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 16, 2022

AMICUS THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-33497 (Commission File Number) 71-0869350 (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)
- $\begin{tabular}{ll} \hline \begin{tabular}{ll} \hline \end{tabular} & \begin{tabular}{$
- $\ \square$ 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 $\S 230.405$) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR $\S 240.12b-2$). Emerging growth company \square

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. \Box

Item 7.01 – Regulation FD Disclosure.

On November 16, 2022, Amicus Therapeutics, Inc. (the "Company") released an updated corporate overview presentation that it plans to use in meetings with investors and analysts. A copy of this presentation is attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information in this Item 7.01, including Exhibit 99.1, is 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 Exhibit 99.1, 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
<u>99.1</u>	November 2022 Corporate Overview Presentation
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 16, 2022 By: Name: Title:

/s/ Ellen S. Rosenberg
Ellen S. Rosenberg
Chief Legal Officer and Corporate Secretary



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 trials, the prospects and timing of the potential regulatory approval 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, expenses, cash position, and future profitability 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 in particular the potential mand uncertainties. For example, with respect to statements regarding the goals, progress, timing, and results of preclinical studies and clinical trials, including as they are impacted by COVID-19 related disruption, are based on current information. The potential impact on operations from the COVID-19 pandemic is inherently unknown and cannot be predicted with confidence and may cause actual results and performance to differ materially from the statements in this release, including without limitation, because of the impact on general political and economic conditions, including as a result of efforts by governmental authorities to mitigate COVID-19, such as travel bans, shelter in place orders and third-party business closures and resource allocations, manufacturing and supply chain disruptions and limitations to mitigate COVID-19 pandemic, actual results may differ materially from those set forth in this release due to the

Non-GAAP Financial Measures

In addition to financial information prepared in accordance with U.S. GAAP, this presentation also contains adjusted financial measures that we believe provide investors and management 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.



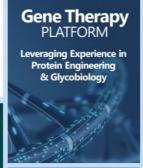
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A Rare Company

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







World-class
CLINICAL
DEVELOPMENT
Capabilities

Non-GAAP
PROFITABILITY
expected in
2H2023

EMPLOYEES in 20 Countries

GLOBAL COMMERCIAL ORGANIZATION



15% - 20% FY22 Galafold Revenue Growth at CER AT-GAA

Cumulative \$2B

Peak Potential

\$354.7M Cash as of 9/30/22



2022 Strategic Priorities to Drive Value

- 1 Double-digit Galafold growth (15-20%) with revenue of \$350M to \$365M at CER¹
- 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
- Maintain strong financial position on path to profitability



Amicus Pipeline

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



Positioned for Significant Value Growth

Focused on Execution and Driving Sustainable Double-digit Revenue Growth 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



Achieve non-GAAP profitability in 2H2023¹

ased on projections of Arrisos non-GAP Net income under current operating plans, which includes successful AT-GAR egulatory (synchronic Galafoid growth, Non-GAP) Net income defined as GAP Net income excluding the impact of share-based compensation expense. changes in income of control or control of the co





Galafold® (migalastat) Continued Growth

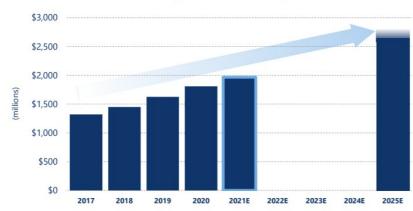
... building a leadership position in the treatment of Fabry disease



Global Fabry Market

Global Fabry Disease Market Growth Continues to be Driven by Diagnosing New Patients in Addition to the Introduction of Galafold

Global Fabry market to exceed \$1.9B in 2021 and tracking toward ~\$2.6B by 2025¹



- Fabry Disease is believed to be significantly underdiagnosed
 - Newborn screening studies suggest Fabry could be one of the more prevalent human genetic diseases (~1:1,000 to ~1:4,000 incidence)
- In 2021, Galafold was the fastest growing medicine for Fabry disease and the greatest contributor to Fabry market growth
 - Introduction of Galafold has led to market expansion with 800+ naive patients diagnosed and treated for the first time

Amic

¹Global market measured by reported sales of approved therapies for Fabry disease – 2025 sales projected using 8% CAGR

Galafold Success (as of September 30, 2022)

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

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



Galafold is indicated for adults with a confirmed diagnosis of Fabry Disease and an amenable variant. The most common adverse reactions reported with Galafold (2:10%) were headache, nasopharyngitis, urinary tract infection, nausea and pyrexia. For additional information about Galafold, including pote full U.S. Prescribing Information, please visit https://pubma.nicus.com/pic/Galafold.gdf (Por further important safety information for Galafold, including posts) 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.



