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): **January 7, 2024**

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 January 7, 2024, Amicus Therapeutics, Inc. (the "Company") issued a press release announcing preliminary 2023 revenue and its 2024 strategic outlook, along with various business updates. A copy of the press release is attached hereto as Exhibit 99.1. As previously announced, the Company will also be presenting at the 42nd Annual J.P. Morgan Healthcare Conference on January 8th, 2024. A copy of the presentation materials management will be using at the conference is also attached hereto as Exhibit 99.2. Both exhibits are incorporated herein by reference.

The information furnished pursuant to this Item 2.02, including Exhibits 99.1 and 99.2, 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 liabilities of that section, and shall not be 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 January 7, 2024
99.2	Presentation Materials – 42nd Annual J.P. Morgan Healthcare Conference
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: January 8, 2024

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

Amicus Therapeutics Reports Preliminary 2023 Revenue and Provides 2024 Strategic Outlook

2023 Total Revenue of ~$399.4M, a 21% Increase Year-Over-Year

>2,400 People Living with Fabry Disease on Galafold® Following a Year of Increased Demand

Expecting 2024 Galafold Revenue Growth of 11-16% at CER

Successful Launches of Pombiliti™ + Opfolda™ Underway in the U.S., U.K., and Germany

PRINCETON, NJ, January 7, 2024 – Amicus Therapeutics (Nasdaq: FOLD), a patient-dedicated global biotechnology company focused on developing and commercializing novel medicines for rare diseases, today provided its preliminary and unaudited 2023 revenue, corporate updates, and full-year 2024 outlook.

In 2023, Amicus met or exceeded its strategic priorities, highlighted by:

- Sustaining double-digit Galafold revenue growth
- Securing FDA, EMA, and MHRA approvals for Pombiliti + Opfolda
- Initiating successful global launches of Pombiliti + Opfolda
- Advancing next-generation pipeline programs
- On-track to achieving non-GAAP profitability in the fourth quarter of 2023

Preliminary and Unaudited 2023 Revenue:

- **Total revenue in 2023 reached ~$399.4 million**, representing a year-over-year **increase of 21%,** reflecting strong operational growth measured at constant exchange rates (CER)[1] of 20% and a favorable currency impact of approximately $2.7 million, or 1%. Fourth quarter total revenue was ~$115.1 million.

- **Galafold (migalastat) net product sales in 2023 were ~$387.8 million,** representing a year-over-year **increase of 18%, or 17% at CER.** Fourth quarter Galafold net product sales were ~$106.6 million.

- **Pombiliti (cipaglucosidase alfa-atga) + Opfolda (miglustat) net product sales in 2023 were ~$11.6 million.** The commercial launch of Pombiliti + Opfolda is successfully underway in the three largest markets with ~120 patients on treatment with commercial product or scheduled to be treated as of the end of 2023. Fourth quarter Pombiliti + Opfolda net product sales were ~$8.5 Million.

Bradley Campbell, President and Chief Executive Officer of Amicus Therapeutics, Inc., stated, "Last year was an incredible year for Amicus highlighted by the continued double-digit growth of Galafold sales and the global regulatory approvals of our second commercial therapy, which is off to a fantastic launch. We expect 2024 to be a truly transformative year as we continue to drive significant revenue growth by treating an increasing number of Fabry patients globally, executing on the global launches of Pombiliti and Opfolda, which we believe has the potential to become the standard of care in a >$1B market today, and delivering our first full year of non-GAAP profitability. We look forward to reporting on our progress throughout this year as we further our mission for people living with rare diseases."

Amicus is focused on the following four key strategic priorities in 2024:

- Delivering double-digit Galafold revenue growth (11-16% at CER)
- Ensuring the successful global launches of Pombiliti + Opfolda
- Advancing ongoing studies to support medical and scientific leadership in Fabry and Pompe diseases
- Achieving full year non-GAAP profitability[2]

Mr. Campbell will discuss the Amicus corporate objectives and key milestones in a presentation at the 42nd Annual J.P. Morgan Healthcare Conference on Monday, January 8, 2024, at 2:15 p.m. PT. A live webcast of the presentation can be accessed through the Investors section of the Amicus Therapeutics corporate website at http://ir.amicusrx.com/events.cfm, and will be archived for 90 days.

[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 2024 Galafold revenue guidance utilizes actual exchange rate as of December 31, 2023.

[2] Non-GAAP Net Income defined as GAAP Net Income excluding the impact of share-based compensation expense, changes in fair value of contingent consideration, loss on impairment of assets, depreciation and amortization, acquisition related income (expense), loss on extinguishment of debt, loss on impairment of assets, restructuring charges, and income taxes.

About Galafold

Galafold® (migalastat) 123 mg capsules is an oral pharmacological chaperone of alpha-Galactosidase A (alpha-Gal A) for the treatment of Fabry disease in adults who have amenable galactosidase alpha gene *(GLA)* variants. In these patients, Galafold works by stabilizing the body's own dysfunctional enzyme so that it can clear the accumulation of disease substrate. Globally, Amicus Therapeutics estimates that approximately 35 to 50 percent of people living with Fabry disease may have amenable *GLA* variants, though amenability rates within this range vary by geography. Galafold is approved in more than 40 countries around the world, including the U.S., EU, U.K., and Japan.

U.S. INDICATIONS AND USAGE

Galafold is indicated for the treatment of adults with a confirmed diagnosis of Fabry disease and an amenable galactosidase alpha gene (*GLA*) variant based on *in vitro* assay data.

