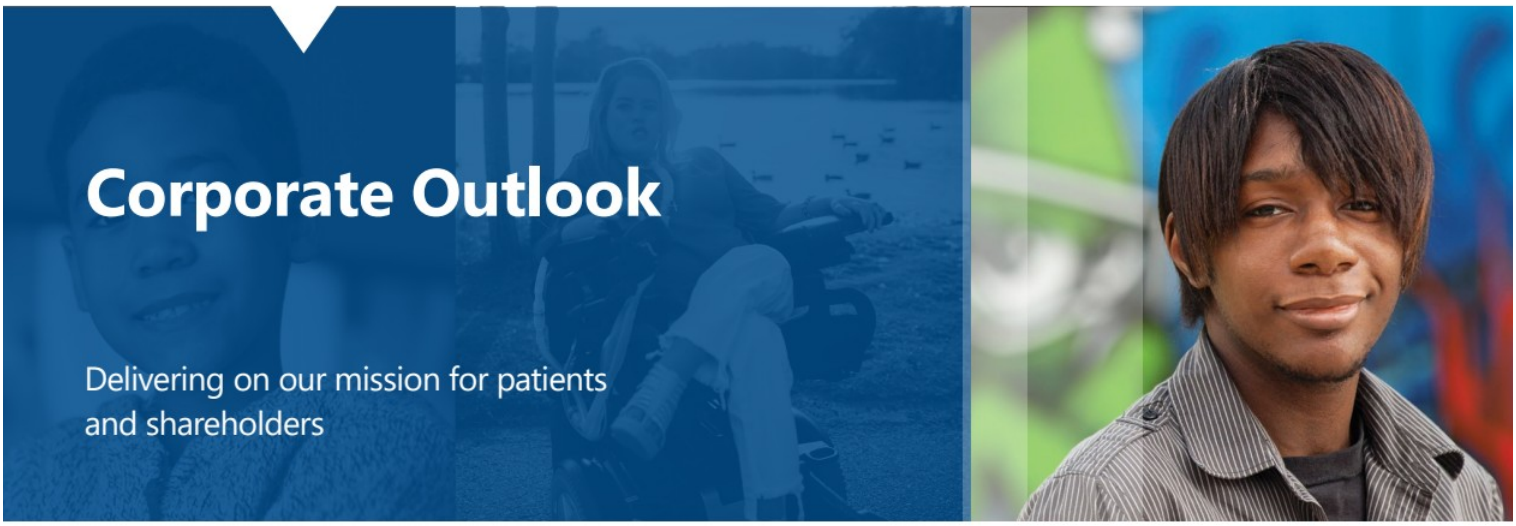


Corporate Outlook

Delivering on our mission for patients and shareholders

2Q 2023 Select Financial Results

2Q23 revenue of $94.5M and growth rate of 17% at CER

(in thousands, except per share data)	Jun. 30, 2023	Jun. 30, 2022
Product Revenue	$94,503	$80,731
Cost of Goods Sold	9,114	8,197
R&D Expense	35,149	78,319
SG&A Expense	65,423	53,379
Changes in Fair Value of Contingent Consideration	337	115
Loss on Impairment of Assets	1,134	—
Depreciation and Amortization	2,206	1,334
Loss from Operations	(18,860)	(60,613)
Income Tax Expense	(2,715)	(911)
Net Loss	(43,232)	(62,157)
Net Loss Per Share	(0.15)	(0.21)

