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): **November 8, 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.)**

47 Hulfish Street, Princeton, New Jersey 08542
(Address of Principal Executive Offices, and Zip Code)

609-662-2000
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 November 8, 2023, Amicus Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended September 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 November 8, 2023 to discuss its third 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 November 8, 2023
99.2	November 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: November 8, 2023

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

Amicus Therapeutics Announces Third Quarter 2023 Financial Results and Corporate Updates

3Q 2023 Total Revenue of $103.5M, a 27% Increase Year-Over-Year and 22% at CER

Galafold® Quarterly Revenue Surpasses $100M for the First Time

Increasing FY 2023 Galafold® Revenue Growth Guidance to 16%-18% at CER

Pombiliti™ + Opfolda™ Approved and Launched in the U.S., EU and U.K.

Non-GAAP Profitability Projected in Q4 2023

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

PRINCETON, NJ, Nov. 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 third quarter ended September 30, 2023.

Bradley Campbell, President and Chief Executive Officer of Amicus Therapeutics, Inc., stated, "This has been a monumental quarter for Amicus highlighted by the U.S. and U.K. approvals of Pombiliti and Opfolda, the global launches of Pombiliti and Opfolda, as well as the continued strong growth of Galafold worldwide. We are now approved in the three largest Pompe markets and are making tremendous progress on our second commercial launch. In addition to the commercial successes, we are well on track to achieve all of our annual strategic priorities, including non-GAAP profitability in the fourth quarter. I am proud of everyone at Amicus who has worked so hard to make a difference in the lives of people living with rare diseases."

Recent Corporate Highlights:

- **Total revenues were $103.5 million** in the third quarter 2023**,** a year-over-year increase of 27%, or 22% at constant exchange rates (CER)[1].

	Three Months Ended September 30,		Year over Year % Growth		Nine Months Ended September 30,		Year over Year % Growth	
(in thousands)	**2023**	**2022**	**Reported**	**at CER[1]**	**2023**	**2022**	**Reported**	**at CER[1]**
Galafold®	100,733	81,631	23%	19%	281,177	241,056	17%	17%
Pombiliti™ + Opfolda™	2,768	60	n/a	n/a	3,097	81	n/a	n/a
Net Product Revenues	$ 103,501	$ 81,691	27%	22%	$ 284,274	$ 241,137	18%	18%

- **Galafold (migalastat) net product sales were $100.7 million** in the third quarter 2023**,** a year-over-year increase of 23%, or 19% at CER[1].

- **Pombiliti (cipaglucosidase alfa-atga) + Opfolda (miglustat) approved in the U.S., EU, and U.K.** The commercial launch of Pombiliti + Opfolda is successfully underway in the three largest markets. Net product sales in the third quarter were $2.8 million. Third quarter revenue represents commercial sales in Germany and the U.K.

- **Amicus entered into a definitive agreement for a $430 million refinancing collaboration with Blackstone.** Blackstone Life Sciences and Blackstone Credit have agreed to provide Amicus with a $400 million senior secured term loan facilitating a refinancing of existing debt under more favorable terms and a $30 million strategic investment in Amicus common stock.

- **Full-year 2023 non-GAAP operating expense guidance of $330 million to $350 million**, driven by prudent expense management while investing in Pombiliti + Opfolda manufacturing and launch activities.

- **Based on the current operating plan, the Company is on-track to achieve non-GAAP profitability[2] in the fourth quarter of 2023, a major milestone for Amicus.**

Third Quarter 2023 Financial Results

- Total revenue in the third quarter 2023 was $103.5 million, a year-over-year increase of 27% from total revenue of $81.7 million in the third quarter 2022. On a constant currency basis, third quarter 2023 total revenue growth was 22%. Currency impact on reported revenue in the third quarter of 2023 represented a benefit of $3.8 million, or 5%.
- Total GAAP operating expenses of $110.6 million for the third quarter 2023 increased by 8% as compared to $102.1 million for the third quarter 2022.
- Total non-GAAP operating expenses of $89.8 million for the third quarter 2023 increased by 5% as compared to $85.5 million for the third quarter 2022.[3]
- Net loss was reduced to $21.6 million, or $0.07 per share for the third quarter 2023, compared to a net loss of $33.3 million, or $0.12 per share, for the third quarter 2022.
- Cash, cash equivalents, and marketable securities totaled $280.3 million at September 30, 2023, compared to $293.6 million at December 31, 2022.