This indication is approved under accelerated approval based on reduction in kidney interstitial capillary cell globotriaosylceramide (KIC GL-3) substrate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

U.S. IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS

The most common adverse 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 X and LinkedIn.

Non-GAAP Financial Measures

In addition to financial information prepared in accordance with U.S. GAAP, this press release also contains adjusted financial measures that we believe provide investors and management with supplemental information relating to operating performance and trends that facilitate comparisons between periods and with respect to projected information. These adjusted financial measures are non-GAAP measures and should be considered in addition to, but not as a substitute for, the information prepared in accordance with U.S. GAAP. We 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 and pricing and reimbursement authorities, are based on current information. Actual results may differ materially from those set forth in this release due to the risks and uncertainties inherent in our business, including, without limitation: the potential that results of clinical or preclinical studies indicate that the product candidates are unsafe or ineffective; the potential that it may be difficult to enroll patients in our clinical trials; the potential that regulatory authorities may not grant or may delay approval for our product candidates; the potential that required regulatory inspections may be delayed or not be successful and delay or prevent product approval; the potential that we may not be successful in negotiations with pricing and reimbursement authorities; the potential that we may not be successful in commercializing Galafold and/or Pombiliti and Opfolda in Europe, the UK, the US and other geographies; the potential that preclinical and clinical studies could be delayed because we identify serious side effects or other safety issues; the potential that we may not be able to manufacture or supply sufficient clinical or commercial products; and the potential that we will need additional funding to complete all of our studies, the manufacturing, and commercialization of our products. With respect to statements regarding corporate financial guidance and financial goals and the expected attainment of such goals and projections of the Company's revenue, non-GAAP profitability and cash position, actual results may differ based on market factors and the Company's ability to execute its operational and budget plans. In addition, all forward-looking statements are subject to other risks detailed in our Annual Report on Form 10-K for the year ended December 31, 2022, and on Form 10-Q for the quarter ended September 30, 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.

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FOLD-G

Exhibit 99.2


AT THE FOREFRONT OF
THERAPIES FOR RARE DISEASES
42nd Annual J.P. Morgan Healthcare Conference
January 8, 2024
Amicus
Therapeutics

Forward-Looking Statements

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Definition:
\əˈmēkəs (noun) *Latin* Friend

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Our Passion is for Patients

Our Mission:

We seek to deliver the highest quality therapies for people living with rare diseases

Our Vision:

Be a leader in rare disease drug development and commercialization leveraging our global capabilities in bringing life-changing therapies to patients

A Rare Company

A leading biotech company with significant revenue growth and near-term profitability

Galafold® (migalastat)
First Oral Precision Medicine for Fabry Disease

LEVERAGEABLE GLOBAL COMMERCIAL ORGANIZATION

2 APPROVED THERAPIES

World Class Clinical Development Capabilities

Non-GAAP PROFITABILITY Q4 2023 ON-TRACK

>500 EMPLOYEES in 20+ Countries

Pombiliti™ (cipaglucosidase alfa-atga) + Opfolda™ (miglustat) 65 mg capsules
First Two-Component Therapy for Pompe Disease

~$399.4M in 2023 Revenue[1]
21% Increase Year-Over-Year

Combined Peak Revenue Potential
$1.5B - $2B

Line of Sight to Generating Positive Cashflow

[1] Preliminary and unaudited

2023 Strategic Priorities Achieved

- Galafold® revenue growth of 12-17% at CER[1], raised to 16-18%
- Secure FDA, EMA, and MHRA approvals for Pombiliti™ + Opfolda™
- Initiate successful global launches of Pombiliti™ + Opfolda™
- Advance best-in-class, next-generation Fabry and Pompe pipeline programs and capabilities
- Maintain strong financial position on path to profitability

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

2023 Key Milestones

2024 Strategic Priorities

A Transformative Year Ahead for Amicus

1. Double-digit Galafold® revenue growth of 11-16% at CER[1]
2. Successful multiple launches of Pombiliti™ + Opfolda™
3. Advance ongoing studies to support medical and scientific leadership in Fabry and Pompe diseases
4. Achieve non-GAAP profitability for the full year

[1]CER: Constant Exchange Rates; 2024 Galafold revenue guidance utilizes actual exchange rate as of December 31, 2023

Amicus Therapeutics®

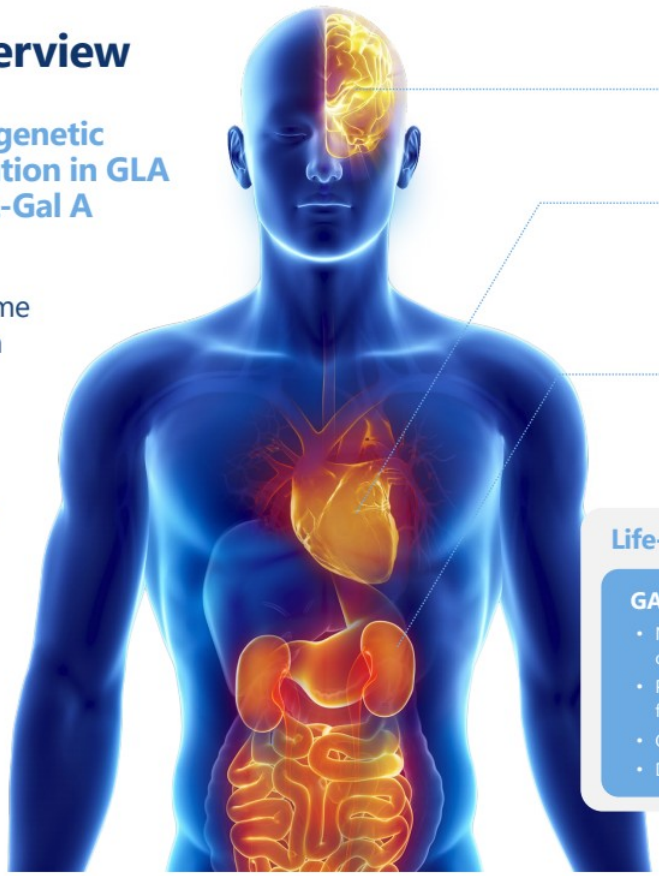
Continued Growth of Galafold® *(migalastat)*

