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): **September 14, 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 8.01 – Other Events

On September 14, 2022, Amicus Therapeutics, Inc. (the "Company") released presentation materials that it will be using in meetings with investors and analysts. A copy of the presentation materials is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits:

Exhibit No.	Description
99.1	September 14, 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.

Date: September 14, 2022

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

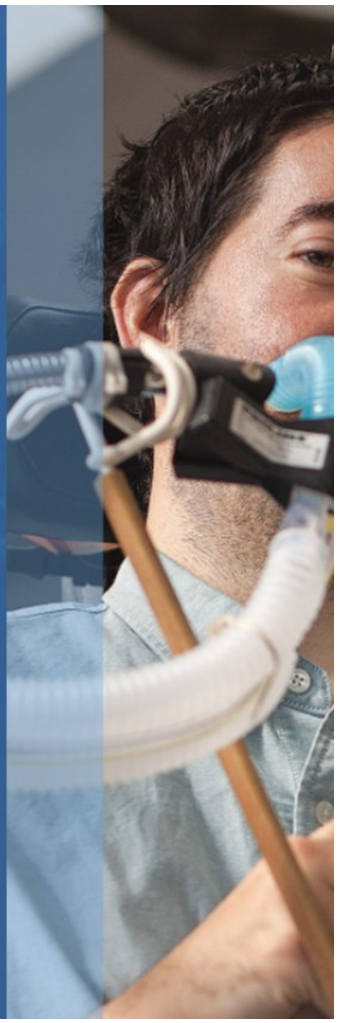
Exhibit 99.1

Amicus Therapeutics®

Corporate Overview

At the Forefront of Therapies for Rare Diseases

September 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 June 30, 2022. You are cautioned not to place undue reliance on these forward-looking statements, which sp 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 rele 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 t 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 27 Countries

GLOBAL COMMERCIAL ORGANIZATION

AT-GAA

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

$350M-$365M

FY22 Global Galafold Revenue at CER

GALAFOLD & AT-GAA

Cumulative $2B Peak Potential

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

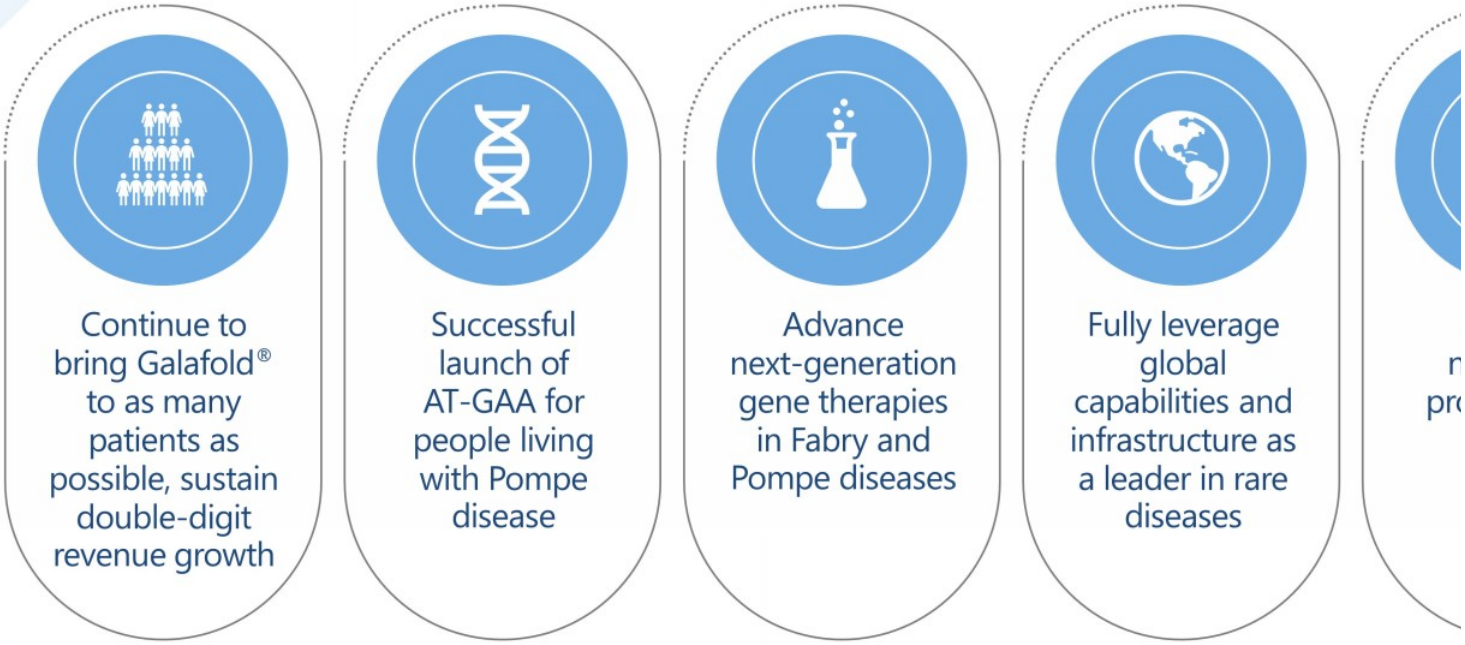
[1]CER: Constant Exchange Rates; 2022 Galafold revenue guidance is based on the average exchange rates for 2021