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Galafold Performance

YTD Reported Revenue Growth of +7.9% to \$241.0M - Strong Operational Growth of +16.2% at CER



- Global demand remains strong: 3-month net new patients trend best in 2 years
- Call volume increasing from same period last year
- Global mix of switch (~55%) and previously untreated patients (~45%)
- Compliance and adherence over 90%+
- Expect non-linear quarterly growth to continue due to uneven ordering patterns and FX fluctuations



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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



11 COM: Composition of Matter

Galafold Initiatives

Building the Body of the Evidence around Galafold

Broadening Labels: Adolescents and Additional Variants

Publications and Medical Presentations Over 500
Patients
Enrolled in a
Global Registry

Ongoing and Planned Phase IV Studies

Strengthening our IP Portfolio

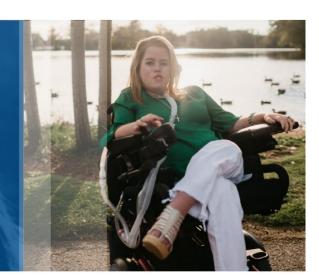


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AT-GAA (cipaglucosidase alfa + miglustat)

... 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 Enzyme GAA



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

Respiratory and cardiac failure are leading causes of morbidity and mortality

Deficiency of GAA leading to lysosomal glycogen accumulation and cellular dysfunction

Symptoms include muscle weakness, respiratory failure, and cardiomyopathy

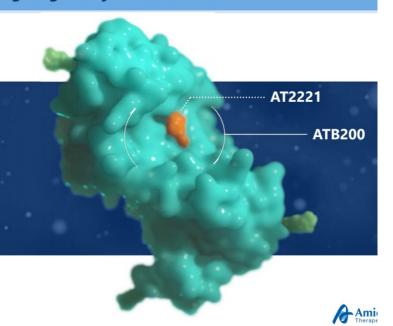
~\$1.2B+ global Pompe ERT sales¹

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AT-GAA: An Innovative Approach to Pompe Disease

Our Scientists Created a Uniquely Glycosylated and Highly Phosphorylated ERT (ATB200) that Significantly Enhances Targeting to Key Affected Muscles

- AT-GAA is a two-component therapy combining ATB200, an ERT, with AT2221, an orally administered enzyme stabilizer
- Consists of a naturally occurring cell line that can be properly processed within the lysosome to its mature form which is required to optimally break down glycogen¹



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

Phase 3 PROPEL Study Results
Primary, Key Secondary and Biomarker Endpoint Heat Map

Endpoints Across Motor Function, Pulmonary Function, Muscle Strength, PROs, and Biomarkers Favored AT-GAA over alglucosidase alfa