Expanding leadership in the treatment of Fabry disease

Fabry Disease Overview

Fabry is a rare inherited genetic disorder caused by mutation in GLA gene and deficiency of α-Gal A enzyme

- Deficiency of α-Gal A enzyme leads to GL-3 accumulation
- >1,000 known mutations
- >17,000 diagnosed WW
- X-linked dominant disease leading to diagnosis of multiple family members



Leading Causes of Death

TRANSIENT ISCHEMIC ATTAC (TIA) & STROKE[1]

HEART DISEASE[2]
- Irregular heartbeat (fast or slow)
- Heart attack or heart failure
- Enlarged heart

KIDNEY DISEASE[3]
- Protein in the urine
- Decreased kidney function
- Kidney failure

Life-limiting Symptoms

GASTROINTESTINAL[3]
- Nausea, vomiting, cramping, diarrhea
- Pain/bloating after eating, feeling full
- Constipation
- Difficulty managing weight

PAIN[3]

FATIGUE[3]

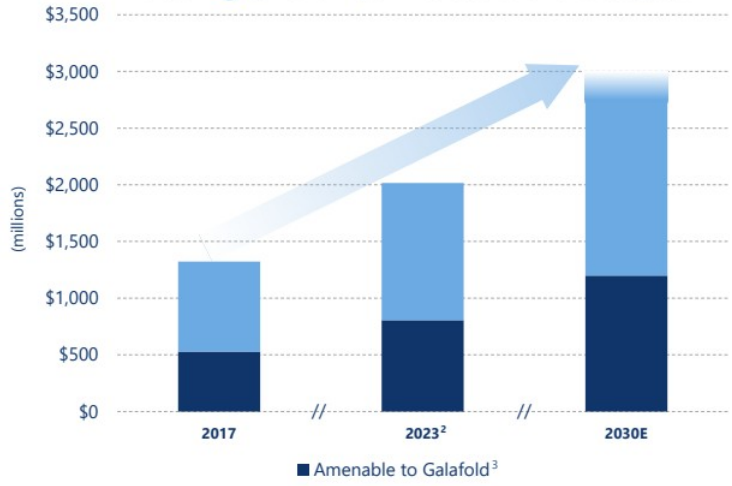
ANHIDROSI

[1] Desnick R, *et al.* Ann Intern Med. 2003
[2] Yousef Z, *et al.* Eur Heart J. 2013
[3] Germain D. Orphanet J Rare Dis. 2010

Global Fabry Market

Fabry market expected to grow to ~$3B by end of the decade

Global Fabry market of ~$2B in 2023 and tracking toward ~$3B+ the end of the decade[1]

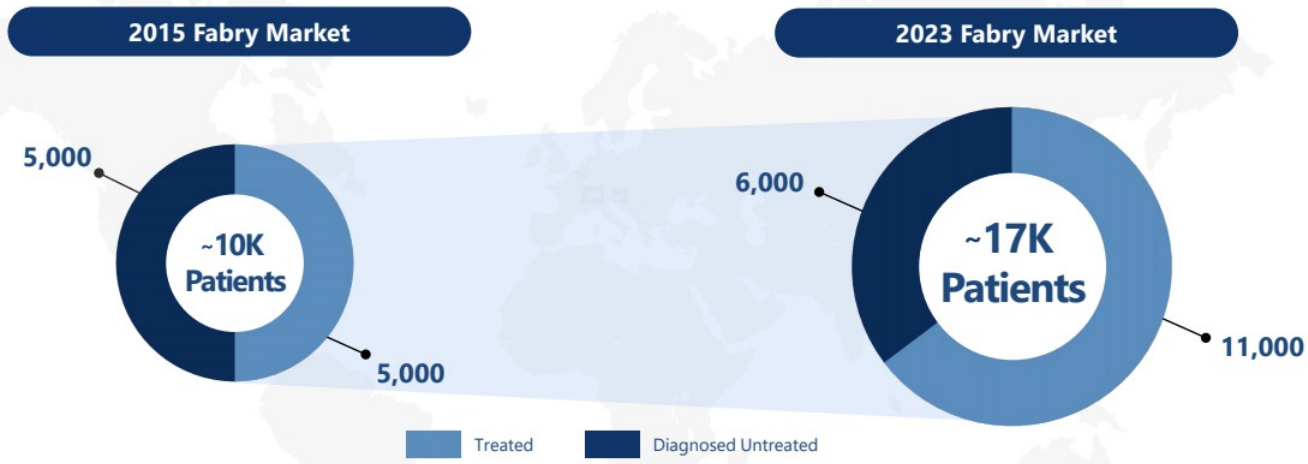


- Significantly underdiagnosed
  - Newborn screening studies suggest Fabry is on of the more prevalent rare genetic diseases (~1:1,000 to ~1:4,000 incidence)
- Continued market growth driven by increased diagnosis
- Galafold continues to be the fastest growing Fabry treatment and the greatest contributor market growth

