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 7, 2022**

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

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

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

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

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

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

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

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

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

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

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

Item 7.01 – Regulation FD Disclosure.

On November 7, 2022, Amicus Therapeutics, Inc. (the "Company") issued a press release announcing an EU regulatory update for AT-GAA. A copy of this press release is attached hereto as Exhibit 99.1. In connection with this announcement, the Company also updated its presentation materials which have been attached hereto as Exhibit 99.2. Both exhibits are incorporated herein by reference.

The information in this Item 7.01, including Exhibits 99.1 and 99.2, are being furnished and shall not be deemed "filed" for purposes of Section 18 of the Act, or otherwise subject to the liabilities of that Section. The information in this Item 7.01, including Exhibits 99.1 and 99.2, shall not be incorporated by reference into any registration statement or other document pursuant to the Act.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits:

Exhibit No.	Description
99.1	Press Release dated November 7, 2022
99.2	November 7, 2022 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 7, 2022

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

Amicus Therapeutics Provides EU Regulatory Update for AT-GAA

PHILADELPHIA, PA, Nov. 7, 2022 – Amicus Therapeutics (Nasdaq: FOLD), a patient-dedicated global biotechnology company focused on developing and commercializing novel medicines for rare diseases, today provided an EU regulatory update for AT-GAA. Earlier this morning, the Committee for Medicinal Products for Human Use (CHMP) issued the agenda for their November meeting indicating possible oral explanations for miglustat and for cipaglucosidase alfa on November 9th. The Company has now been informed that oral explanations will not take place as originally anticipated. The Company continues to prepare for a CHMP opinion on AT-GAA as early as December 2022 and will assess any potential change in timelines.

About AT-GAA

AT-GAA is an investigational two-component therapy that consists of cipaglucosidase alfa (ATB200), a unique recombinant human acid alpha-glucosidase (rhGAA) enzyme with optimized carbohydrate structures, particularly bis-phosphorylated mannose-6 phosphate (bis-M6P) glycans, to enhance uptake into cells, administered in conjunction with miglustat (AT2221), a stabilizer of cipaglucosidase alfa.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 relating timing of the potential regulatory approval of AT-GAA. 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. 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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Amicus Therapeutics
Diana Moore
Head of Global Corporate Communications
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(609) 662-5079

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Exhibit 99.2


Amicus
Therapeutics®
3Q22 Financial Results
Conference Call & Webcast
At the Forefront of Therapies
for Rare Diseases
November 7, 2022

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 deve candidates, the timing and reporting of results from preclinical studies and clinical trials, the prospects and timing of the potential regulatory approval of c commercialization plans, manufacturing and supply plans, financing plans, and the projected revenues, expenses, cash position, and future profitability for the Cor 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 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 stateme progress, timing, and outcomes of discussions with regulatory authorities, and in particular the potential goals, progress, timing, and results of preclinical studies and cli 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 u predicted with confidence and may cause actual results and performance to differ materially from the statements in this release, including without limitation, because of 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 and resource allocations, manufacturing and supply chain disruptions and limitations on patient access to commercial or clinical product. In addition to the impact of th 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 potenti 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 p authorities, including the FDA, EMA, and PMDA, may not grant or may delay approval for our product candidates; the potential that we may not be successful in com Europe, Japan, the US and other geographies or our other product candidates if and when approved; the potential that preclinical and clinical studies could be delay 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 funding to complete all of our studies, manufacturing and launch preparations. Further, the results of earlier preclinical studies and/or clinical trials may not be predictiv respect to statements regarding projections of the Company's revenue, expenses, cash position, and future profitability, actual results may differ based on market fact 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 1 December 31, 2021 and Form 10-Q for the quarter ended September 30, 2022, that was filed today. You are cautioned not to place undue reliance on these forward-loo 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 u to reflect events or circumstances after the date hereof.

Non-GAAP Financial Measures

In addition to financial information prepared in accordance with U.S. GAAP, this presentation also contains adjusted financial measures that we believe provide investors supplemental information relating to operating performance and trends that facilitate comparisons between periods and with respect to projected information. T 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 e 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 comp measures in different ways. When we provide our expectation for non-GAAP operating expenses on a forward-looking basis, a reconciliation of the differences b expectation and the corresponding GAAP measure generally is not available without unreasonable effort due to potentially high variability, complexity and low visibi 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 sign unpredictable, impact on our future GAAP results.

