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 12, 2025**

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, NJ 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 12, 2025, Amicus Therapeutics, Inc. (the "Company") issued a press release announcing preliminary 2024 revenue and its 2025 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 43rd Annual J.P. Morgan Healthcare Conference on January 13th, 2025. 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 12, 2025
99.2	Presentation Materials – 43rd 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 13, 2025

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

Exhibit 99.1

Amicus Therapeutics Reports Preliminary 2024 Revenue and Provides 2025 Strategic Outlook

2024 Total Revenue of $528M, Representing Significant Growth of 32% Year-Over-Year[1]

Strong and Growing Demand for Galafold® and Pombiliti® + Opfolda®

Total Revenue Growth of 17-24% at CER Expected in 2025

>3,000 People Treated with an Amicus Therapy Today[2]

PRINCETON, NJ, January 12, 2025 – 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 2024 revenue, corporate updates, and full-year 2025 outlook.

Bradley Campbell, President and Chief Executive Officer of Amicus Therapeutics, Inc., said, "For Amicus, 2024 was a remarkable year in which we set out high expectations and met or exceeded each of them. Amicus delivered significant revenue growth of 32% in addition to Full Year non-GAAP profitability. We grew our core Galafold business and delivered a strong first full year of launch for Pombiliti + Opfolda while securing regulatory and reimbursement milestones that provide the foundation for sustained double-digit growth in 2025 and beyond. The combination of two approved medicines in growing markets, our strong intellectual property position, accelerating profitability, and our unique and leverageable global rare disease organization will enable us to deliver sustainable revenue growth and expand our portfolio over time. We have the capabilities and infrastructure to achieve our vision to become one of the leading rare disease companies bringing transformative therapies to patients and creating significant value for shareholders."

Corporate Highlights:

- **Total revenue in 2024 reached $528.5 million** (preliminary and unaudited), representing a year-over-year increase of 32%, reflecting strong operational growth of 32% at constant exchange rates (CER)[3]. Fourth quarter total revenue was $149.9 million. For the full year 2025, the Company anticipates total revenue growth of 17-24% on a constant currency basis[3].

- **Galafold (migalastat) net product sales in 2024 were $458.2 million** (preliminary and unaudited)**,** representing a year-over-year increase of 18%, or 18% at CER[3]. Fourth quarter Galafold net product sales were $127.7 million. Given significant growth in patient demand and continued market leadership, there were ~2,730 patients living with Fabry disease on Galafold as of the end of 2024. For the full year 2025, the Company anticipates Galafold revenue growth of 10-15% on a constant currency basis[3].

- **Pombiliti (cipaglucosidase alfa-atga) + Opfolda (miglustat) net product sales in 2024 were $70.3 million** (preliminary and unaudited)**.** Fourth quarter Pombiliti + Opfolda net product sales were $22.2 million. Following a successful first full year of commercial launch, there were ~220 patients treated or scheduled with commercial product as of the end of 2024. For the full year 2025, the Company anticipates Pombiliti + Opfolda revenue growth of 65-85% on a constant currency basis[3].

- **Multiple Pombiliti + Opfolda pricing and reimbursement agreements recently achieved**. Agreements completed in late 2024 and early 2025 include Italy, Sweden, Switzerland, and Czech Republic. First commercial patients from these countries are anticipated to begin treatment over the first half of 2025. The Company also anticipates new regulatory decisions in Australia, Canada, and Japan in 2025 as well as additional reimbursement agreements throughout the year.

- **As previously announced, Amicus reached a settlement with Teva on the Galafold U.S. patent litigation.** Based on the settlement terms, Teva will not be able to commercialize generic migalastat in the U.S. until Jan 2037.

- **Amicus is focused on delivering significant long-term revenue growth and anticipates surpassing $1 billion in total sales in 2028.** The Company anticipates continuing to grow its current commercial business with Galafold and Pombiliti + Opfolda resulting in strong revenue growth. Based on current operating plans, Amicus anticipates achieving **positive GAAP Net Income** during H2 2025.

Amicus is focused on the following key strategic priorities in 2025:

- Delivering total revenue growth of 17-24% at CER[3]
- Galafold revenue growth of 10-15% at CER[3]
- Pombiliti + Opfolda revenue growth of 65-85% at CER[3]
- Advancing ongoing studies to broaden labels and scientific leadership in Fabry and Pompe diseases
- Delivering positive GAAP Net Income during H2 2025

[1] Preliminary and unaudited

[2] Including clinical trial and expand access participants

[3] At constant exchange rates (CER). In order to illustrate underlying performance, Amicus discusses its results in terms of CER growth. This represents growth calculated as if the exchange rates had remained unchanged from those used in the comparative period.

Mr. Campbell will discuss the Amicus corporate objectives and key milestones in a presentation at the 43rd Annual J.P. Morgan Healthcare Conference on Monday, January 13, 2025, at 3:00 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.

About Galafold

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

U.S. INDICATIONS AND USAGE

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

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

U.S. IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS

The most common adverse reactions reported with Galafold (≥10%) were headache, nasopharyngitis, urinary tract infection, nausea and pyrexia.

USE IN SPECIFIC POPULATIONS

There is insufficient clinical data on Galafold use in pregnant women to inform a drug-associated risk for major birth defects and miscarriage. Advise women of the potential risk to a fetus.

It is not known if Galafold is present in human milk. Therefore, the developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Galafold and any potential adverse effects on the breastfed child from Galafold or from the underlying maternal condition.

Galafold is not recommended for use in patients with severe renal impairment or end-stage renal disease requiring dialysis.

The safety and effectiveness of Galafold have not been established in pediatric patients.

To report Suspected Adverse Reactions, contact Amicus Therapeutics at 1-877-4AMICUS or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

For additional information about Galafold, including the full U.S. Prescribing Information, please visit https://www.amicusrx.com/pi/Galafold.pdf.

About Pombiliti + Opfolda

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

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

SAFETY INFORMATION

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

About Amicus Therapeutics
Amicus Therapeutics (Nasdaq: FOLD) is a global, patient-dedicated biotechnology company focused on discovering, developing and delivering novel high-quality medicines for people living with rare diseases. With extraordinary patient focus, Amicus Therapeutics is committed to advancing and expanding a pipeline of cutting-edge, first- or best-in-class medicines for rare diseases. For more information, please visit the Company's website at www.amicusrx.com, and follow on X and LinkedIn.