2023 Financial Guidance

- For the full-year 2023, the Company is increasing the Galafold revenue growth guidance to between 16 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.
- Non-GAAP operating expense guidance for the full-year 2023 is $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 fourth quarter of 2023.

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

- Sustain double-digit Galafold revenue growth (16-18% 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. Amicus defines non-GAAP Net Income as GAAP Net Income excluding the impact of stock-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 appears 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, November 8, 2023, at 8:30 a.m. ET to discuss the third 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 drug reactions reported with Galafold (≥10 %) are headache, nasopharyngitis, urinary tract infection, nausea, and pyrexia.

DRUG INTERACTIONS

Avoid co-administration of Galafold with caffeine at least 2 hours before and 2 hours after taking Galafold.

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-atga, a bis-M6P-enriched rhGAA that facilitates high-affinity uptake through the M6P receptor while retaining its capacity for processing into the most active form of the enzyme, and the oral enzyme stabilizer, miglustat, that's designed to reduce loss of enzyme activity in the blood.

U.S. INDICATIONS AND USAGE

POMBILITI in combination with OPFOLDA is indicated for the treatment of adult patients with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) weighing ≥40 kg and who are not improving on their current enzyme replacement therapy (ERT).

SAFETY INFORMATION

HYPERSENSITIVITY REACTIONS INCLUDING ANAPHYLAXIS: Appropriate medical support measures, including cardiopulmonary resuscitation equipment, should be readily available. If a severe hypersensitivity reaction occurs, POMBILITI should be discontinued immediately and appropriate medical treatment should be initiated. INFUSION-ASSOCIATED REACTIONS (IARs): If severe IARs occur, immediately discontinue POMBILITI and initiate appropriate medical treatment. RISK OF ACUTE CARDIORESPIRATORY FAILURE IN SUSCEPTIBLE PATIENTS: Patients susceptible to fluid volume overload, or those with acute underlying respiratory illness or compromised cardiac or respiratory function, may be at risk of serious exacerbation of their cardiac or respiratory status during POMBILITI infusion. See PI for complete Boxed Warning. CONTRAINDICATION: POMBILITI in combination with Opfolda is contraindicated in pregnancy**. EMBRYO-FETAL TOXICITY:** May cause embryo-fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception during treatment and for at least 60 days after the last dose**. Adverse Reactions:** Most common adverse reactions ≥ 5% are headache, diarrhea, fatigue, nausea, abdominal pain, and pyrexia**. Please see full PRESCRIBING INFORMATION, including BOXED WARNING, for POMBILITI (cipaglucosidase alfa-atga) LINK and full PRESCRIBING INFORMATION for OPFOLDA (miglustat) LINK.**

EU 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 and/or Pombiliti and Opfolda in Europe, the UK, the US and other geographies; the potential that preclinical and clinical studies could be delayed because we identify serious side effects or other safety issues; the potential that we may not be able to manufacture or supply sufficient clinical or commercial products; and the potential that we will need additional funding to complete all of our studies, the manufacturing, and commercialization of our products. With respect to statements regarding corporate financial guidance and financial goals and the expected attainment of such goals and projections of the Company's revenue 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 September 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.