A Rare Company

Patient-dedicated, Rare Disease Biotechnology Company with Sustained Double-dig
Growth, a Global Commercial Infrastructure, and Late-stage Development Capal

Galafold® (migalastat)

First Oral Precision Medicine for Fabry Disease

Gene Therapy PLATFORM

Leveraging Experience in Protein Engineering & Glycobiology

World-class CLINICAL DEVELOPMENT Capabilities

EMPLOYEES in 20 Countries

GLOBAL COMMERCIAL ORGANIZATION

AT-GAA

a Two-component Therapy Under Global **Regulatory Reviews** for **Pompe Disease**

15% - 20%

FY22 Galafold Revenue Growth at CER

GALAFOLD & AT-GAA

Cumulative $2B Peak Potential

Positioned for Significant Value Growth

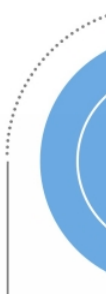
Focused on Execution and Driving Sustainable Double-digit Revenue Grow on Path to Profitability

Continue to bring Galafold® to as many patients as possible, sustain double-digit revenue growth

Successful launch of AT-GAA for people living with Pompe disease

Advance next-generation gene therapies in Fabry and Pompe diseases

Fully leverage global capabilities and infrastructure as a leader in rare diseases



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

2022 Strategic Priorities to Drive Value

1. Double-digit Galafold growth (15-20%) with revenue of $350M to $365M
2. Secure FDA approval and positive CHMP opinion for AT-GAA
3. Initiate successful, rapid launch in U.S. for AT-GAA
4. Advance best-in-class, next-generation genetic medicines and capabilities
5. Maintain strong financial position on path to profitability

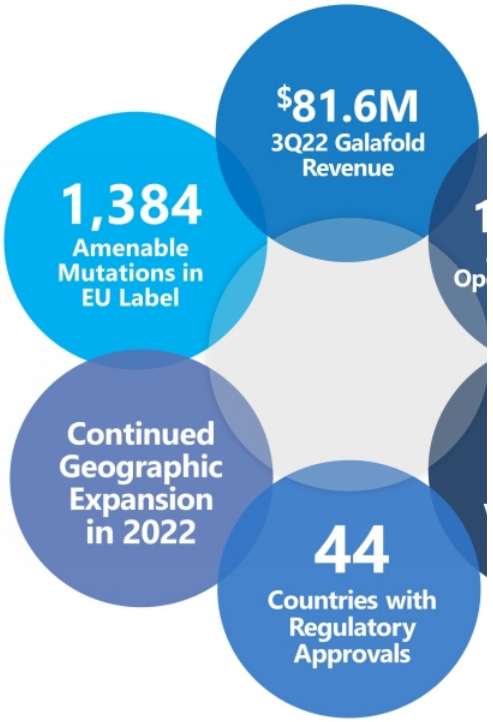
[1]CER: Constant Exchange Rates; 2022 Galafold revenue guidance is based on the average exchange rates for 2021

Amicus Therapeutics®

Galafold Success (as of September 30, 2022)

Building on Galafold's Success and Leveraging Leadership Position to Drive Continu

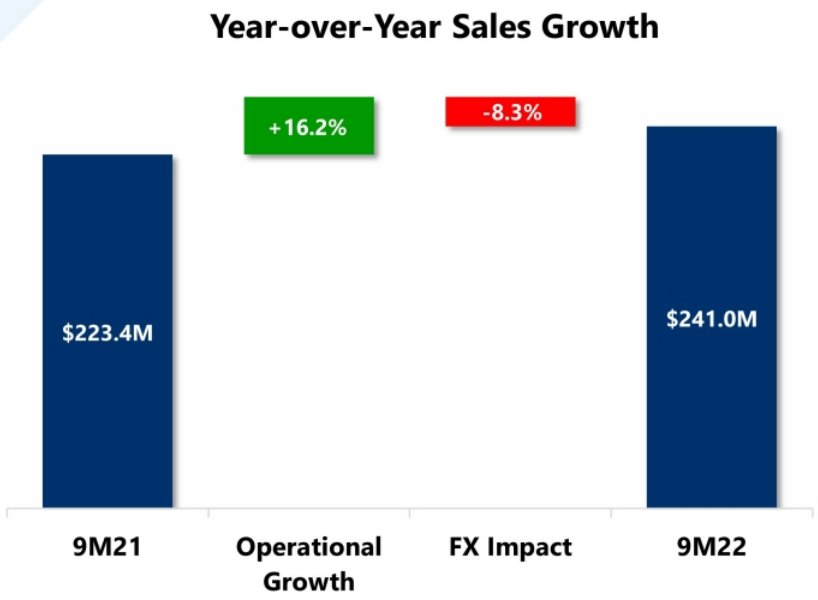
Galafold is the first and only approved oral treatment option with a unique mechanism of action for Fabry patients with amenable variants