Non-GAAP Financial Measures
In addition to financial information prepared in accordance with U.S. GAAP, this press release also contains adjusted financial measures that we believe provide investors and management with supplemental information relating to operating performance and trends that facilitate comparisons between periods and with respect to projected information. These adjusted financial measures are non-GAAP measures and should be considered in addition to, but not as a substitute for, the information prepared in accordance with U.S. GAAP. We use these non-GAAP measures as key performance measures for the purpose of evaluating operational performance and cash requirements internally. We typically exclude certain GAAP items that management does not believe affect our basic operations and that do not meet the GAAP definition of unusual or non-recurring items. Other companies may define these measures in different ways. When we provide our expectation for non-GAAP operating expenses and profitability on a forward-looking basis, a reconciliation of the differences between the non-GAAP expectation and the corresponding GAAP measure generally is not available without unreasonable effort due to potentially high variability, complexity and low visibility as to the items that would be excluded from the GAAP measure in the relevant future period, such as unusual gains or losses. The variability of the excluded items may have a significant, and potentially unpredictable, impact on our future GAAP results.

Forward Looking Statement
This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 relating to the prospects and timing of the potential regulatory and pricing and reimbursement approvals of our products, commercialization plans, manufacturing and supply plans, financing plans, and the projected revenues, profitability 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, 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 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 we will not be able to effectively compete in our approved markets: the potential that generic or new competitor products enter the market; 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 support 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 and GAAP profitability and cash position, actual results may differ based on market factors and the Company's ability to execute its operational and budget plans. In addition, all forward-looking statements are subject to other risks detailed in our Annual Report on Form 10-K for the year ended December 31, 2023, and on Form 10-Q for the quarter ended September 30, 2024. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, and we undertake no obligation to revise or update this news release to reflect events or circumstances after the date hereof.

CONTACT:

Investors:
Amicus Therapeutics
Andrew Faughnan
Vice President, Investor Relations
afaughnan@amicusrx.com
(609) 662-3809

Media:
Amicus Therapeutics
Diana Moore
Head of Global Corporate Communications
dmoore@amicusrx.com
(609) 662-5079

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Exhibit 99.2


AT THE FOREFRONT OF
THERAPIES FOR RARE DISEASES
43rd Annual J.P. Morgan Healthcare Conference
January 13, 2025
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 the prospects and timing of the potenti regulatory and pricing and reimbursement approvals of our products, commercialization plans, manufacturing and supply plans, financing plans, and the projected revenu profitability 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 achieve 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 unknov risks and uncertainties. For example, statements regarding the goals, progress, timing, and outcomes of discussions with regulatory authorities and pricing and reimburseme authorities, are based on current information. Actual results may differ materially from those set forth in this presentation due to the risks and uncertainties inherent in our busine including, without limitation: the potential that regulatory authorities may not grant or may delay approval for our product candidates; the potential that required regulato 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 reimburseme authorities; the potential that we may not be successful in commercializing Galafold and/or Pombiliti and Opfolda in Europe, the U.K., the U.S. and other geographies; the potenti that we will not be able to effectively compete in our approved markets: the potential that generic or new competitor products enter the market; the potential that we may not be ab to manufacture or supply sufficient clinical or commercial products; and the potential that we will need additional funding to support the manufacturing and commercialization of o 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 revenu non-GAAP and 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. addition, all forward-looking statements are subject to other risks detailed in our Annual Report on Form 10-K for the year ended December 31, 2023, and on Form 10-Q for t quarter ended September 30, 2024. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looki statements are qualified in their entirety by this cautionary statement, and we undertake no obligation to revise or update this presentation to reflect events or circumstances after t date hereof.

Non-GAAP Financial Measures

In addition to financial information prepared in accordance with U.S. GAAP, this presentation also contains adjusted financial measures that we believe provide investors a management with supplemental information relating to operating performance and trends that facilitate comparisons between periods and with respect to projected informatio 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 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-recurri 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 reconciliatio of the differences between the non-GAAP expectation and the corresponding GAAP measure generally is not available without unreasonable effort due to potentially high variabili 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 t excluded items may have a significant, and potentially unpredictable, impact on our future GAAP results.

Definition:
\əˈmēkəs (noun) *Latin* Friend

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 commercializatio leveraging our global capabilities in bringing life-changing therapies to patients

A Rare Company

A unique story in biotech with significant revenue growth and profitability

~$528M
2024 Total Revenue[1]
(+32% Growth)[2]

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

10-15%
FY 2025 Galafold Revenue Growth[2]

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

65-85%
FY 2025 Pombiliti + Opfolda Revenue Growth[2]

FY 2024 Non-GAAP Profitability Achieved

Leverageable Global Commercial Organization

$1B+
Total Revenues Expected in 2028

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

2024 Strategic Priorities

Delivered

- Galafold® revenue growth of 11-16% at CER[1], raised to 16-18%
- Execute multiple successful launches of Pombiliti® + Opfolda®
- Advance ongoing studies to support medical and scientific leadership in Fabry and Pompe diseases
- Achieve non-GAAP profitability for the full year

[1]CER: Constant Exchange Rates;

2024 Key Milestones

Highest Patient Demand for Galafold Since Early Launch

U.S. Galafold IP Settlement with Teva Provides Long Runway of Growth

Galafold: A Fast Growing Treatment in Fabry Disease & SoC in Amenable Population

Non-GAAP Profitability Achieved in 2024

Successful First Year of Launch of Pombiliti + Opfold

Positive Feedback for Pombiliti + Opfolda Increasing Among Patients and Physicians

Reduced OPEX Guidance and Judiciously Managed Expenses

2025 Strategic Priorities

1. Deliver total revenue growth of 17-24% at CER[1]
2. Double-digit Galafold® revenue growth of 10-15% at CER[1]
3. Pombiliti® + Opfolda® revenue growth of 65-85% at CER[1]
4. Advance ongoing studies to broaden labels and strengthen scientific leadership in Fabry and Pompe diseases
5. Deliver positive GAAP Net Income during H2 2025