Financial Outlook and Path to Profitability

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

Sustain Revenue Growth

$180.8M 1H 2023 revenue, **+16%** YoY operational growth

2023 Galafold revenue growth guidance of **+14-18%** 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

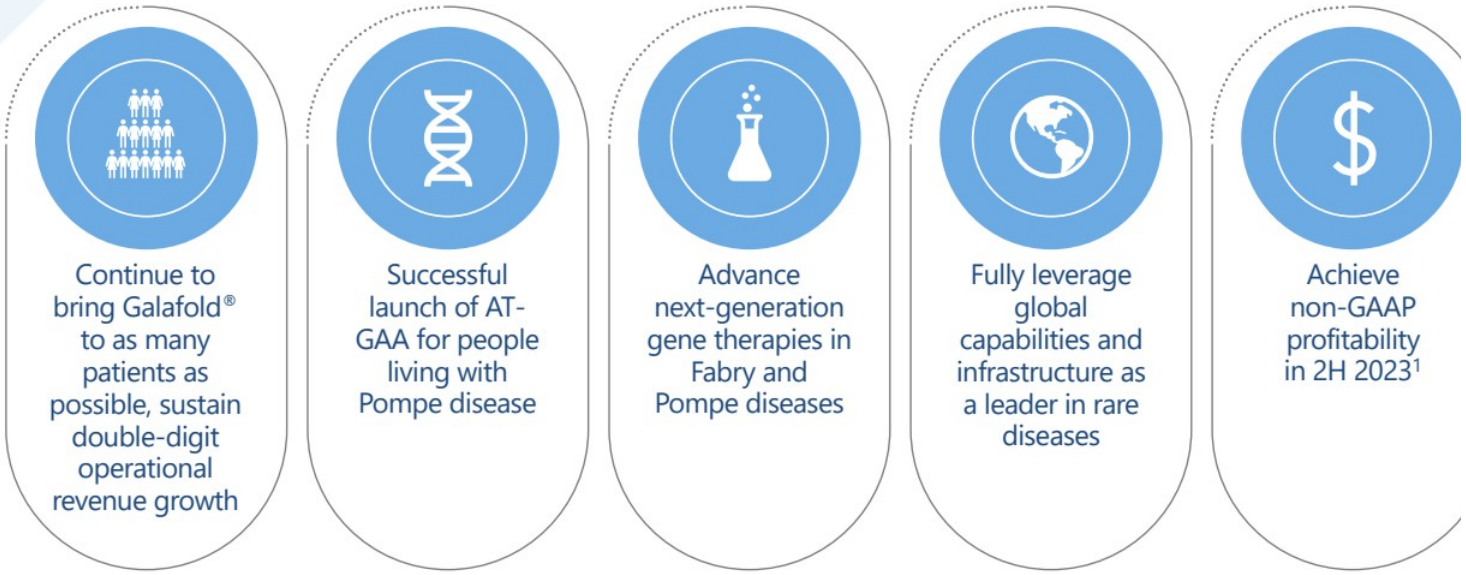
2023 non-GAAP operating expense guidance of **$330M-$350M**

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



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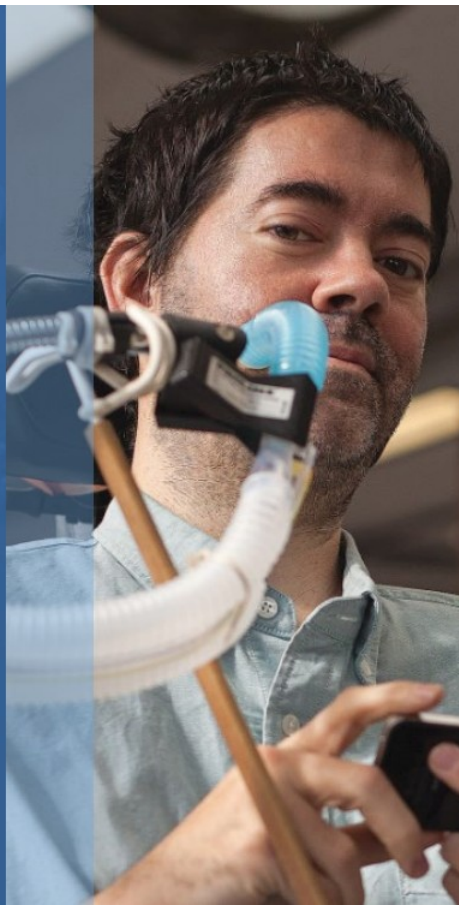
Appendix