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TABLE 1

Amicus Therapeutics, Inc.
Consolidated Statements of Operations
(Unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Net product sales	$ 103,501	$ 81,691	$ 284,274	$ 241,137
Cost of goods sold	9,946	13,436	26,002	29,215
Gross profit	93,555	68,255	258,272	211,922
Operating expenses:				
Research and development	40,704	52,970	117,352	212,806
Selling, general, and administrative	65,651	47,272	205,031	158,767
Changes in fair value of contingent consideration payable	1,995	567	2,583	(506)
Loss on impairment of assets	—	—	1,134	6,616
Depreciation and amortization	2,228	1,286	5,691	4,031
Total operating expenses	110,578	102,095	331,791	381,714
Loss from operations	(17,023)	(33,840)	(73,519)	(169,792)
Other income (expense):				
Interest income	1,471	563	5,407	1,052
Interest expense	(12,986)	(9,620)	(37,322)	(26,024)
Other income (expense)	3,833	13,634	(13,007)	22,804
Loss before income tax	(24,705)	(29,263)	(118,441)	(171,960)
Income tax benefit (expense)	3,128	(4,023)	700	(8,743)
Net loss attributable to common stockholders	$ (21,577)	$ (33,286)	$ (117,741)	$ (180,703)
Net loss attributable to common stockholders per common share — basic and diluted	$ (0.07)	$ (0.12)	$ (0.40)	$ (0.63)
Weighted-average common shares outstanding — basic and diluted	295,759,435	289,223,709	293,314,167	288,841,092

TABLE 2

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

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 263,320	$ 148,813
Investments in marketable securities	16,980	144,782
Accounts receivable	73,331	66,196
Inventories	56,936	23,816
Prepaid expenses and other current assets	52,689	40,209
Total current assets	463,256	423,816
Operating lease right-of-use assets, net	29,511	29,534
Property and equipment, less accumulated depreciation of $25,018 and $22,281 at September 30, 2023 and December 31, 2022, respectively	31,072	30,778
Intangible assets, less accumulated amortization of $1,682 and $0 at September 30, 2023 and December 31, 2022, respectively	21,318	23,000
Goodwill	197,797	197,797
Other non-current assets	21,130	19,242
Total Assets	$ 764,084	$ 724,167
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 23,154	$ 15,413
Accrued expenses and other current liabilities	138,535	93,636
Contingent consideration payable	—	21,417
Operating lease liabilities	7,765	8,552
Total current liabilities	169,454	139,018
Long-term debt	394,071	391,990
Operating lease liabilities	52,454	51,578
Deferred reimbursements	5,906	4,656
Deferred income taxes	—	4,939
Other non-current liabilities	8,962	8,939
Total liabilities	630,847	601,120
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.01 par value, 500,000,000 shares authorized, 290,667,041 and 281,108,273 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	2,890	2,815
Additional paid-in capital	2,787,275	2,664,744
Accumulated other comprehensive loss:		
Foreign currency translation adjustment	(6,573)	(11,989)
Unrealized loss on available-for-sale securities	(195)	(116)
Warrants	71	83
Accumulated deficit	(2,650,231)	(2,532,490)
Total stockholders' equity	133,237	123,047
Total Liabilities and Stockholders' Equity	$ 764,084	$ 724,167

TABLE 3

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Total operating expenses - as reported GAAP	**$ 110,578**	**$ 102,095**	**$ 331,791**	**$ 381,714**
Research and development:				
Stock-based compensation	4,380	5,428	16,987	19,172
Selling, general and administrative:				
Stock-based compensation	12,131	9,344	50,995	38,714
Loss on impairment of assets	—	—	1,134	6,616
Changes in fair value of contingent consideration payable	1,995	567	2,583	(506)
Depreciation and amortization	2,228	1,286	5,691	4,031
Total operating expense adjustments to reported GAAP	20,734	16,625	77,390	68,027
Total operating expenses - as adjusted	$ 89,844	$ 85,470	$ 254,401	$ 313,687


AT THE FOREFRONT OF
THERAPIES FOR RARE DISEASES
3Q23 Results
Conference Call
& Webcast
November 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 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 Galafold and Pombiliti and Opfolda in Europe, the UK, the US and other geographies; the potential that preclinical and clinical studies could be delayed because we identify serious side effects or other saf 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 studies, the manufacturing, and commercialization of our products. With respect to statements regarding corporate financial guidance and financial goals and the expected attainment of su goals and 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. 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 end September 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-look 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 d 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 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 biotech 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 **Q4 2023**

EMPLOYEES in 20+ Countries

Pombiliti™ (cipaglucosidase alfa-atga)
+
Opfolda™ (miglustat) 65 mg capsules

Approved in the U.S., EU, and U.K.