[1]CER: Constant Exchange Rates

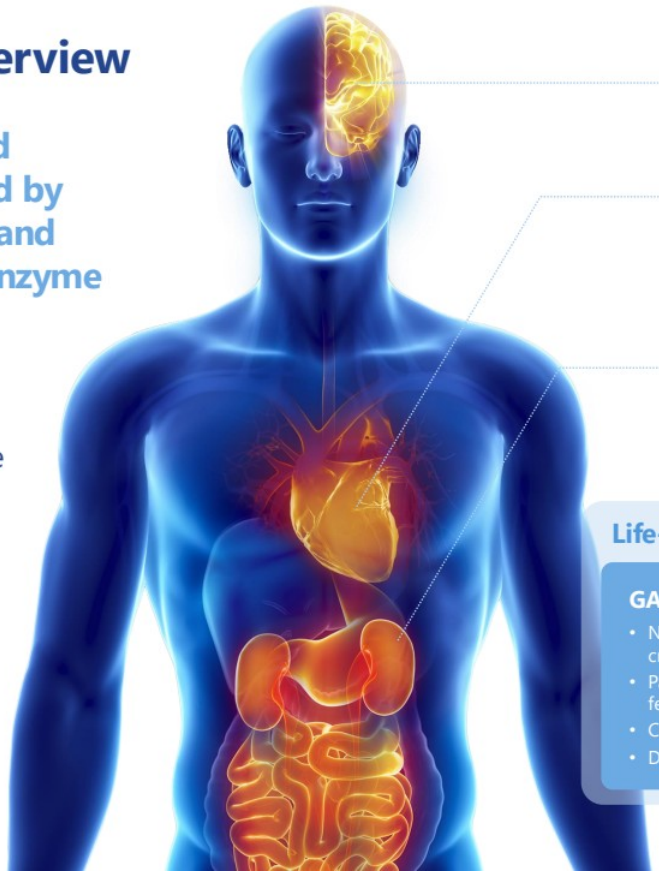
Galafold® *(migalastat)*
Continued Growth

Building a leadership position
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

- >1,000 known mutations
- >18,000 diagnosed WW
- X-linked dominant disease leading to diagnosis of multiple family members



Leading Causes of Death

TRANSIENT ISCHEMIC ATTACK (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]

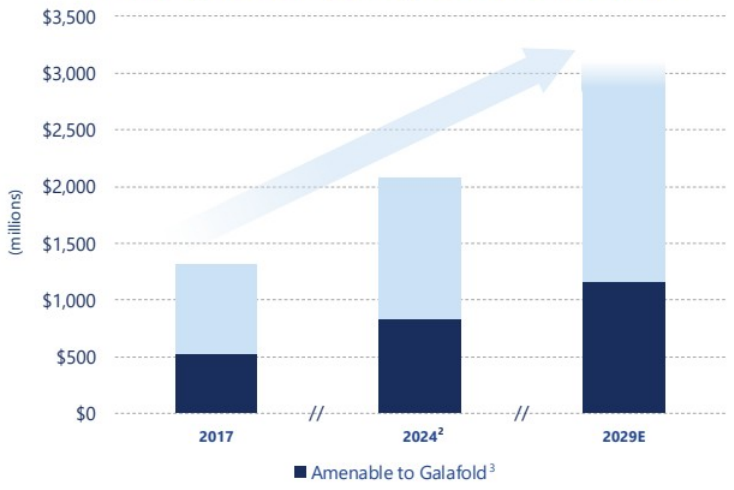
ANHIDROSIS

[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 2029

Global Fabry market of ~$2.1B in 2024 and tracking toward ~$3B+ by the end of the decade[1]

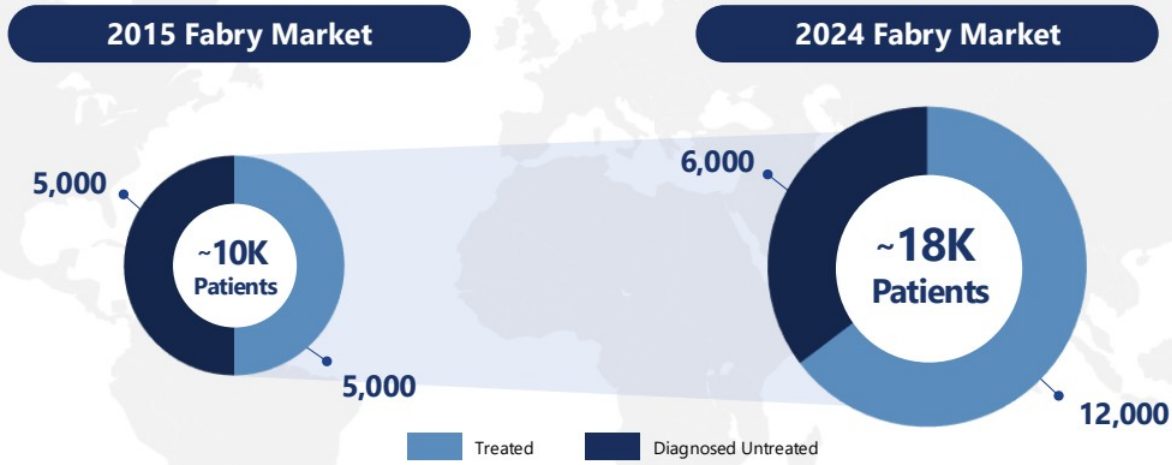


- Significantly underdiagnosed
  - Newborn screening studies suggest Fabry is o of the more prevalent rare genetic diseases (~1:1,500 to ~1:4,000 incidence)[4]
- Continued market growth driven by increase diagnosis
- Anticipate market size for amenable patients to surpass $1B in 2029
- Galafold continues to be the greatest contributor to market growth

[1] Global market measured by reported sales of approved therapies for Fabry disease – 2029 sales projected using ~7% CAGR
[2] LTM ended September 30, 2024
[3] Assumes ~40% amenability to Galafold
[4] Burton 2017 J Pediatr 2017;190:130-5 ; Mechtler *et al.*, The Lancet, 2011 Dec.; Hwu *et al.*, Hum Mutation, 2009 Jun; Spada *et al.*, Am J Human Genet., 2006 Jul