Appendix

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Total operating expenses - as reported GAAP	**$104,249**	**$133,147**	**$221,213**	**$279,619**
Research and development:				
Stock-based compensation	4,117	4,379	12,607	13,744
Selling, general and administrative:				
Stock-based compensation	12,460	8,084	38,864	29,370
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Total operating expenses - as adjusted	$83,995	$119,235	$164,557	$228,217

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 Q2 2023

Currency Variances: USD/	Q2 2022	Q2 2023	YoY Variance
EUR	1.066	1.089	2.2%
GBP	1.257	1.251	(0.5%)
JPY	0.008	0.007	(5.6%)

Full Year 2023 Revenue Sensitivity

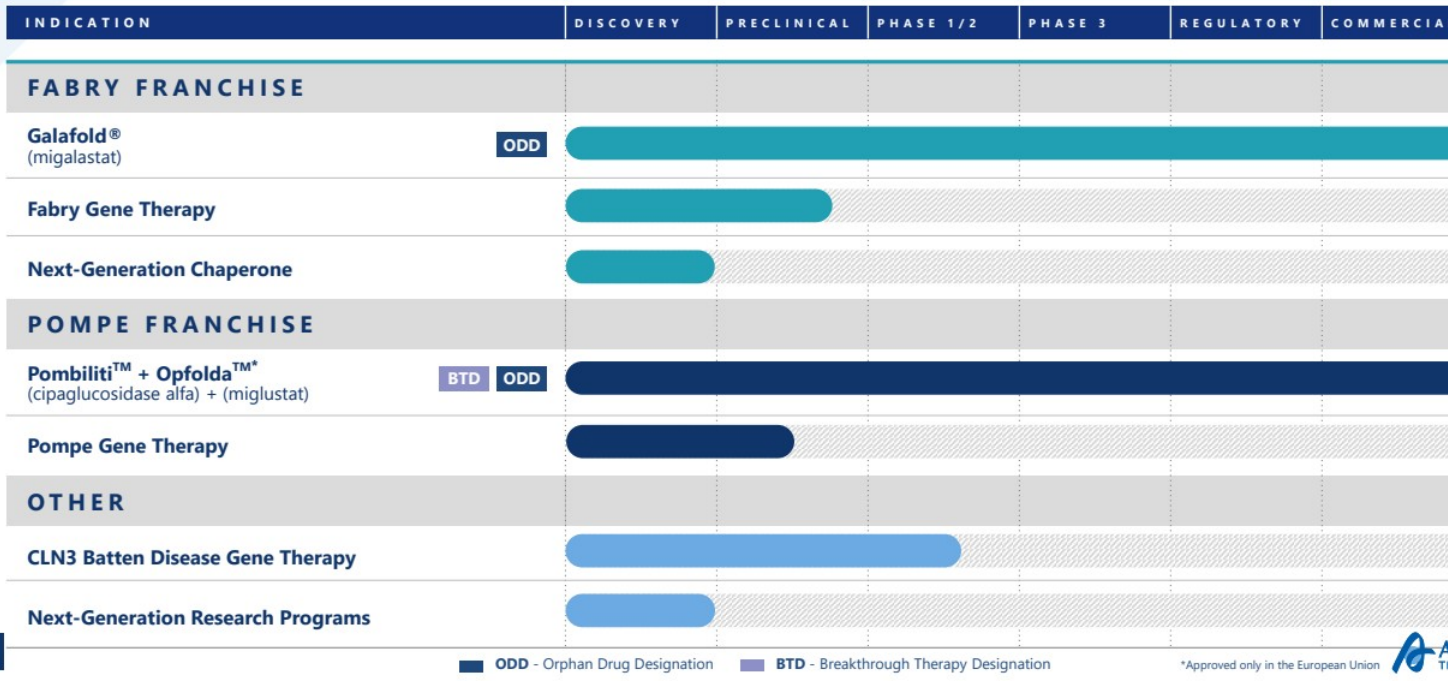
Given the high proportion of Amicus revenue is Ex-US, a change in exchange rates of +/- 5% compared to year end 2022 rates could lead to a $11M-$12M change in global reported revenues in 2023.

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



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Thank you