[1] Global market measured by reported sales of approved therapies for Fabry disease – 2030 sales projected using ~7% CAGR
[2] LTM ended September 30, 2023
[3] Assumes ~40% amenability to Galafold

Fabry Patient Dynamics

Number of people on a Fabry treatment has more than doubled since 2015



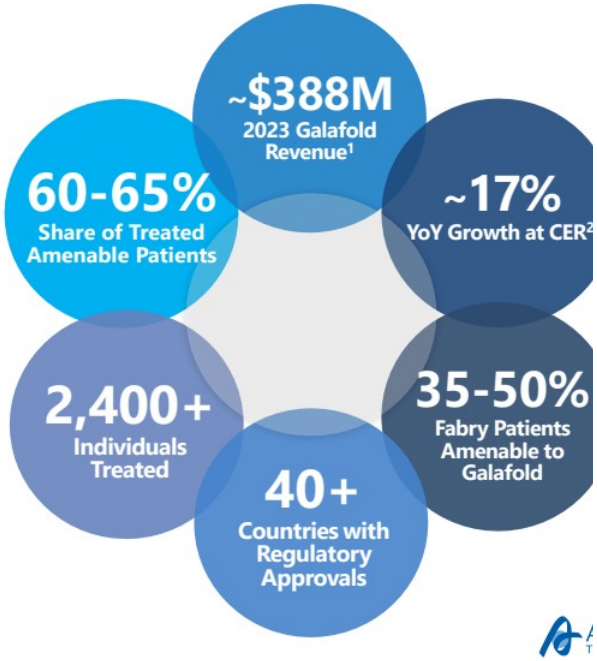
Significant pool of diagnosed untreated patients remain

Based on Amicus data on file

2023 Galafold Success (as of December 31, 2023)

Galafold is the only approved oral treatment option in Fabry disease

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.

[1] Preliminary and unaudited
[2] CER: Constant Exchange Rates

Key Growth Drivers for 2024

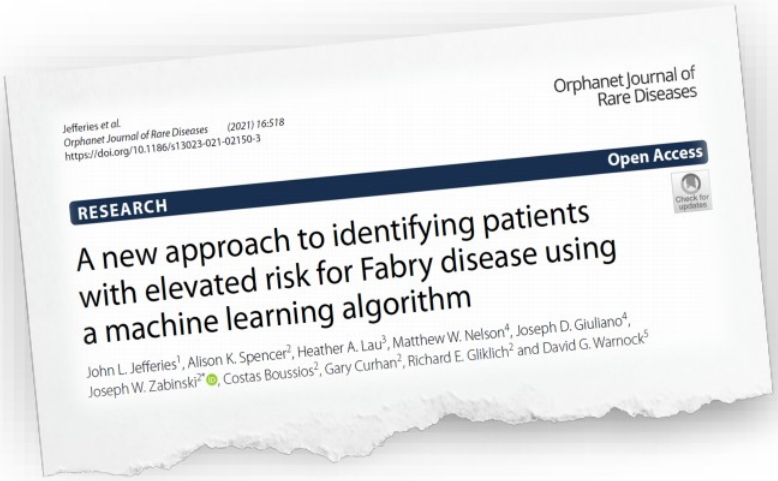
Strong patient demand laying groundwork for continued double-digit Galafold growth

- Improve diagnosis of patients through medical education, screening, and testing
- Drive market share of treated amenable patients through excellent execution
- Expand market through uptake in naïve population as well as geographic and label expansion
- Maintain >90% adherence and compliance through HCP and patient education and support

Improving Diagnosis of Fabry Disease

Harnessing AI to improve diagnosis of people living with Fabry and predicting patient outcome

OM1®



Jefferies et al.
Orphanet Journal of Rare Diseases (2021) 16:518
https://doi.org/10.1186/s13023-021-02150-3

Orphanet Journal of Rare Diseases

RESEARCH

Open Access

A new approach to identifying patients with elevated risk for Fabry disease using a machine learning algorithm

John L. Jefferies[1], Alison K. Spencer[2], Heather A. Lau[3], Matthew W. Nelson[4], Joseph D. Giuliano[4], Joseph W. Zabinski[2*], Costas Boussios[2], Gary Curhan[2], Richard E. Gliklich[2] and David G. Warnock[5]

- Partnership with OM1 and leading healthca system in the U.S. to pilot algorithm
- Finding undiagnosed patients and variation in patient phenotype
- Predicting health outcomes including seriou events
- Applying AI tools to additional Fabry marke

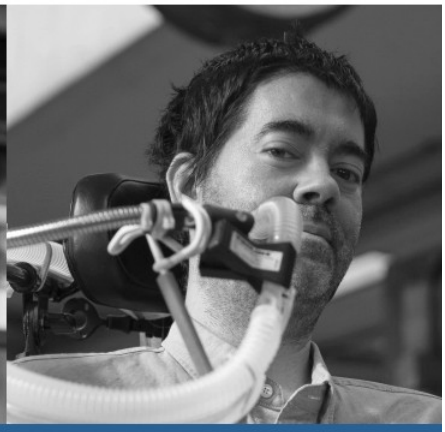
Launch Underway of Pombiliti™ + Opfolda™