		Overall population			ERT-experienced				
	Endpoints	Cipaglucosidase alfa/miglustat n=85		Alglucosidase alfa/placebo n=37		Cipaglucosidase alfa/miglustat n=65		Alglucosidase alfa/placebo n=30	
		Baseline, mean	CFBL at week 52, mean (SE)	Baseline, mean	CFBL at week 52, mean (SE)	Baseline, mean	CFBL at week 52, mean (SE)	Baseline, mean	CFBL at week 52, mean (SE)
Motor function	6MWD, m	357.9	20.8 (4.6)	351.0	7.2 (6.6)	346.9	16.9 (5.0)	334.6	0.0 (7.2)
	GSGC total score	14.5	-0.5 (0.3)	14.5	0.8 (0.3)	15.6	-0.5 (0.3)	15.5	0.6 (0.4)
	10-meter walk, s	9.7	-0.5 (0.6)	9.6	1.9 (1.0)	10.4	-0.6 (0.9)	10.2	2.5 (1.2)
	4-stair climb, s	14.1	-8.5 (7.9)	8.2	0.3 (1.0)	17.3	-11.1 (10.5)	9.3	0.6 (1.2)
	Gower's maneuver, s	10.8	-0.3 (0.7)	19.8	-2.2 (1.4)	11.5	-0.4 (0.8)	23.9	-2.6 (1.9)
	Rising from chair, s	13.6	-10.2 (9.7)	4.5	-0.5 (0.7)	17.6	-13.7 (13.0)	5.2	-0.4 (0.9)
Pulmonary function	FVC, % predicted	70.7	-0.9 (0.7)	69.7	-4.0 (0.8)	67.9	0.1 (0.7)	67.5	-4.0 (0.9)
	MIP, % predicted	61.8	2.1 (2.1)	59.9	-2.7 (2.8)	61.3	1.0 (2.5)	55.0	-1.7 (1.5)
	MEP, % predicted	70.7	0.6 (2.4)	65.1	-1.6 (2.1)	70.7	-2.7 (2.7)	62.2	-3.9 (1.8)
Muscle strength	Lower MMT score	28.0	1.6 (0.4)	27.7	0.9 (0.4)	26.4	1.6 (0.5)	26.1	0.9 (0.5)
	Upper MMT score	34.3	1.5 (0.4)	34.7	0.7 (0.6)	33.7	1.8 (0.4)	34.2	0.4 (0.7)
	Total MMT score	62.3	3.1 (0.7)	62.4	1.4 (0.8)	60.1	3.4 (0.9)	60.3	1.1 (0.9)
PROs	PROMIS®-Physical Function	66.9	1.9 (0.8)	68.0	0.2 (1.8)	64.4	1.8 (0.9)	66.9	-1.0 (2.0)
	PROMIS*-Fatigue	22.3	-2.0 (0.6)	21.1	-1.7 (1.1)	22.0	-1.9 (0.7)	20.4	-0.3 (1.0)
Biomarkers	Urine Hex4, mmol/mol	4.6	-1.9 (0.3)	6.9	1.2 (0.7)	4.6	-1.7 (0.3)	7.2	1.9 (0.8)
	Serum CK, U/L	447.0	-130.5 (25.1)	527.8	60.2 (26.2)	441.8	-118.0 (28.4)	492.3	79.6 (26.9)

Based on LOCF means

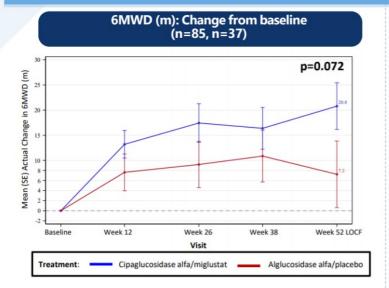
Treatment group favored Nominal statistical significance (P<0.05)

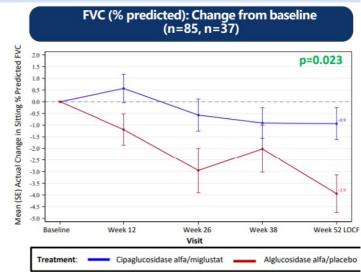


Phase 3 PROPEL Study Results

Overall Population (n=122*)

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



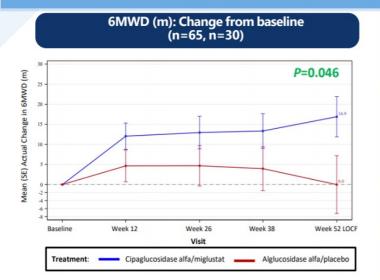


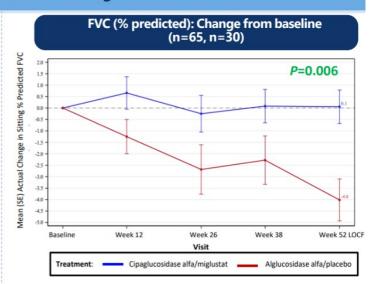
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6MWD=6-minute walk distance; FVC=forced vital capacity; SE=standard error. P values are nominal 2-sided; FVC data normally distributed and P value is from ANCOVA. 6MWD data not normally distributed and P value is for nonparametric ANCOVA; *Results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

Phase 3 PROPEL Topline Results: ERT Experienced Population (n=95)