+16-18%

FY23 Galafold Revenue Growth at CER

GALAFOLD & POMBILITI + OPFOLDA

Cumulative $1.5B-$2B Peak Potential

$280M

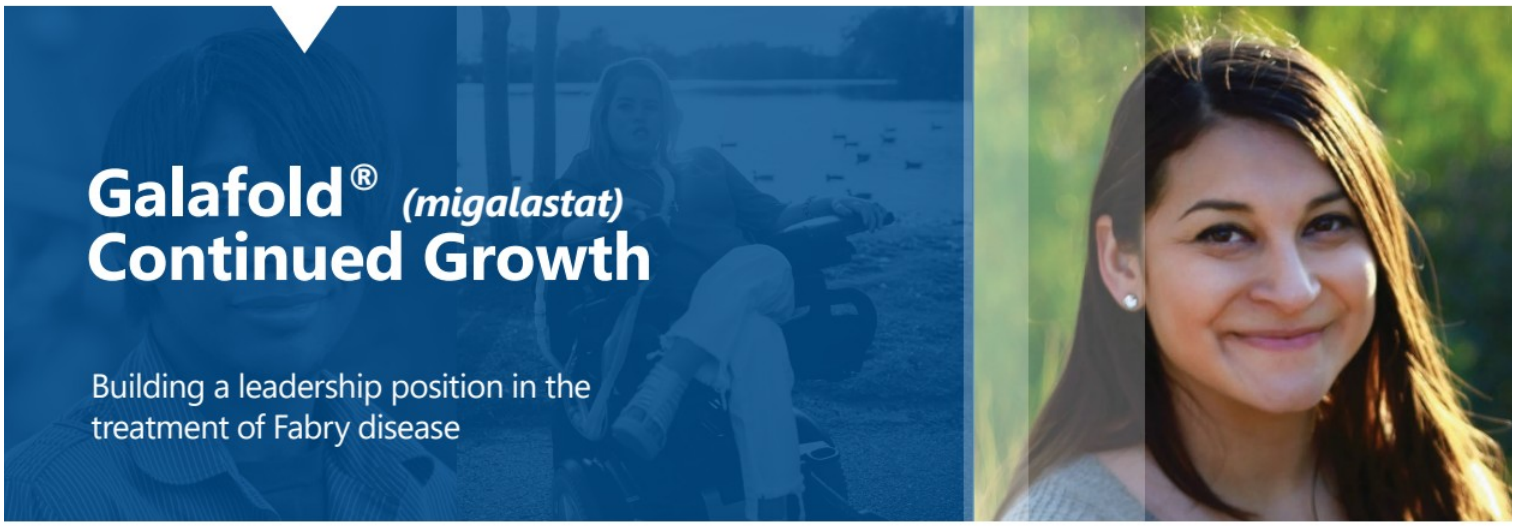
Cash as of 9/30/2023

2023 Strategic Priorities

1. Galafold® revenue growth of 12-17% at CER[1], now raised to 16-
2. Secure FDA, EMA, and MHRA approvals for Pombiliti™ + Opfold
3. Initiate successful global launches of Pombiliti™ + Opfolda™
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 September 30, 2023)