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

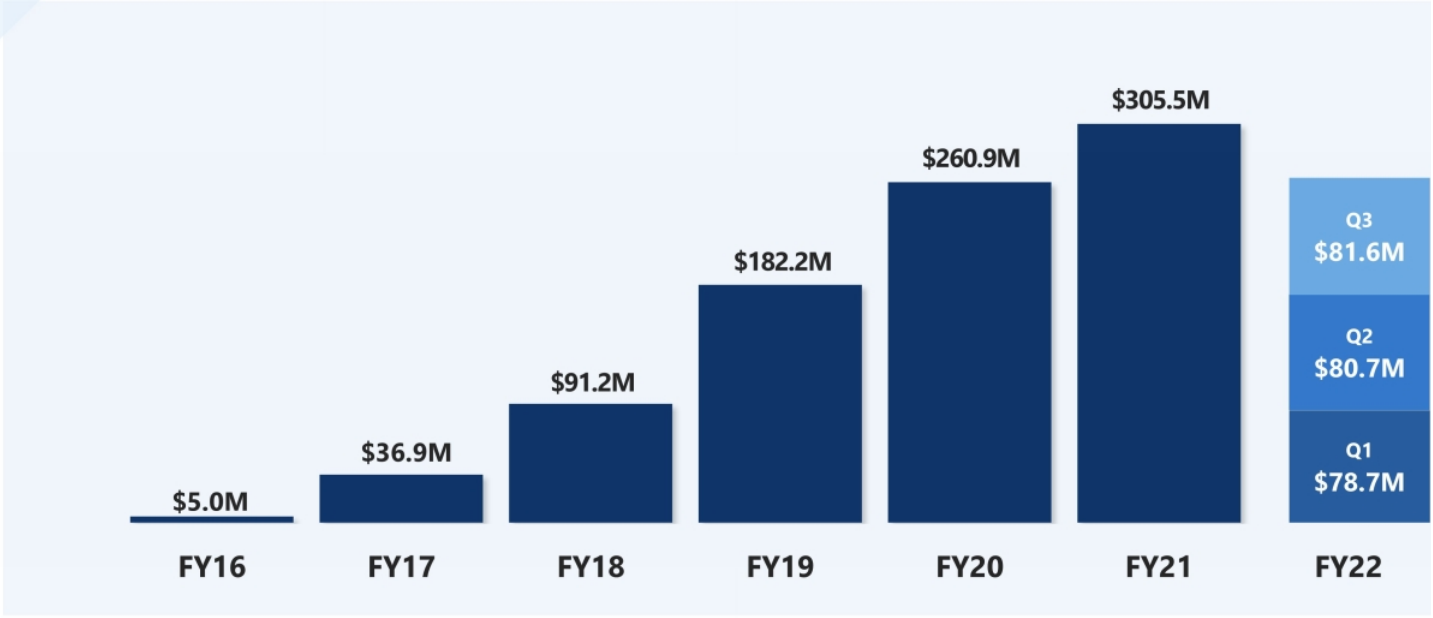
YTD Reported Revenue Growth of +7.9% to $241.0M – Strong Operational Growth of +1



- Global demand remains strong: 3-mont patients trend best in 2 years
- Call volume increasing from same perio
- Global mix of switch (~55%) and previo patients (~45%)
- Compliance and adherence over 90%+
- Expect non-linear quarterly growth to c uneven ordering patterns and FX fluctu