(cipaglucosidase alfa-atga) *(miglustat)*

Resetting expectations for people living with late-onset Pompe disease

Late-onset Pompe Disease is a Rare, Inherited Genetic Disorder Caused by Mutation in GAA Gene and Deficiency of α-Glucosidase Enzyme





~5,000-10,000 people diagnosed globally

Deficiency of GAA leading to lysosomal glycogen accumulation and cellular dysfunction

Significantly underdiagnosed

Respiratory failure is maj cause of mortality

Significant unmet need

Symptoms include systemic muscle weakness that worsens over time

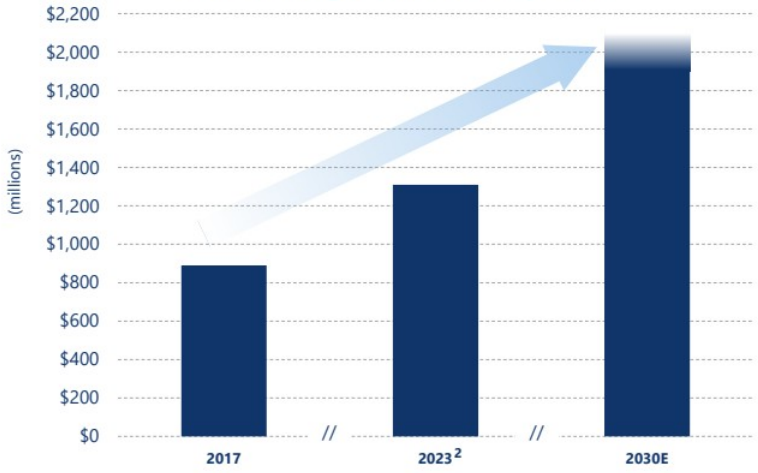
~$1.3B+ global Pompe ERT sales[1]

[1] Based on 12 months ended September 30, 2023.

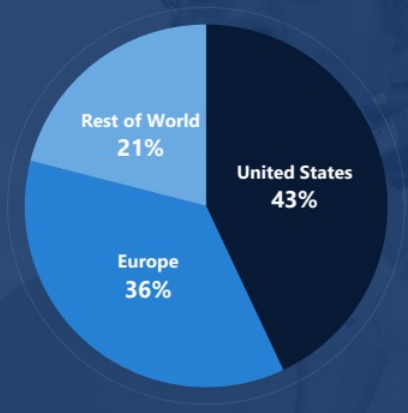
Global Pompe Market

Global Pompe disease market growth continues to be driven by the diagnosis of new patients

Global Pompe Market of ~$1.3B in 2023 and Tracking toward $2B+ by 2030[1]



Global Pompe Market Sales Split YTD 2023[2]



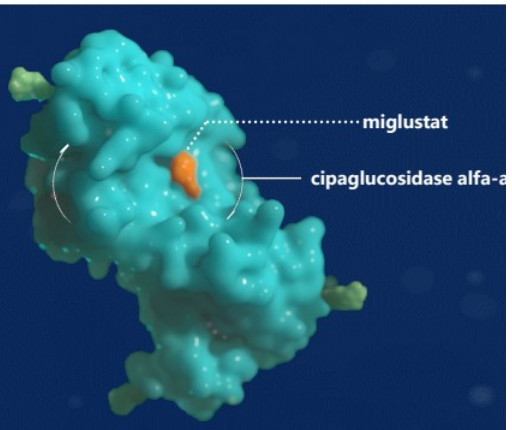
An estimated 3,500-4,000 Pompe patients globally are being treated by ERT[3]

[1] Global market measured by reported sales of approved therapies for Pompe disease – 2029 sales projected using ~8% CAGR
[2] LTM ended September 30, 2023
[3] Amicus Data on File from Market Mapping

Pombiliti + Opfolda Mechanism of Action

The only two-component therapy for the treatment of Pompe disease

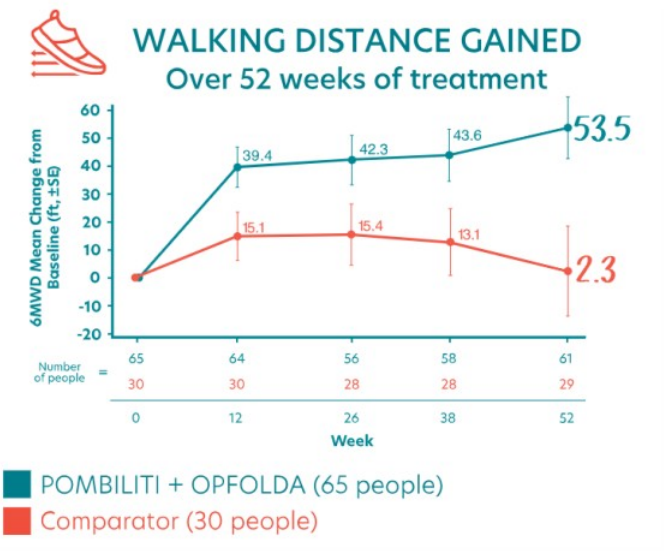
- Pombiliti + Opfolda combines cipaglucosidase alfa-atga, an ERT, with miglustat, an orally administered enzyme stabilizer
- Pombiliti is expressed in a unique cell line producing a naturally glycosylated and highly phosphorylated M6P that can be properly processed to its mature form, which is required for greater lysosomal GAA activity[1]