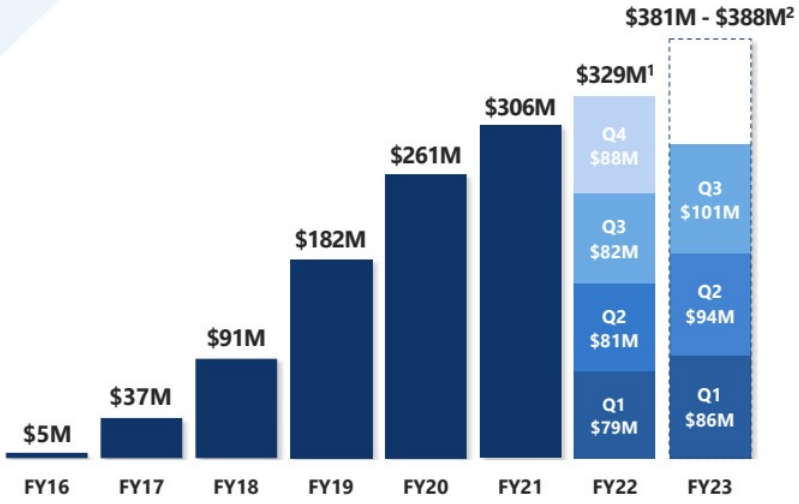
Galafold quarterly revenue surpasses $100M for the first time in 3Q23

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

Galafold YTD reported revenue growth of +17% to $281M



- 3Q23 revenue growth of +19% at CER
- Global mix of switch (~42%) and previously untreated patients (~58%)[3]
- Compliance and adherence over 90%
- Expect non-linear quarterly growth to continue due to uneven ordering patterns and FX fluctuations

Increasing FY23 revenue growth guidance to +16% to 18% at CER

[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 September 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-atga)*
+
Opfolda™ *(miglustat)*

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

Pombiliti™ + Opfolda™

(cipaglucosidase alfa-atga) (miglustat) 65 mg capsules

NOW APPROVED

In the U.S., EU, & U.K.

Global Launch of Pombiliti + Opfolda Successfully Underway

60+ patients on commercial therapy as of early November;
Early days of launch exceeding expectations providing strong foundation for 2024

Pombiliti™ (cipaglucosidase alfa-atga) + Opfolda™ (miglustat) 65 mg capsules

Performance

Patient Demand

Initial focus on clinical trial and expanded access patients

Multiple patients switching from other ERTs

On track to transition all trial and expanded access patients within 90 days of launch

KOL and Patient Outreach

Promotion and Education Efforts

Successfully engaged with top prescribers in each approved country within first 30 days

Existing relationships with HCPs at key treatment centers

Ongoing disease education

Access and Reimbursemer

Positive Interactions with Payors

Focus on broad patient ac

Country-by-country reimbursement process underway

Active discussions to demonstrate value

Conversion of EAP and Clinical Trial Patients to Pombiliti + Opfolda

Well on-track to transition all clinical trial and expanded access patients to commercial supply by year end

- Expanded access and clinical trial conversions progressing ahead of schedule in each respective launch country:
  - **Germany:** 100% patients converted
  - **U.K.:** ~85% patients converted
  - **U.S.:** ~66% patients received PRFs
- Multiple patients switching from other ERTs in each geography, in addition to naive patients in Germany and the U.K.

Additional Regulatory and Clinical Updates

Building the body of evidence through ongoing clinical studies and expanding commercial access through multiple regulatory submissions

- Multiple regulatory submissions expected in 2024
- Ongoing clinical studies in children and adolescents[1] with LOPD and infantile-onset Pompe disease (IOPD)
- Amicus registry for Pompe disease initiated
- ~75 treatment centers worldwide have participated in clinical trials and access programs