Fabry Market Dynamics

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



6,000 diagnosed untreated patients remain

Based on Amicus data on file

2024 Galafold Success (as of December 31, 2024)

Only approved oral treatment in Fabry disease and standard of care for amenable patients

A unique mechanism of action for Fabry patients with amenable variants

~$458M
FY24 Galafold Revenue[1]

>60%
Share of Treated Amenable Patients

10-15%
2025 Galafold Growth at CER[2]

~2,730
Individuals Treated[3]

35-50%
Fabry Patients Amenable to Galafold

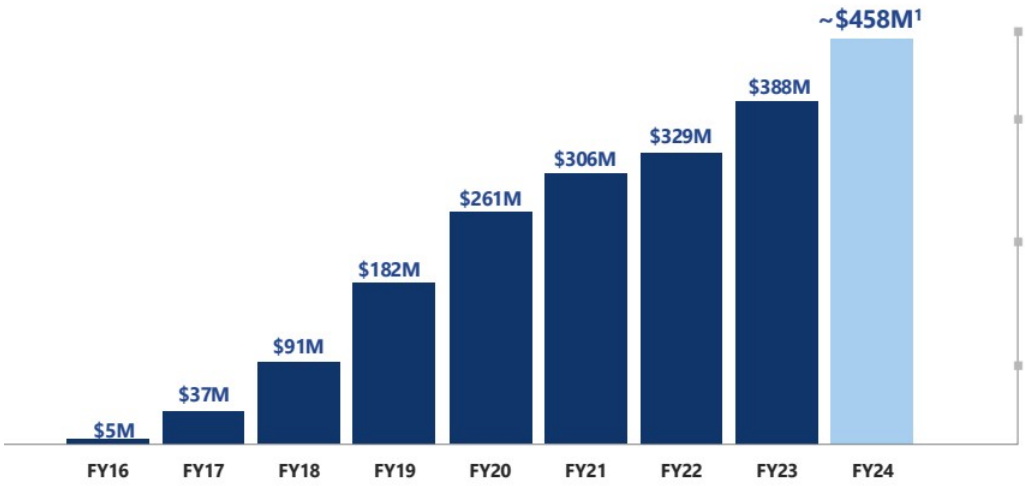
40+
Countries with Regulatory Approvals

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://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
[3] As of YE 2024

Galafold Performance

Growing patient demand in 2024 lays foundation for continued strong growth



- Global mix of naïve (~60%) and switc (~40%) patients[2]
- Expanding market through uptake in naïve population as well as geograph and label expansion
- Maintaining >90% adherence and compliance through HCP and patien education and support
- Expect non-linear quarterly growth to continue due to uneven ordering patterns and FX fluctuations

Strong FY 2025 Galafold growth guidance of 10-15% at CER[3]

[1] Preliminary and unaudited
[2] Data on file
[3] At CER: Constant Exchange Rates

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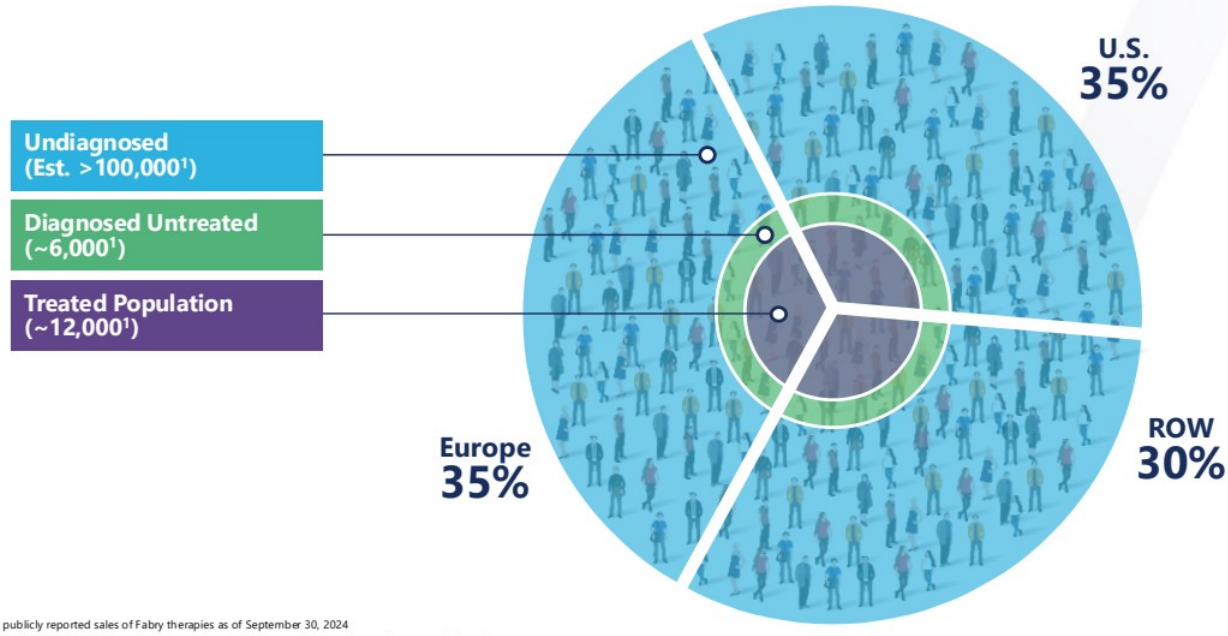
Fabry Market: Significant Remaining Unmet Need

Research suggests there could be >100k people living with Fabry disease who remain undiagnosed



Based on publicly reported sales of Fabry therapies as of September 30, 2024

[1]Applying incidence of multiple newborn screening studies to population estimates in commercial markets: Burton 2017 J Pediatr 2017;190:130-5 ; Mechtler *et al.*, The Lancet, 2011 Dec.; Hwu *et al.*, Hum Mutation, 2009 Jun; Spada *et al.*, Am J Human Genet., 2006 Jul

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Improving Diagnosis of Fabry Disease

Multiple initiatives leveraging AI and family screening to drive Dx and address health inequitie

Collaboration using AI to diagnose Fabry

OM1 Penn Medicine


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

- 580K+ medical records screened
- 100 people with highest risk of Fabry identified
- Outreach ongoing to offer genetic testing