Amicus Pipeline

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

Positioned for Significant Value Growth

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

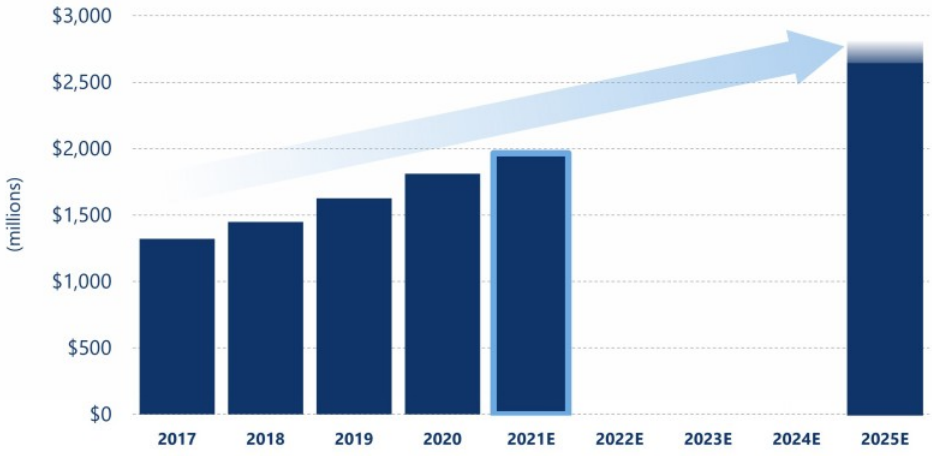


Amicus Therapeutics®

Global Fabry Market

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

Global Fabry market to exceed $1.9B in 2021 and tracking toward ~$2.6B by 2025[1]



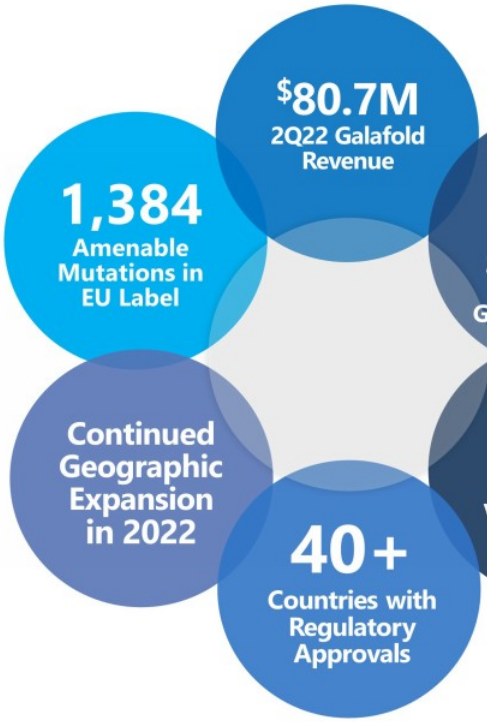
- Fabry Disease is believed to be underdiagnosed
  - Newborn screening studies sug could be one of the more preva genetic diseases (~1:1,000 to ~ incidence)
- In 2021, Galafold was the fastes medicine for Fabry disease and contributor to Fabry market gro
  - Introduction of Galafold has led expansion with 800+ naive pati and treated for the first time