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

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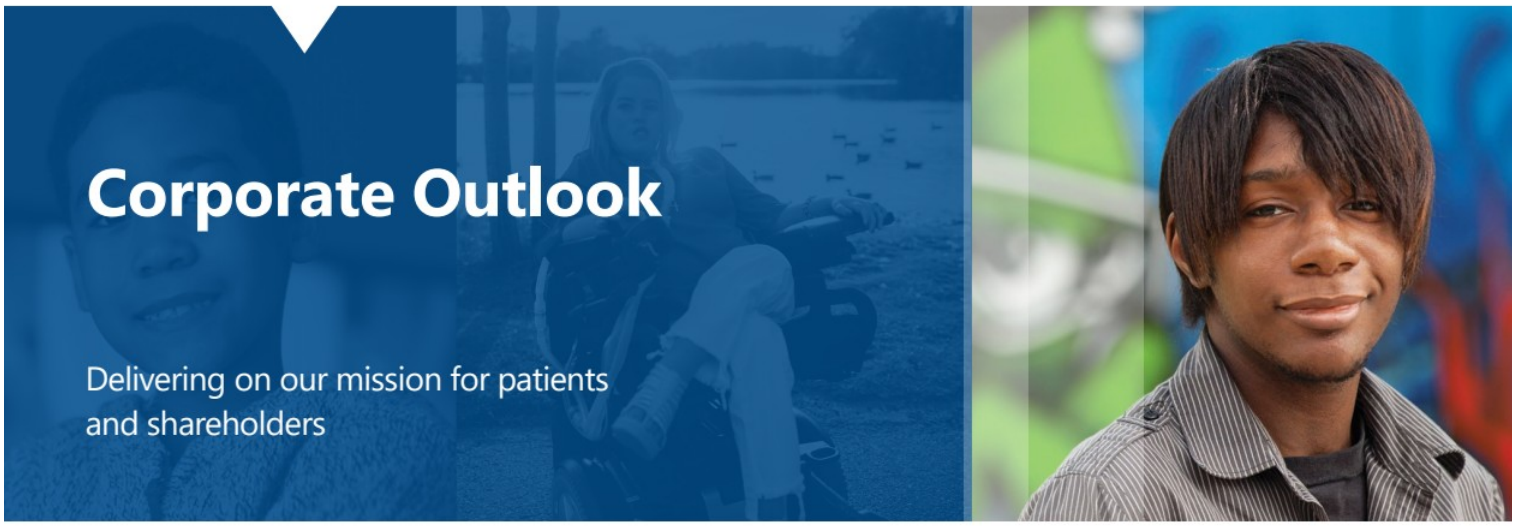


Corporate Outlook

Delivering on our mission for patients and shareholders

3Q 2023 Select Financial Results

3Q23 revenue of $103.5M, up 22% at CER, and net loss significantly reduced

(in thousands, except per share data)	Sep. 30, 2023	Sep. 30, 2022
Product Revenue	$103,501	$ 81,691
Cost of Goods Sold	9,946	13,436
R&D Expense	40,704	52,970
SG&A Expense	65,651	47,272
Changes in Fair Value of Contingent Consideration	1,995	567
Depreciation and Amortization	2,228	1,286
Loss from Operations	(17,023)	(33,840)
Interest Income	1,471	563
Interest Expense	(12,986)	(9,620)
Other Income (Expense)	3,833	13,634
Income Tax Benefit (Expense)	3,128	(4,023)
Net Loss	(21,577)	(33,286)
Net Loss Per Share	(0.07)	(0.12)

Q3 weighted-average common shares outstanding: 295,759,435; Q2 2022: 289,223,709

Financial Outlook and Path to Profitability

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

Sustain Revenue Growth

YTD total revenue of **$284.3M**, **+18%** YoY growth

2023 Galafold revenue growth guidance of **+16-18%** YoY ***at CER***

Successfully Launch Pombiliti + Opfolda

Galafold and Pombiliti + Opfolda expected to drive strong **double-digit growth long term**