[1] Selvan et al. 2021, J Biol Chem 2021 Jan-Jun;296:100769
ERT: Enzyme Replacement Therapy

PROPEL Phase 3 Data

Resetting expectations for Pompe treatment with Pombiliti + Opfolda – Improvement is Possibl



- Pombiliti + Opfolda was evaluated in adults with late-onset Pompe disease (LOPD) in a randomized, controlled clinical study over 52 weeks
- ERT-experienced people were on treatment for an average of 7.4 years before the study
- Pombiliti + Opfolda was shown to improve walking distance and breathing function vs the comparator[1] in ERT-experienced adult

[1]An alglucosidase alfa product not approved in the US + placebo.
POMBILITI + OPFOLDA is not approved for use in ERT-naïve people.
Results of the 6MWT and FVC for ERT-experienced people were numerically favorable but were not tested to determine statistical superiority of POMBILITI + OPFOLDA vs the comparator.

Successful Global Launch of Pombiliti + Opfolda Underway

FY 2023 revenue of ~$11.6M[1] provides strong foundation for 2024

Patient Demand

~120 patients treated with commercial product or scheduled to be treated

- ~105 patients from clinical trials and early access
- ~15 new patients from competitor ERTs or naïve

Very positive early feedback from real-world experience

KOL Outreach

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 Reimbursement

Positive interactions with US and EU payors

Focus on broad patient access

Country-by-country reimbursement process underway

Multiple launches expected in 2H 2024

Pombiliti™
(cipaglucosidase alfa-atga)

+

Opfolda™
(miglustat) 65 mg capsules

Focus in 2024 is on maximizing the number of patients on therapy by year end

[1] Preliminary and unaudited

International: EU and U.K. Update and Market Opportunity

EU and U.K. Pompe markets collectively represent sizeable market opportunity

Strong indication statement:

Pombiliti™ (cipaglucosidase alfa) is a long-term enzyme replacement therapy used in combination with the enzyme stabiliser 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]
- >200 patients are estimated to be treated in the U.K.[1]
- Broad experience from a wide set of KOLs through clinical trials and early access programs
- Leveraging EU label and regulatory outcome to extend into other geographies

LAUNCH DYNAMICS

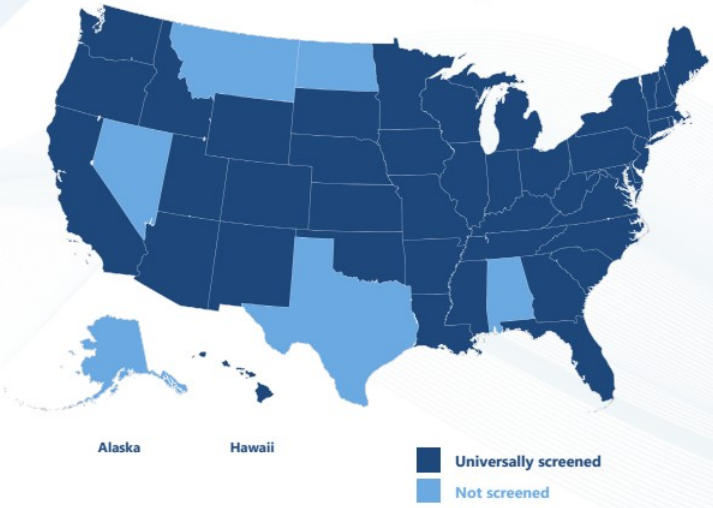
- All EAP and clinical trial patients transitioned
- Multiple new patient starts from both switch and naïve patients
- Robust interest from physician community and treatment centers

[1] Amicus Data on File from Market Mapping

U.S. Update and Market Opportunity

U.S. Pompe market currently represents a sizeable and growing market opportunity of >$500M

Pompe Disease Newborn Screening in 44 U.S. States[2]



- ~80% of the 800 treated patients in the U.S. are adults[1]
- Based on reported revenues, ~45% of patients remain on legacy ERT (alglucosidase alfa)
- >25 clinical trial sites across the country with experience of Pombiliti + Opfolda

LAUNCH DYNAMICS

- All eligible clinical trial patients treated with commercial product or scheduled to be treated
- Majority of new commercial patients switched from newer ERT (avalglucosidase alfa-ngpt)
- Positive initial feedback from patient and physician communities