Galafold Success and FY22 Revenue Guidance

Galafold Momentum on Track to Achieve Full-year 2022 Revenue Guidance at



Reiterating FY22 Revenue Growth Guidance of 15% and 20% growth at CER

[1]2022 Galafold revenue guidance utilizes the average actual rates for 2021

Galafold Growth Opportunity

$1B Annual Sales Opportunity at Peak

Sustained double-digit revenue growth:

3Q operational revenue growth of +13.4%

Near-term growth to $500M driven by:

Continued penetration into existing markets

Expansion into new geographies

Broadening of labels

Long-term growth towards peak sales potential driven by:

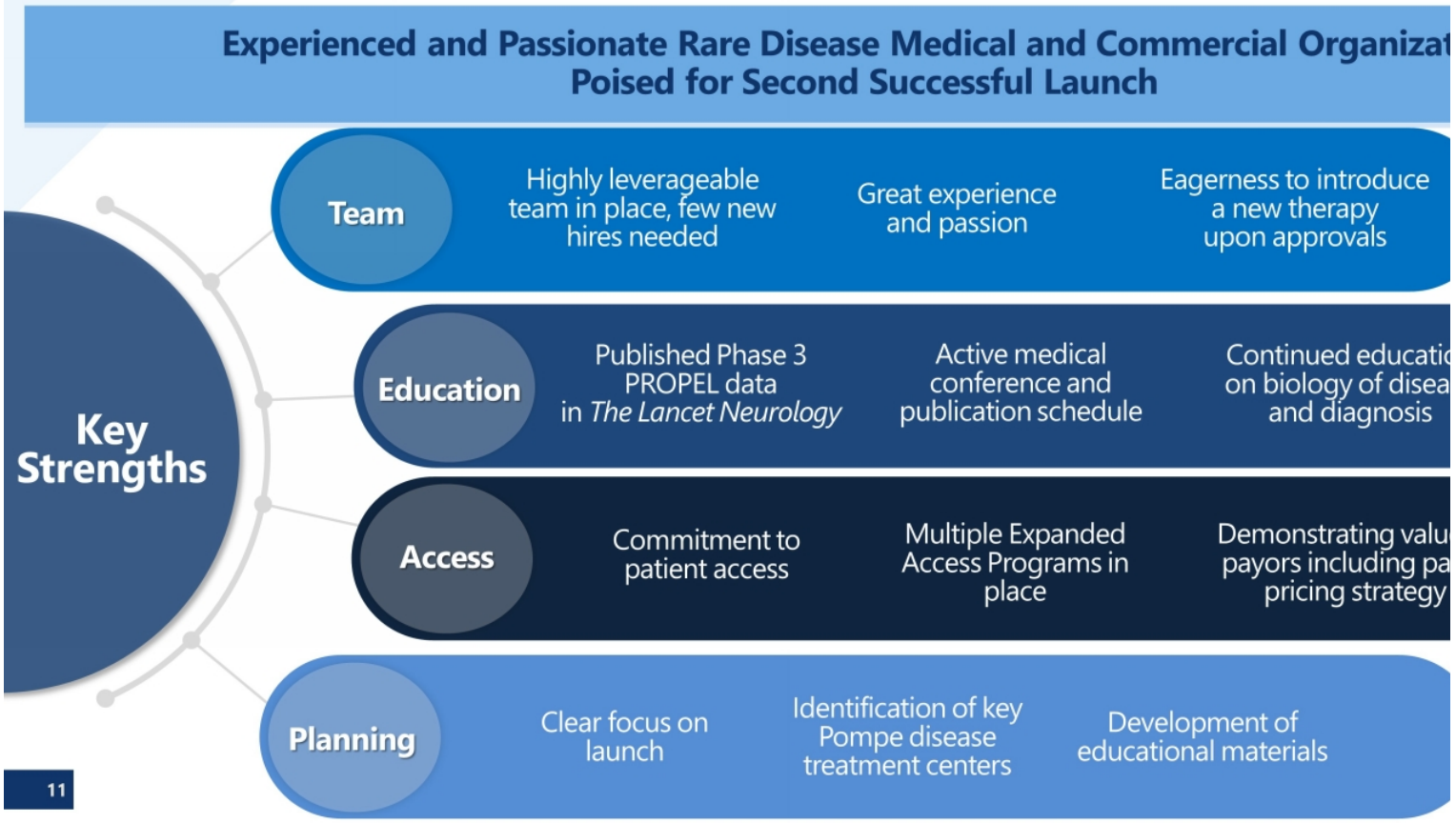
Penetration of the diagnosed untreated population