Collaboration for change in health inequity

NHS

- Initial findings from Fabry pilot programs in U.K.
  - Minority and low-income groups significantly under-represented
  - >90% of diagnosed Fabry population white
  - ~85% from the least deprived areas
- Initiative already identified low-income families who otherwise wouldn't have been diagnosed

Additional initiatives in several countries ongoing leveraging AI and/or targeted screening

Amic Therape

Long-Term Outlook:
Clear Path to $1B+ Galafold Revenue

Many Thousands of Patients and $1B+ in Peak Sales

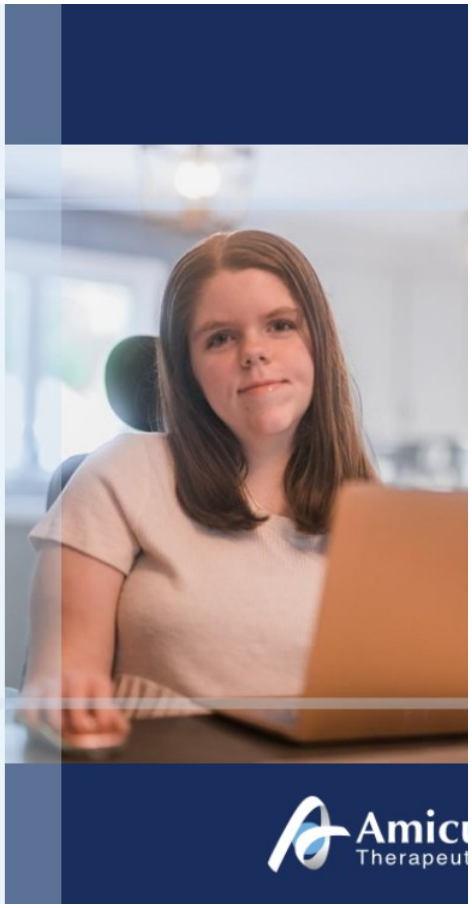
The Next 12 Years

Today
~2,730
Patients
~$458M
Revenue

Global IP protection provides Galafold long runway to becoming a $1B+ product

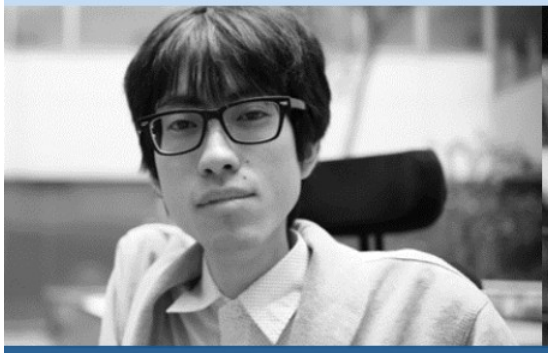
Pombiliti® *(cipaglucosidase alfa-atga)*
+ Opfolda® *(miglustat)*

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



Pompe Disease Overview

Late-onset Pompe Disease is a Rare, inherited genetic disorder caused by mutation in GAA gen and deficiency of α-glucosidase enzyme



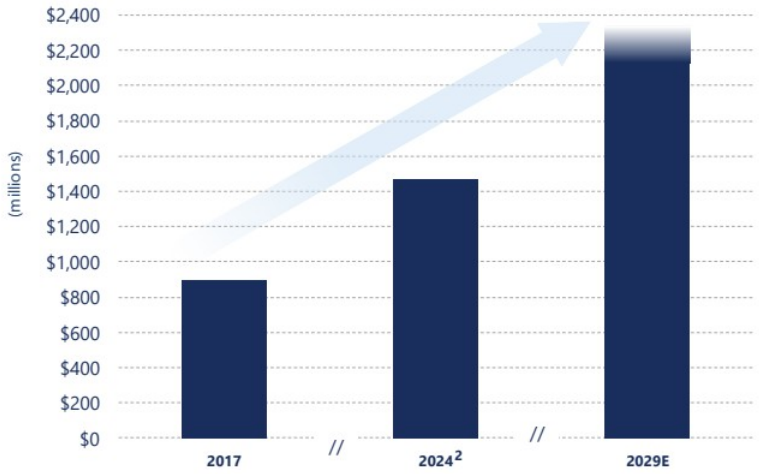
- ~5,000-10,000 people diagnosed globally
- Deficiency of GAA leading to lysosomal glycogen accumulation and cellular dysfunction
- Significantly underdiagnosed
- Respiratory failure is major cause of mortality
- Symptoms include systemic muscle weakness that worsens over time
- ~$1.5B+ global Pompe ERT sales[1]

[1] Based on 12 months ended September 30, 2024

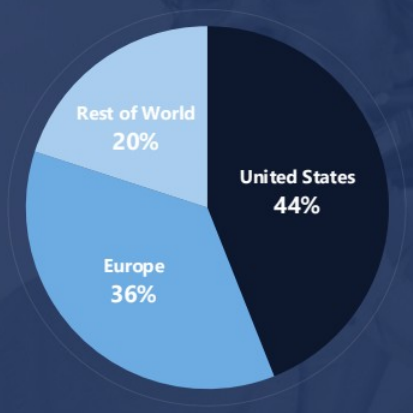
Global Pompe Market

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

Global Pompe Market of ~$1.5B in 2024 and Tracking toward $2B+ by 2029[1]



Global Pompe Market Sales Split YTD 2024[2]



An estimated >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, 2024
[3] Amicus Data on File from Market Mapping

Pombiliti + Opfolda Profile

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

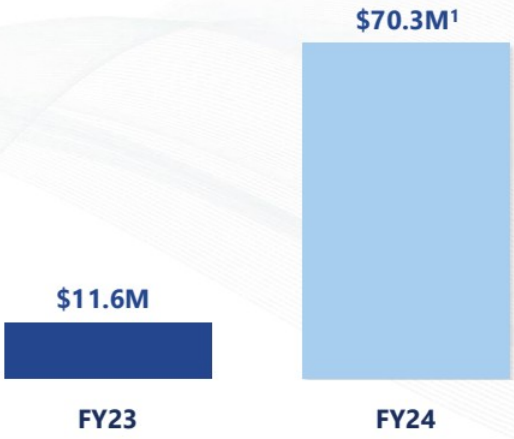
- Differentiated **mechanism of action** combining cipaglucosidase alfa-atga, an ERT, with miglustat, an orally administered enzyme stabilizer
- Only Pompe therapy with **Phase 3** study that included **ERT-experienced** patients
- Phase 3 PROPEL study demonstrated mean improvement in **6MWD** and stabilization in **FVC** in patients switching from SoC