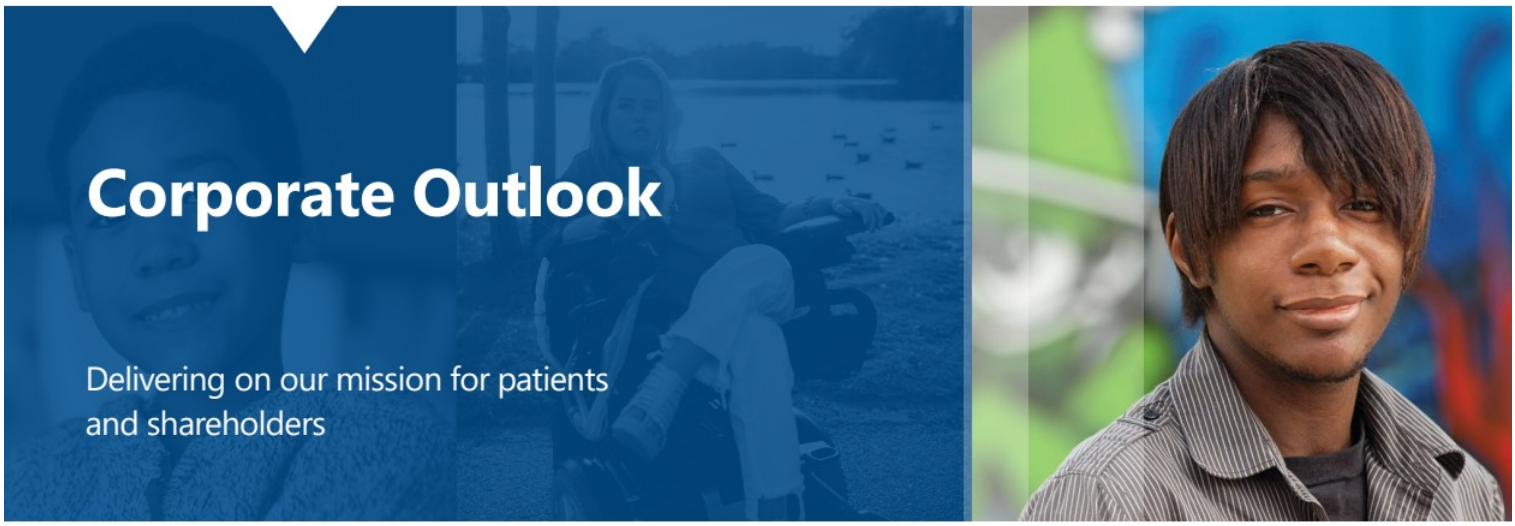
[1] Amicus Data on File from Market Mapping
[2] 2024, Jan 06. Newborn Screening Status for All Disorders. https://www.newsteps.org/resources/data-visualizations/newborn-screening-status-all-disorders

Regulatory and Clinical Updates

Building the body of evidence and expanding commercial access

- >10 reimbursement dossiers submitted and multiple regulatory submissions throughout 2024
- Ongoing clinical studies in children with late-onset Pompe disease and infantile-onset Pompe disease (IOPD)
- Amicus registry for Pompe disease expected to continue generating evidence on differentiated MOA and long-term effect

Amicus Therapeutics®



Corporate Outlook

Delivering on our mission for patients and shareholders

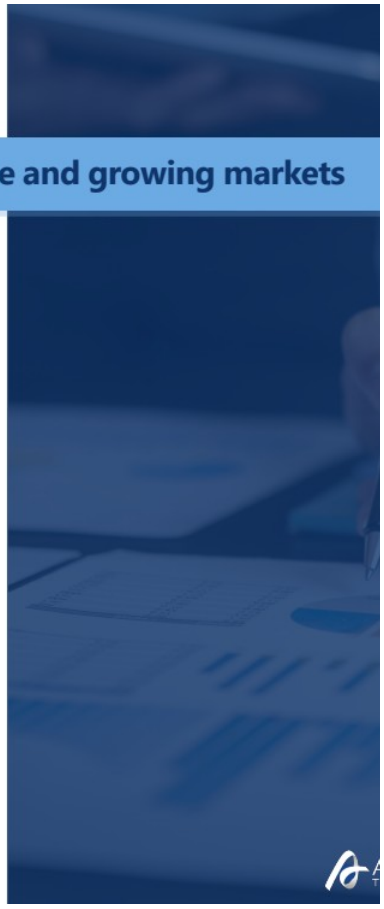
Positioned for Significant Value Creation in 2024

Unlocking the value of two unique commercial therapies in sizeable and growing markets

Accelerating total revenue growth

Delivering full-year non-GAAP[1] profitability

Clear line of sight to generating positive cashflow



[1]Non-GAAP Net Income defined 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.

Ultimate Measure of Success: Impacting the Lives of People Living with Rare Diseases