Increase in newborn screening and diagnostic initiatives

Strong IP rights, including COM protection through 2038

COM: Composition of Matter

AT-GAA Launch Preparations



Amicus Therapeutics®

AT-GAA
(cipaglucosidase alfa + miglustat)

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

Pompe Disease Overview

Pompe is a Severe and Fatal Neuromuscular Disease Caused by the Deficiency of Lysosomal

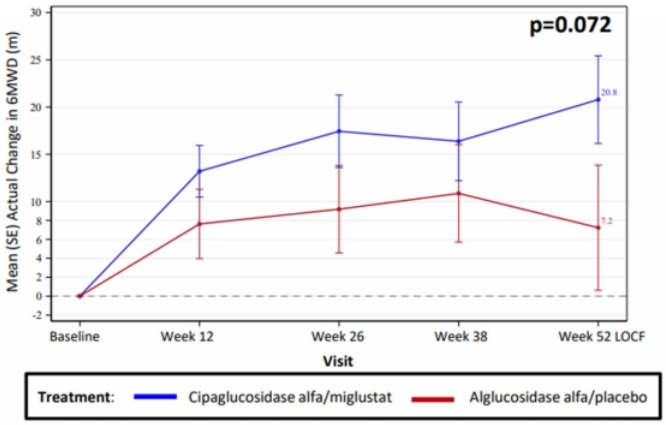
- Estimated incidence of ~1:28,000; newborn screening suggests significant underdiagnosis
- Age of onset ranges from infancy to adulthood
- Majority of patients on current standard of care decline after ~2 years
- Respirato failure are le morbidity
- Deficiency of GAA leading to lysosomal glycogen accumulation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

1. Based on 12 months ended December 31, 2021. Source: Sanofi Press Release

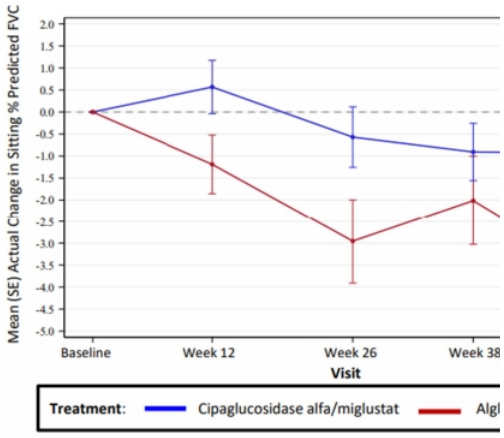
Phase 3 PROPEL Study Results
Overall Population (n=122*)

Primary and First Key Secondary Endpoint Showed Greater Improvement with AT alglucosidase alfa in the Overall Population of ERT-Naïve and ERT-Experienced P

6MWD (m): Change from baseline (n=85, n=37)



FVC (% predicted): Change from (n=85, n=37)



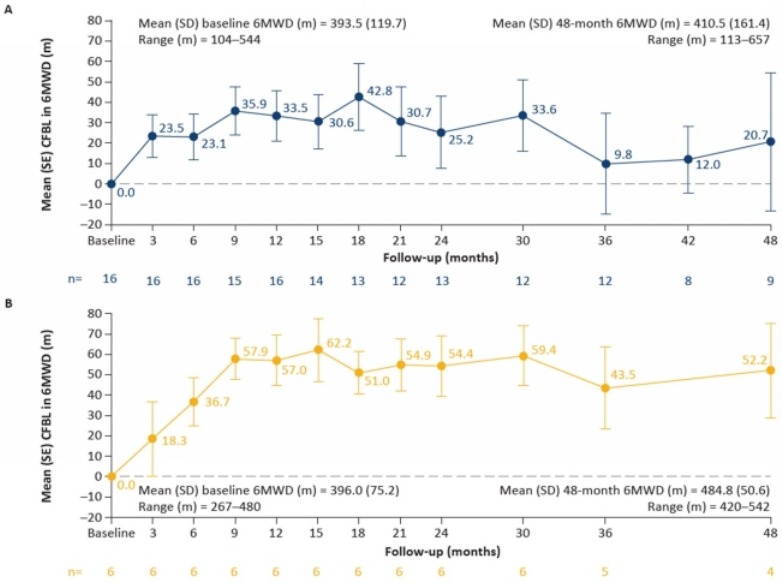
Results in ERT-Experienced Patients (n=92) Showed Meaningful Improvement for Both 6MWD (P=0.046) and FVC