ERT Experienced Patients Treated with AT-GAA Demonstrated Improvements over Time in 6MWD and Stabilization over Time in FVC Versus alglucosidase alfa





NOTE: Baseline is Mean (STDEV); CFBL is Mean (SE); P-values are nominal 2-sided; FVC data normally distributed and p-values are from ANCOVA 6MWD data not normally distributed and 6MWD p-value is for non-parametric ANCOVA; 6MWD parametric MMRM p-value was p=0.078



Phase 3 PROPEL Study Publication

Clinically Meaningful Outcomes from Phase 3 PROPEL Study Provide the Basis for Global Regulatory Submissions of AT-GAA

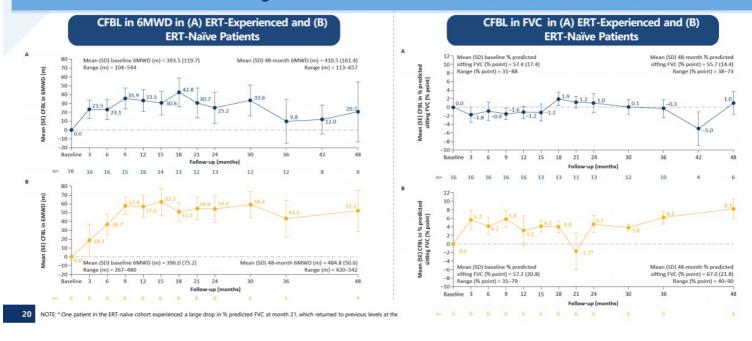


- Peer-reviewed results from PROPEL suggest that treatment with AT-GAA provided clinically meaningful improvements over standard of care, including ERT-experienced patients with high unmet need
- The authors deemed AT-GAA to provide a differentiated mechanism of action and potential alternative treatment option for people living with late-onset Pompe Disease



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

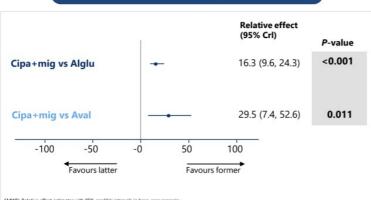
Persistent and Durable Improvements in Motor and Respiratory Function and Reductions in Biomarkers of Muscle Damage and Disease Substrate Observed in Patients out to 48 Months



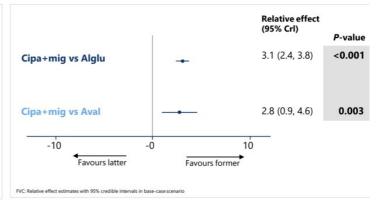
AT-GAA: Ongoing Evidence Generation

Indirect Treatment Comparison across Pompe ERT Studies Recently Presented at World Muscle Society 2022 Congress to Support Reimbursement Discussions for AT-GAA

Relative Effect (6MWD Change from Baseline at Week 52)



Relative Effect (FVC Change from Baseline at Week 52)



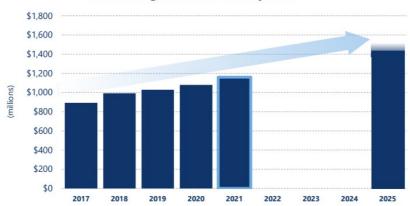
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21 Any comparisons are based on published data. No clinical, safety, or efficacy conclusions may be drawn from this data.

Global Pompe Market

Global Pompe Disease Market Growth Continues to be Driven by the Diagnosis of New Patients - Only One Approved Therapy on the Market up until 2021

Global Pompe Market to exceed \$1.1B in 2021 and tracking toward \$1.5B+ by 2025¹



- Pompe Disease believed to be significantly underdiagnosed
 - Newborn screening studies suggests
 Pompe to be more prevalent than medical literature suggest (~1:10,000 to ~1:30,000)
 - Newborn screening already occurring in 27 U.S. states with 9 additional U.S. states pursuing NBS implementation for Pompe disease

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¹Global market measured by reported sales of approved therapies for Pompe disease – 2025 sales projected using 8% CAGR