>350 Patients*

>2,600 Patients*

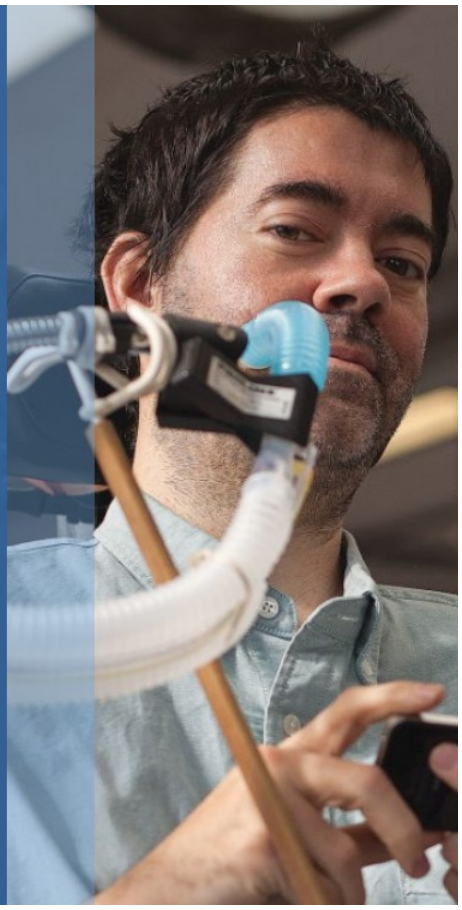
Many Thousands of Patients*

YE17 → YE23 → 2024+

*Clinical and commercial, all figures approximate

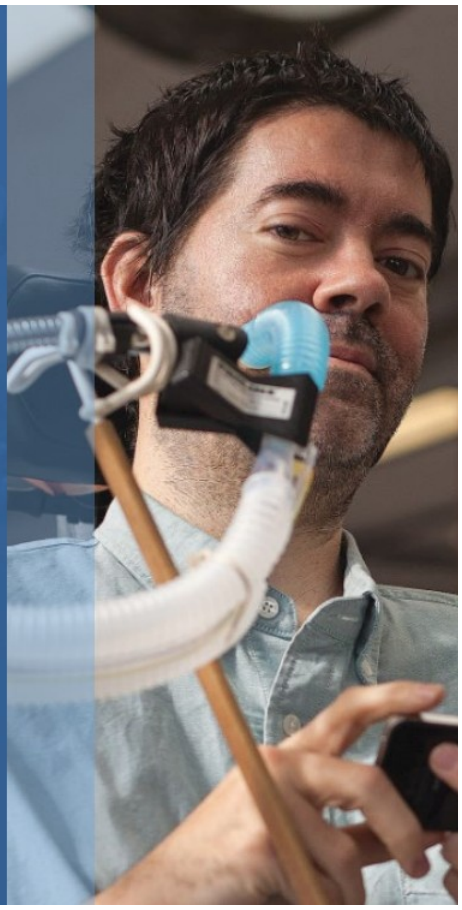
Amicus Therapeutics®

Thank You



Amicus Therapeutics®

Appendix



FX Sensitivity and Galafold Distribution of Quarterly Sales

Impact from Foreign Currency Q4 2023[1]

Currency Variances: USD/	Q4 2022	Q4 2023	YoY Variance
EUR	1.021	1.076	5.4%
GBP	1.174	1.241	5.7%
JPY	0.007	0.007	(4.4%)

Full-year 2024 Revenue Sensitivity[1]

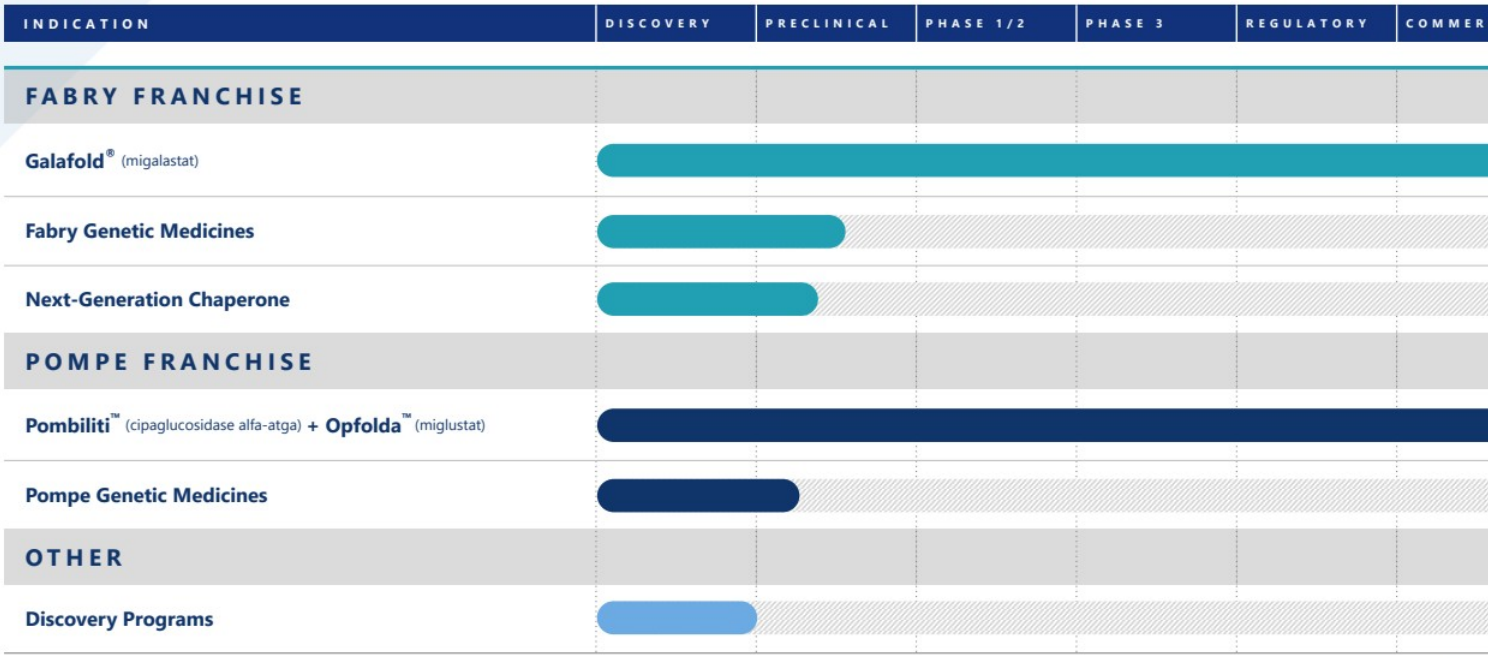
Given the high proportion of Amicus revenue Ex-US (~60%), a change in exchange rates of +/- 5% compared to year-end 2023 rates could lead to a $15M move in global reported revenues in 2024.

Distribution of Galafold Revenue by Quarter over Past 5 years:

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

[1] Preliminary and unaudited

Streamlined Rare Disease Pipeline with Focus on Fabry Disease and Pompe Disease Franchises



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 Jan 2024:
32 patients / **24** 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 i 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 p culture that drives performance and ultimately att 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 Development

Reimagined performance management process t measure the *what* and the *how*, rewarding those w role-model our **Mission-focused Behaviors**.