6MWD=6-minute walk distance;; FVC=forced vital capacity; SE=standard error. P values are nominal 2-sided; FVC data normally distributed and P value is from ANCOVA. 6MWD data not normally distributed and P value is for nonparametric ANCOV
*Results exclude one outlier subject

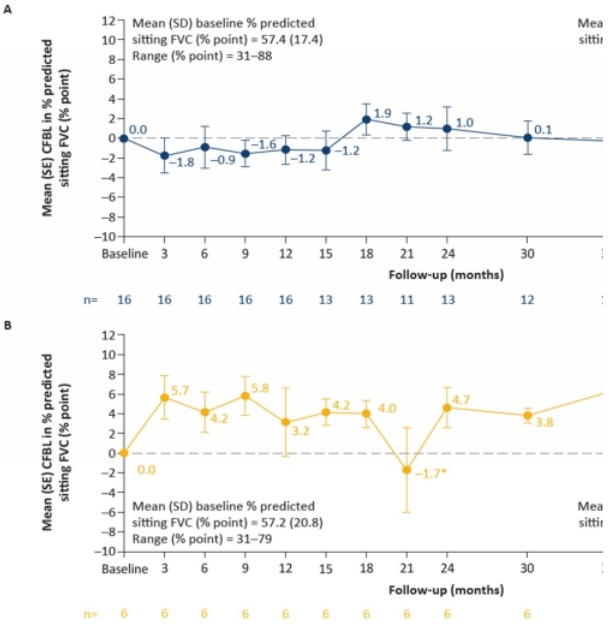
Long-Term Data from Phase 1/2 Clinical Study (ATB200-02)

Persistent and Durable Improvements in Motor and Respiratory Function and Redu
Biomarkers of Muscle Damage and Disease Substrate Observed in Patients out to 4

CFBL in 6MWD in (A) ERT-Experienced and (B) ERT-Naïve Patients



CFBL in FVC in (A) ERT-Experienced ERT-Naïve Patients

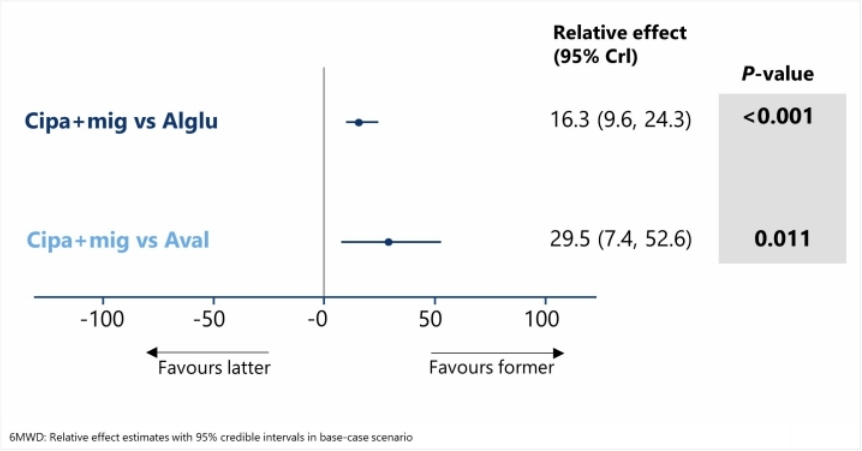


NOTE: * One patient in the ERT-naïve cohort experienced a large drop in % predicted FVC at month 21, which returned to previous levels at the