ERT: Enzyme Replacement Therapy

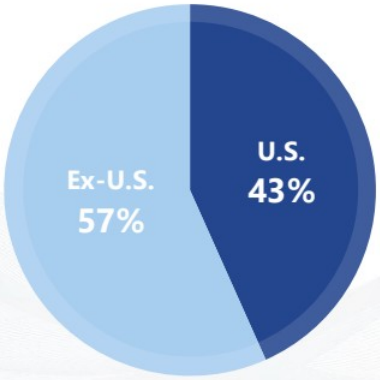
Pombiliti + Opfolda Performance

Successful first full year of launch with revenue of $70.3M sets foundation for 2025

Annual Revenue



2024 Geographic Mix



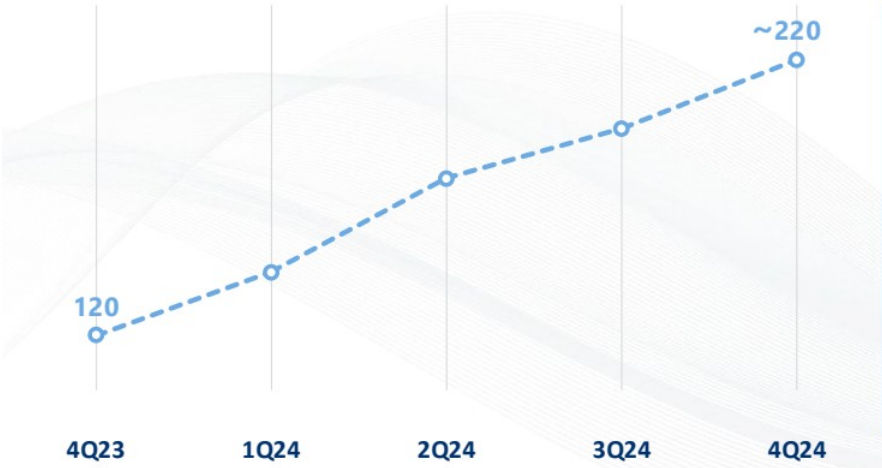
~50/50 revenue split between U.S. and ex-U.S. exiting 2024

[1] Preliminary and unaudited

Pombiliti + Opfolda Global Launch Metrics

~220 Individuals Treated or Scheduled Provides Strong Foundation for 2025

Global Launch: Individuals Treated or Scheduled



- **~220** patients have been treated or scheduled be treated with commercial product
  - ~209 treated patients
  - ~25 new prescriptions in Q4
- All eligible clinical trial patients from launched markets on commercial therapy by end of 1H2
- New commercial patients time through U.S. insurance process optimized to <30 days
- Patients starting Pombiliti + Opfolda at proportional rate to the respective market shar

Amic
Therape

Geographic Expansion

3 new regulatory approvals and up to 10 new launch countries in 2025

Regulatory

- 3 additional regulatory approvals anticipated in 2025

Reimbursement

- In 2025, expect to launch in up to 10 new countries, including 4 recent agreements
  - >650 LOPD patients 18+ in those 10 countries
- First commercial patients from those new launch countries anticipated over H1 2025
- Anticipate >20 individuals switching from clinical trials or early access programs in new countries in 2025

Regulatory approvals anticipated in 2025:


JAPAN


AUSTRALIA


CANADA

Combined ~150-200 people 18+ living with LOPD and being treated with a Pompe therapy

New reimbursement agreements completed in:


ITALY

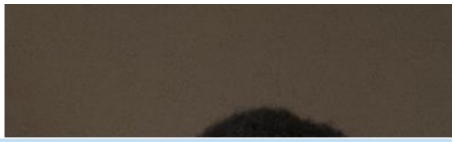

CZECH REPUBLIC


SWITZERLAND

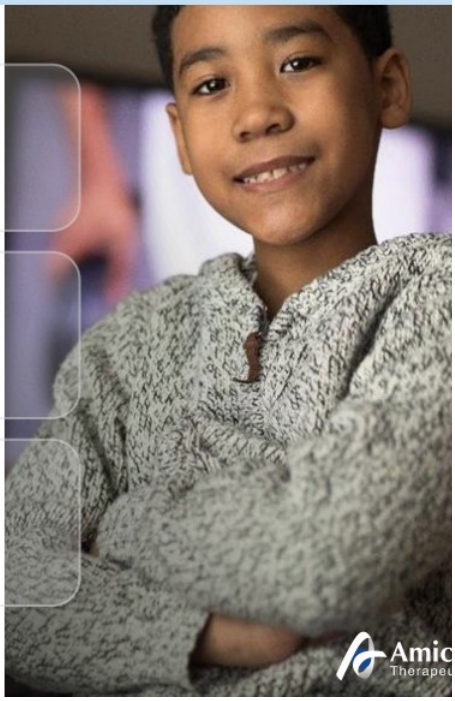

SWEDEN

Combined ~200-250 people 18+ living with LOPD and being treated with a Pompe therapy

Ongoing Clinical Studies



Continuing to build the body of evidence to support planned label expansion



ZIP — Clinical study in children with infantile-onset Pompe disease (IOPD)

ROSSELLA — Clinical study in children with late-onset Pompe disease (LOPD)