Deliver on Financial Goals

Focused on prudent expense management

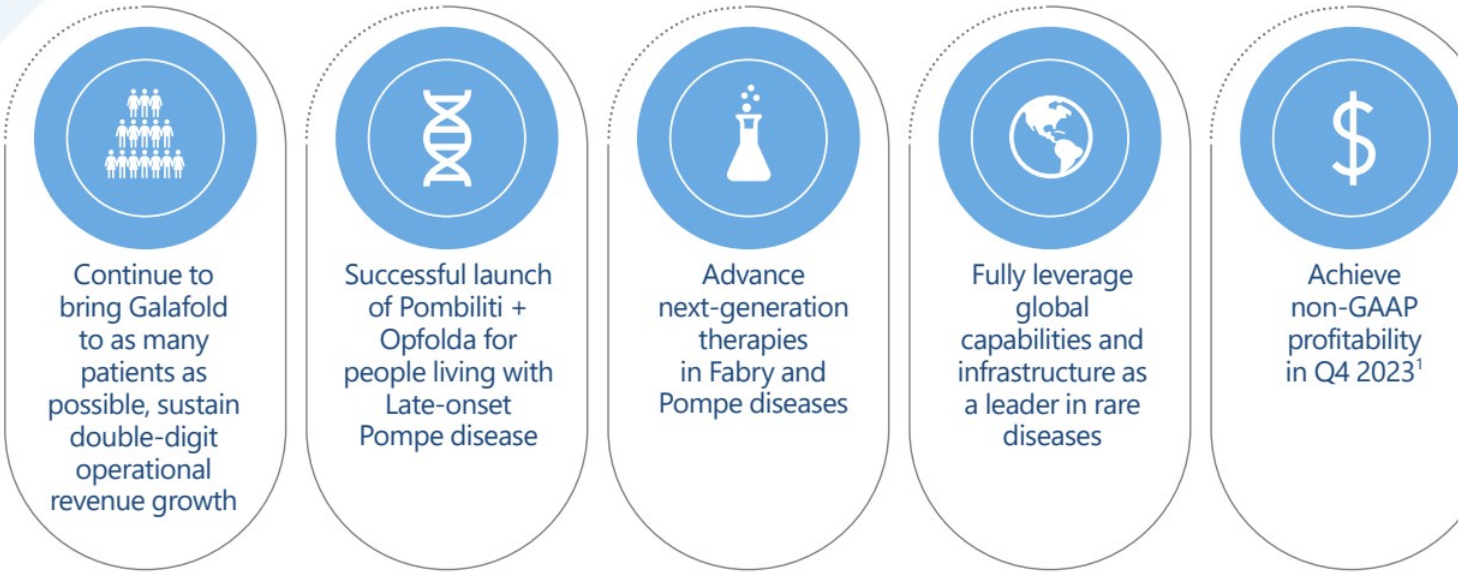
2023 non-GAAP operating expense guidance of **$330M-$350M**

Achieve non-GAAP profitability[1] in Q4 2023

[1] Based on projections of Amicus non-GAAP Net Income under current operating plans. We define non-GAAP Net Income as GAAP Net Income excluding the impact of stock-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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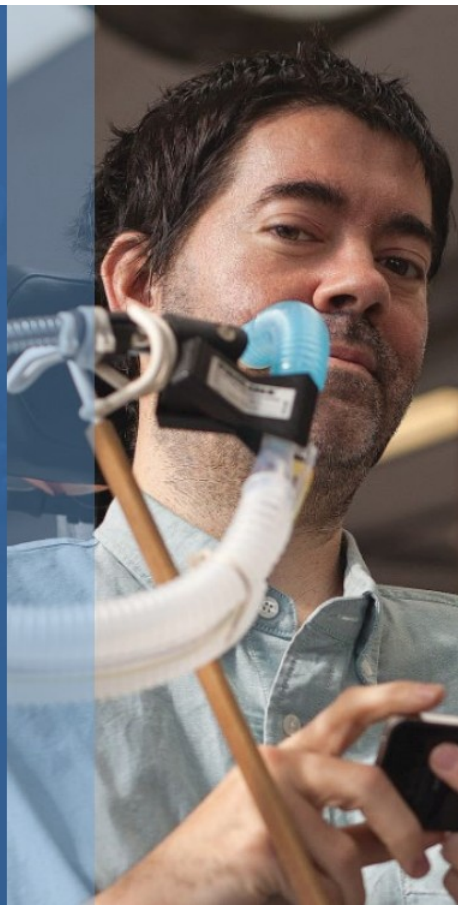
Appendix