AT-GAA: Ongoing Evidence Generation

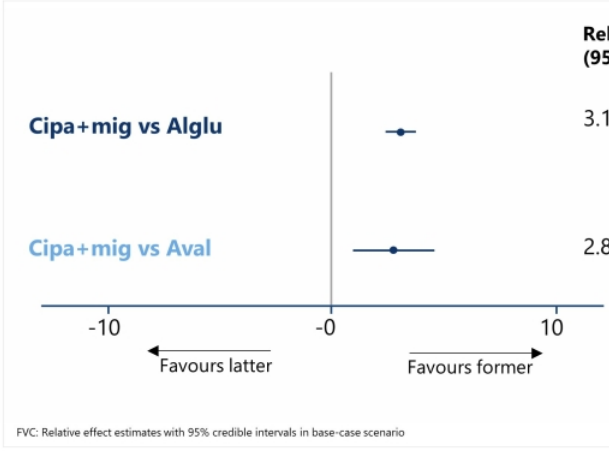
Indirect Treatment Comparison across Pompe ERT Studies Recently Presente at World Muscle Society 2022 Congress Highlights Potential Clinical Differentiation

Relative effect (6MWD change from baseline at week 52)



6MWD: Relative effect estimates with 95% credible intervals in base-case scenario

Relative effect (FVC change from ba week 52)



FVC: Relative effect estimates with 95% credible intervals in base-case scenario

Any comparisons are based on published data. No clinical, safety, or efficacy conclusions may be drawn from this data.

AT-GAA: Key Takeaways

Focused on Advancing AT-GAA to as Many Patients as Possible through Global Regulatory Pathways and Expanded Access Mechanisms

- U.S. Regulatory status update:
  - PDUFA action date deferred due to Agency's inability to conduct manufacturing inspection in China[1]
  - At the Agency's direction, the Company has requested a Type A meeting to develop plans and logistics for a pre-approval inspection
- International Regulatory status update:
  - CHMP opinion expected as early as December 2022
  - On track for additional regulatory submissions
- Multiple expanded access mechanisms in place, including in the U.S., U.K., Germany, France, Japan, and others
- ~190 people living with Pompe disease are now on AT-GAA across our clinical extension studies and expanded access programs
- Ongoing supportive studies:
  - LOPD in children and adolescents aged 0 to <18; Infantile-Onset Pompe Disease (IOPD)

[1]FDA has not provided anticipated action dates as they continue to monitor the public health situation and travel restrictions in China; The Company expects the FDA to approve the NDA and BLA applications togeth