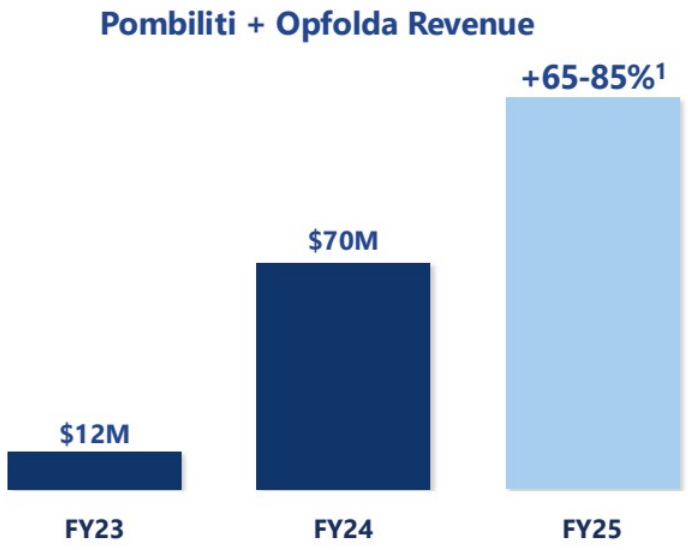
followME Pompe Journey — Amicus registry adding to evidence on differentiated MOA and long-term effect

Pombiliti + Opfolda Real-World Evidence

Ongoing publications demonstrate the impact of Pombiliti + Opfolda's differentiated MOA on long-term outco

Pombiliti + Opfolda Growth Drivers

Amicus focused on key drivers of growth in 2025

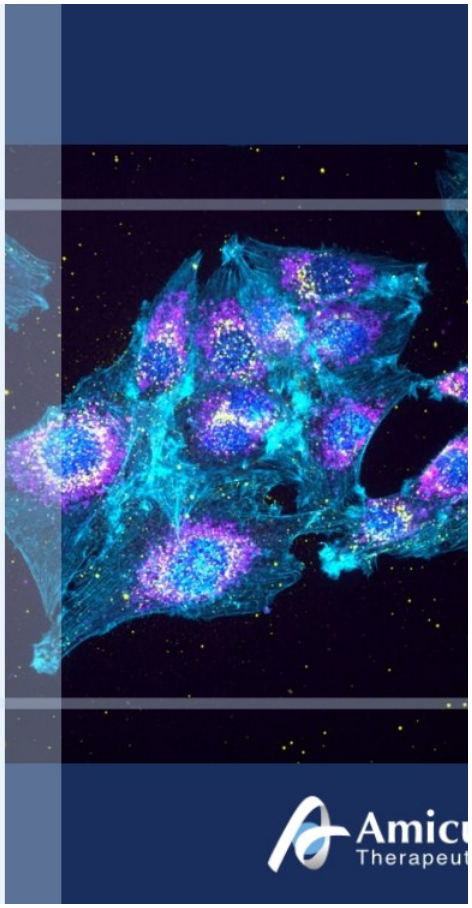


- Increasing number of net new patients
- Increasing depth and breadth of prescribers
- Expect to launch in up to 10 new countries throughout 2025
- Continuing to drive differentiation through evidence generation and real-world evidenc
- Anticipate 90%+ compliance and adherence