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

Galafold Success (as of June 30, 2022)

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

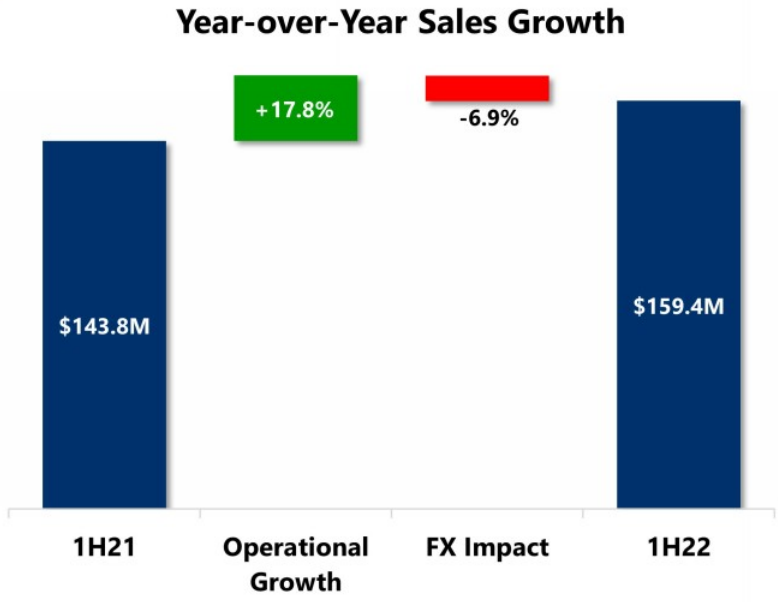
Galafold is the first and only approved oral treatment option with a unique mechanism of action for Fabry patients with amenable variants



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

1H22 Reported Revenue Growth of +10.9% to $159.4M - Operational Growth of +17



- Global 3-month net new patients trend
  6-month and 12-month
- In the U.S., the month of June saw highe
  patients and PRFs since April 2021
- Global mix of switch (~55%) and previou
  patients (~45%)
- Compliance and adherence over 90%+
- Expect non-linear quarterly growth to co
  uneven ordering patterns

Galafold Growth Opportunity

$1B Annual Sales Opportunity at Peak

Sustained double-digit revenue growth:

1H operational revenue growth of +17.8%

Near-term growth to $500M driven by:

Continued penetration into existing markets

Expansion into new geographies

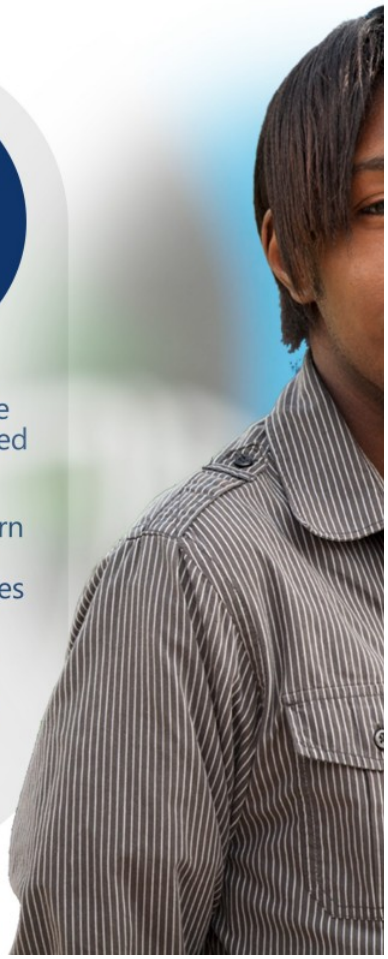
Broadening of labels

Long-term growth towards peak sales potential driven by:

Penetration of the diagnosed untreated population

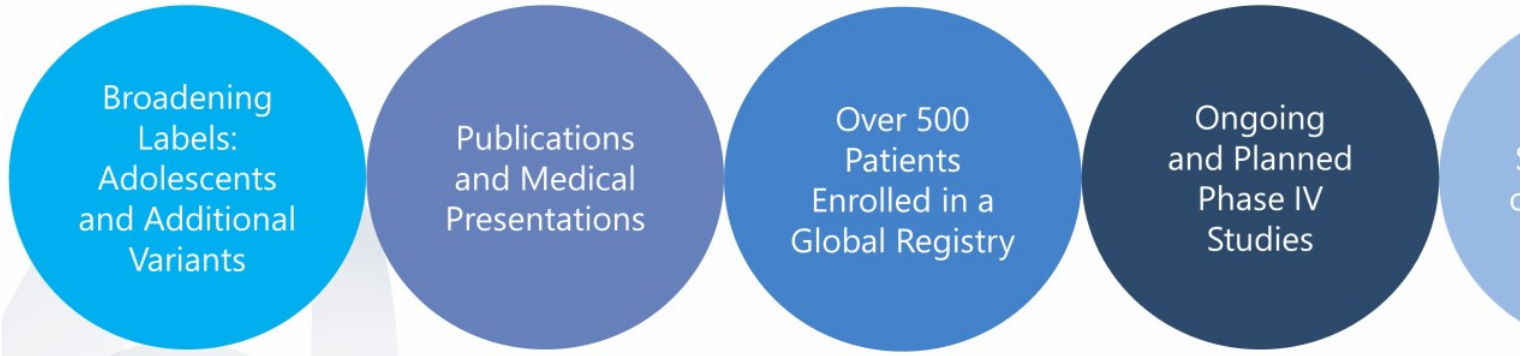
Increase in newborn screening and diagnostic initiatives

Strong IP rights, including COM protection through 2038



Galafold Initiatives

Building the Body of the Evidence around Galafold



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

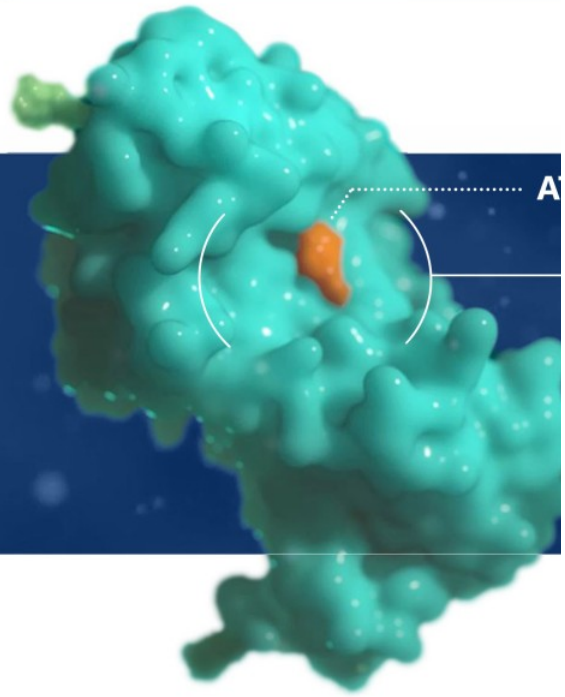
- Estimated incidence of ~1:28,000; newborn screening suggests significant underdiagnosis
- Age of onset ranges from infancy to adulthood
- Majority of patients on current standard of care decline after ~2 years
- Respirato failure are le morbidity
- Deficiency of GAA leading to lysosomal glycogen accumulation 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

AT-GAA: An Innovative Approach to Pompe Disease

Our Scientists Created a Uniquely Glycosylated and Highly Phosphorylated ERT (A 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 glycogen[1]



[1]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 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/p 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 v mean
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 (
	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 (
	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 (
	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 (
	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 (
	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 (
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 (
	MIP, % predicted	61.8	2.1 (2.1)	59.9	-2.7 (2.8)	61.3	1.0 (2.5)	55.0	-1.7 (
	MEP, % predicted	70.7	0.6 (2.4)	65.1	-1.6 (2.1)	70.7	-2.7 (2.7)	62.2	-3.9 (
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 (
	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 (
	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 (
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 (
	PROMIS®-Fatigue	22.3	-2.0 (0.6)	21.1	-1.7 (1.1)	22.0	-1.9 (0.7)	20.4	-0.3 (
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 (
	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 (