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 China¹
 - At the Agency's direction, the Company has scheduled a Type A meeting to develop plans and logistics for a pre-approval inspection
- European Regulatory status update:
 - Expect de-coupled CHMP opinions for cipaglucosidase alfa and miglustat respectively
 - · Cipaglucosidase alfa: CHMP opinion expected as early as December 2022
 - Miglustat: CHMP opinion expected 2Q 2023 based on 4-month clock stop in order to complete requested confirmatory analytical testing
- 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 in children and adolescents² with LOPD as well as in Infantile-Onset Pompe Disease (IOPD)

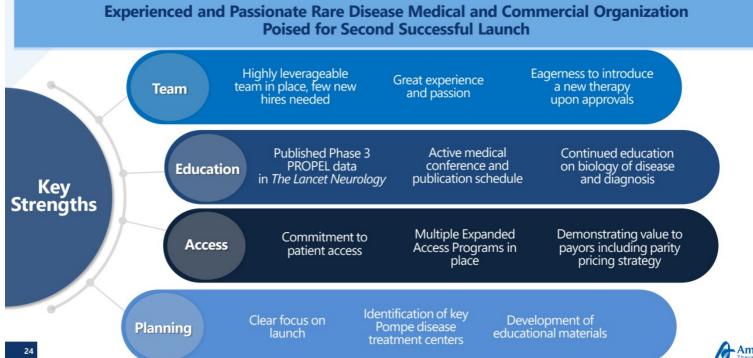




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¹ FDA has not provided anticipated action dates as they continue to monitor the public health situation and travel restrictions in China; The Company expects the FDA to approve the NDA and BLA applications togeth ² Children and adolescents aged 0 to <18 years old

AT-GAA Launch Preparations







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 Strong Operational Growth of +13.6% at CER Offset by Negative FX impact of -10.9%

Year-over-Year Sales Growth



- Significant currency exposure as 63% of Galafold revenue generated outside the U.S.
- Applying average October 2022 exchange rates, the negative FX impact on full-year 2022 reported sales would be approximately -9%, or ~\$28.5 million.



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Financial Outlook and Path to Profitability

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



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 on Financial Goals

Focused on prudent expense management

2022 non-GAAP operating expense guidance of \$430M-\$440M

Achieve profitability¹ in 2H2023

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









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

Pledge for a Cure

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

Expanded Access through Nov 2022:

71 patients / 21 countries

Contributions allocated: **\$1,677,000** us

\$832,976 Intl.

Amicus supported community programs

20+

Volunteer hours (US): 770

Diversity, Equity & Inclusion (DEI)

Pledge to support a more inclusive culture to impact our employees, our communities, and

2023 and Beyond:

- Maintain strength in global gender diversity
- Increase US diversity through intentional and ongoing action
- Continuously evaluate compensation practices to ensure pay parity

Global Employees % female employees 496 58%

% Hiring Slate Diversity 82%

Board of Directors

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

Director Diversity

3 Female2 Veteran Status1 African American

80% Board Independence

60% Overall Board Diversity

Environmental Management

Eco-friendly decision-making has unearthed economic efficiencies while continuing to bolster our standing as a good Green buildir design

Energy & wat conservation

Hazardous wa managemer

Employee Recruitment, Engagement, and Retention

Leverage employee capabilities and expertise to ultimately attracts, energizes, and retains critical

Pulse surveys reveal employees feel high personal satisfaction in their job, are proud of their work and what they contribute to the community

Career Developme

Reimagined performance management proc to measure the what and the how, reward those who role-model our **Mission-Focus**



Appendix

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

	Three Month	Ended September 30,	Nine Months E	Nine Months Ended September 30,			
	2022	2021	2022	2021			
Total operating expenses - as reported GAAP	\$ 102,09	\$ 110,248	\$ 381,714	\$ 331,033			
Research and development:							
Share-based compensation	5,42	3,775	19,172	13,232			
Selling, general and administrative:							
Share-based compensation	9,34	4 8,066	38,714	30,699			
Loss on impairment of assets	_		6,616	_			
Changes in fair value of contingent	56	7 3,288	(506)	4,780			
consideration payable							
Depreciation and amortization	1,28	5 1,520	4,031	4,691			
Total operating expense adjustments to reported	16,62	16,649	68,027	53,402			
GAAP							
Total operating expenses - as adjusted	\$ 85,470	\$ 93,599	\$ 313,687	\$ 277,631			