[1] At CER: Constant Exchange Rates

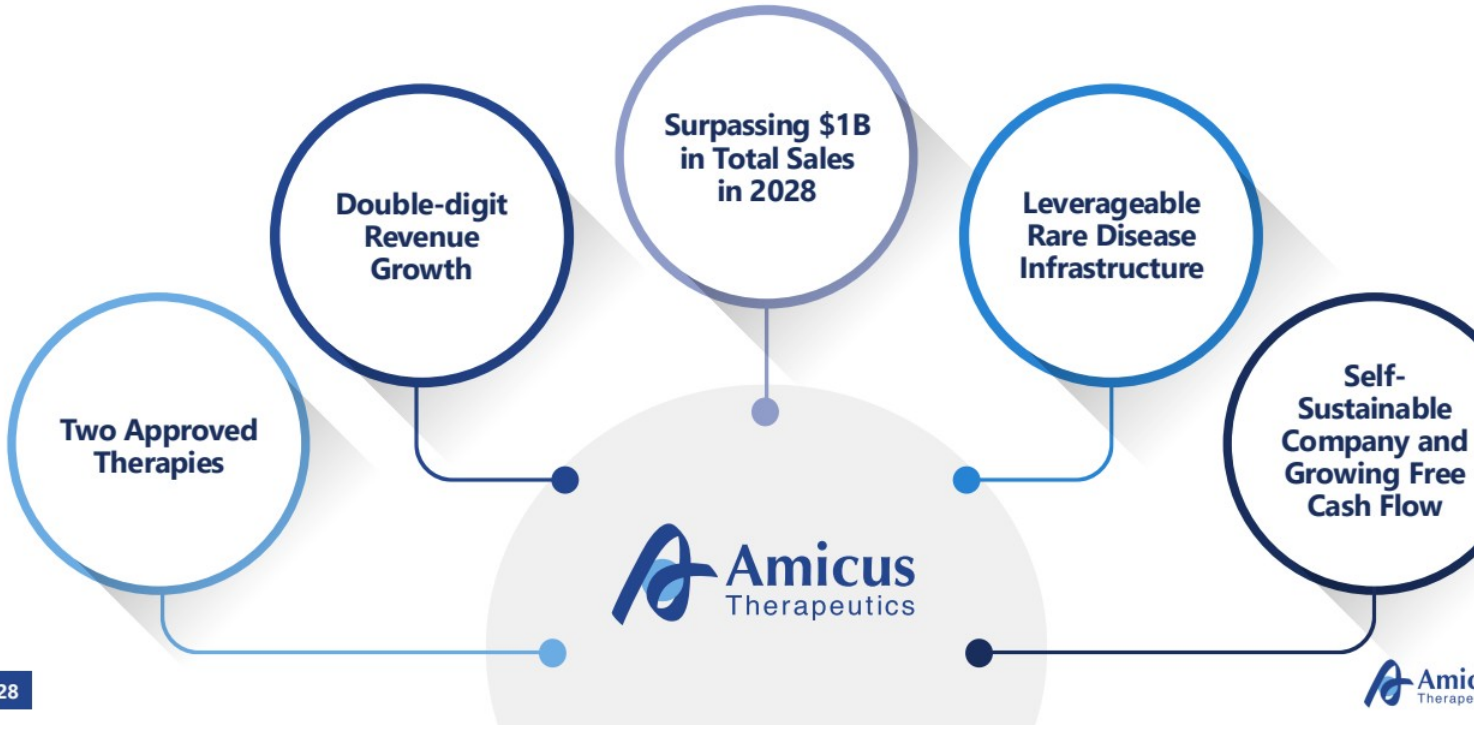
Corporate Outlook

Delivering on our mission for patients and shareholders

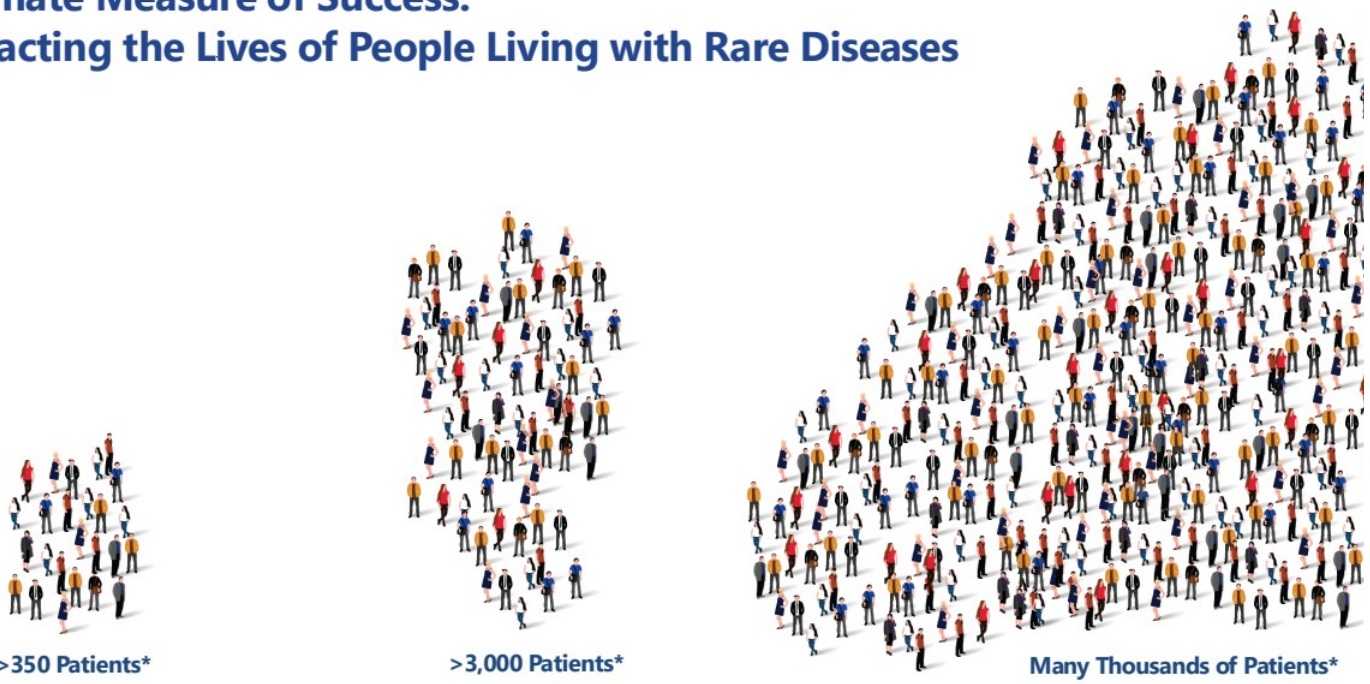


A Rare Company

A unique story in biotech with significant revenue growth and profitability



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



>350 Patients*

>3,000 Patients*

Many Thousands of Patients*

YE17 → YE24 → 2025+

*Clinical, early access, and commercial, all figures approximate

Amicus Therapeutics

Thank You

Amicus Therapeutics

Appendix

Full-Year 2025 Revenue Guidance and Sensitivity

FY 2025 Revenue Guidance[1]	2025
Total Revenue Growth[1]	17% to 24%
Galafold Revenue Growth[1]	10% to 15%
Pombiliti + Opfolda Revenue Growth[1]	65% to 85%

[1] Full-Year 2025 guidance is provided at CER (Constant Exchange Rates) using Full-Year 2024 Average Exchange Rates

FY 2025 Revenue Sensitivity

Given the proportion of Amicus revenue ex-US (**~60%** in 2024), a change in USD exchange rates of **+/- 1%** compared to year-end 2024 rates could lead to a **~$3.6M** move in Total Reported Revenues in 2025

Exchange Rates

Q4 2024 Currency Average Rates

FX Rates	Q4 2023	Q4 2024	Variance
USD/EUR	1.076	1.067	(0.8%)
USD/GBP	1.241	1.282	3.3%
USD/JPY	0.007	0.007	(3.0%)

Year-End 2024 vs. Full-Year 2024 Currency Average Rates[1]

FX Rates	Year-End 2024	Full-Year 2024	Variance
USD/EUR	1.041	1.082	(3.8%)
USD/GBP	1.255	1.278	(1.8%)
USD/JPY	0.006	0.007	(3.5%)

[1] The variance between **Year-End 2024** and **Full-Year 2024** USD exchange rates of **~4%** would translate into a negative impact of **~$15M** on Total Revenue in 2025 if rates were to remain at Year-End 2024 level

Distribution of Quarterly Sales

Distribution of Galafold® Revenue by Quarter over Past 5 Years

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

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

(as of December 31, 2023)

Contributions allocated:

$1,980,516 U.S.

$706,417 Intl.

Expanded Access as of Nov. 2024:

40 patients / **16** countries

Amicus-supported community programs: **37**

Volunteer hours (U.S.): **511**

Environmental Management

Committed to producing transformative medicines for people living with rare diseases 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 Scope 1 and Scope 2 Emissions**

(as of December 31, 2023)

Global Employees **517**

% Female Employees **58%**

(as of December 31, 2024)

Board of Directors

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

Director Diversity

3 Female
1 Veteran Status
1 African American

89% **Board Independence**

56% **Overall Board Diversity**

Diversity, Equity, & Inclusion (DEI)

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

We have embedded DEI into our units, our Belief Statement, and Focused B

Employee Recruitment, Engagement, & Retention

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

*Amicus is Certified as a **Great Place to Work** U.S., U.K., Italy, Germany, Spain, France, and*

Career Development

90% Employees say Amicus is a great place compared to 57% of employees at a t U.S.-based company

Amic Therape