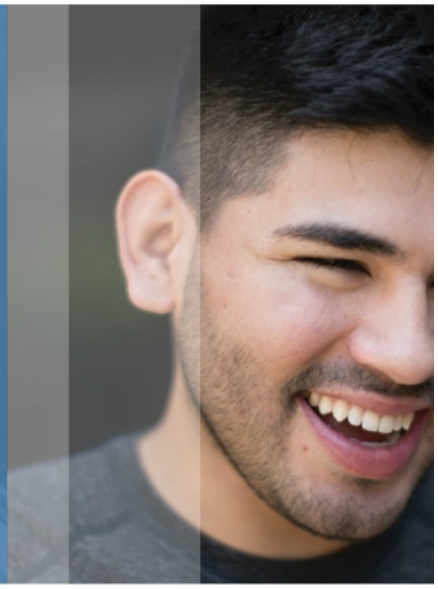
Amicus Pipeline

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

Amicus Therapeutics®

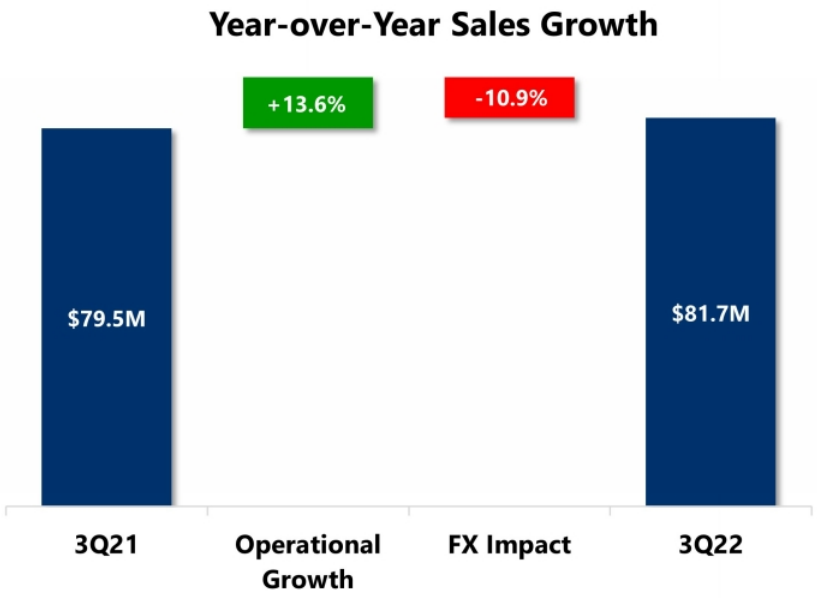
Financial & Operational Strategy

... maintaining a strong financial outlook



Q3 2022 Revenue Performance

Q3 2022 Reported Revenue Growth of +2.7% to $81.7M resulting from Stro
Operational Growth of +13.6% at CER Offset by Negative FX impact of -10.9



- Significant currency exposure a Galafold revenue generated ou
- Applying average October 202 rates, the negative FX impact o 2022 reported sales would be a -9%, or ~$28.5 million.

Q3 2022 Select Financial Results

Q3 2022 OpEx Decrease Related to the Reprioritization of the Gene Therapy Po

(in thousands, except per share data)	Sep. 30, 2022	Sep. 30, 202
Product Revenue	$81,691	$79,545
Cost of Goods Sold	13,436	11,696
R&D Expense	52,970	59,333
SG&A Expense	47,272	46,107
Changes in Fair Value of Contingent Consideration	567	3,288
Depreciation and Amortization	1,286	1,520
Loss from Operations	(33,840)	(42,399)
Income Tax (Expense) Benefit	(4,023)	182
Net Loss	(33,286)	(50,294)
Net Loss Per Share	(0.12)	(0.19)

Financial Outlook and Path to Profitability

Clear Strategy to Build Our Business, Advance Our Portfolio, and Achieve Profit

Sustain Galafold Revenue Growth

$241M YTD revenue, +16.2% YoY Operational Growth

2022 Galafold revenue growth guidance of **+15-20%** YoY ***at CER***

Secure Approvals of AT-GAA

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

Deliver Financial

Focused on expense man

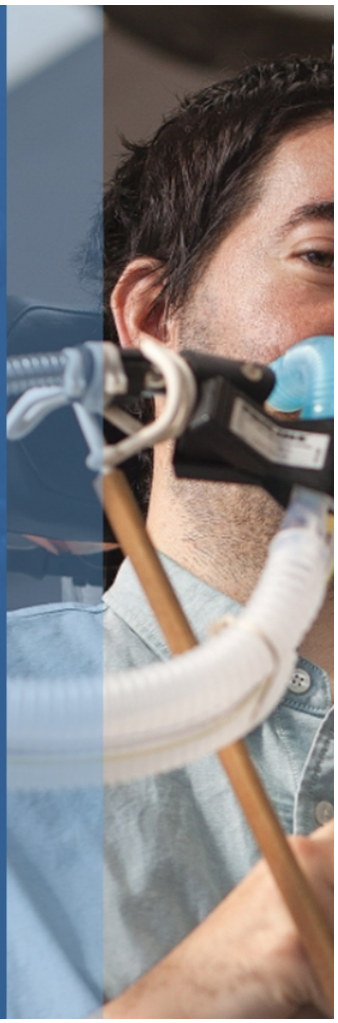
2022 non-GAA expense gui **$430M-$**

Achieve pro in 202

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

Amicus Therapeutics®

Appendix



Appendix

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Total operating expenses - as reported GAAP	**$ 102,095**	**$ 110,248**	**$ 381,714**	**$ 331,033**
Research and development:				
Share-based compensation	5,428	3,775	19,172	13,232
Selling, general and administrative:				
Share-based compensation	9,344	8,066	38,714	30,699
Loss on impairment of assets	—	—	6,616	—
Changes in fair value of contingent consideration payable	567	3,288	(506)	4,780
Depreciation and amortization	1,286	1,520	4,031	4,691
Total operating expense adjustments to reported GAAP	16,625	16,649	68,027	53,402
Total operating expenses - as adjusted	$ 85,470	$ 93,599	$ 313,687	$ 277,631