Appendix

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Total operating expenses - as adjusted	$89,844	$85,470	$254,401	$313,687

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%

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 Q3 2023

Currency Variances: USD/	Q3 2022	Q3 2023	YoY Variance
EUR	1.008	1.088	8.0%
GBP	1.177	1.266	7.5%
JPY	0.007	0.007	(4.4%)

Full Year 2023 Revenue Sensitivity

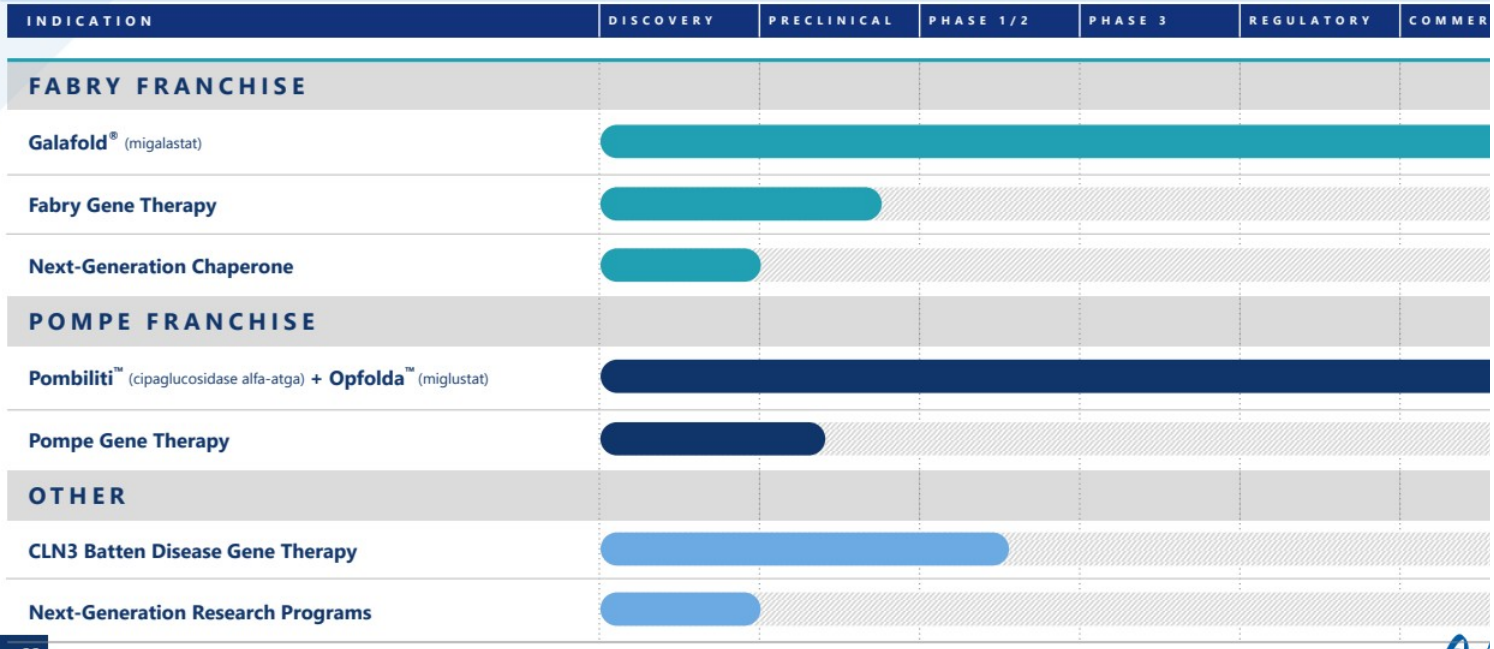
Given the high proportion of Amicus revenue Ex-US, a change in exchange rates of +/- 5% compared to year end 2022 rates could lead to a $11M-$12M change in global reported revenues in 2023.

Distribution of Galafold Revenue by Quarter over 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