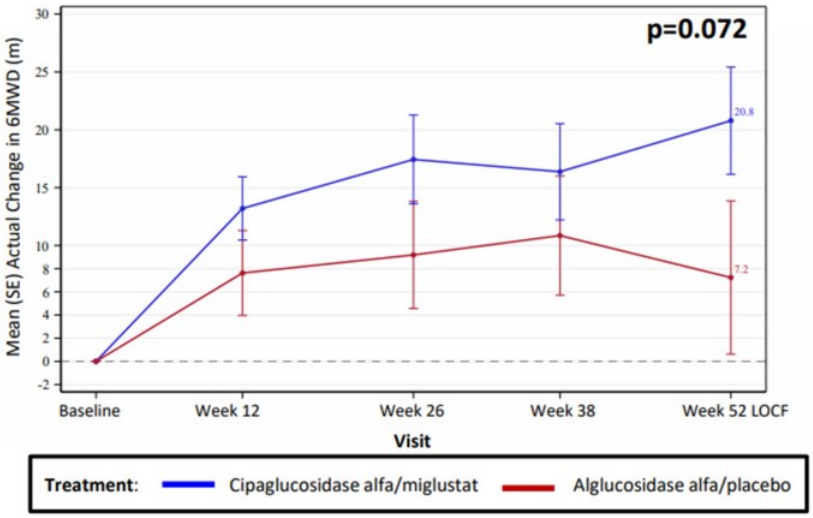
Based on LOCF means

Treatment group favored | Nominal statistical significance

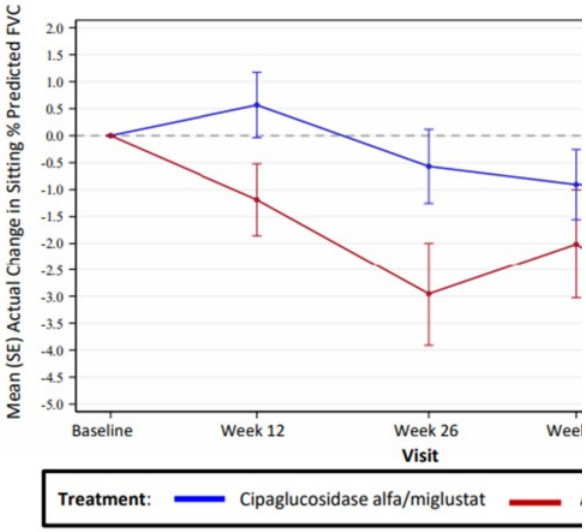
Phase 3 PROPEL Study Results
Overall Population (n=122*)

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

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



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

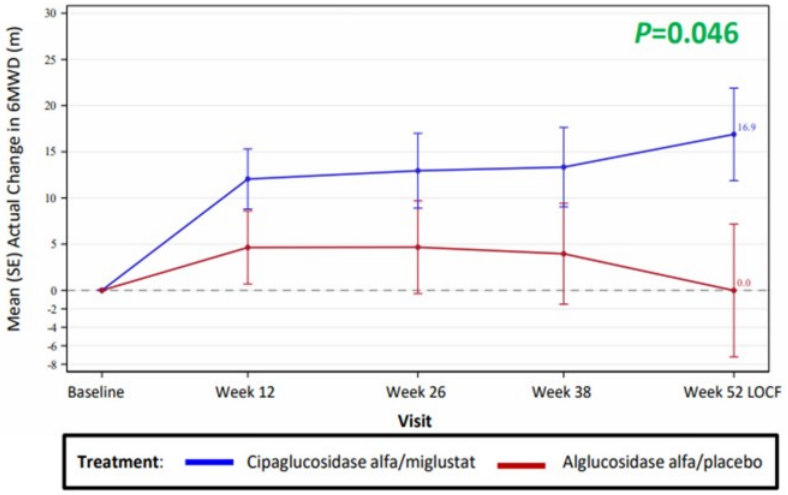


6MWD=6-minute walk distance;; FVC=forced vital capacity; SE=standard error. P values are nominal 2-sided; FVC data normally distributed and P value is from ANCOVA. 6MWD data not normally distributed and P value is for nonparametric ANCOVA;
*Results exclude one outlier subject

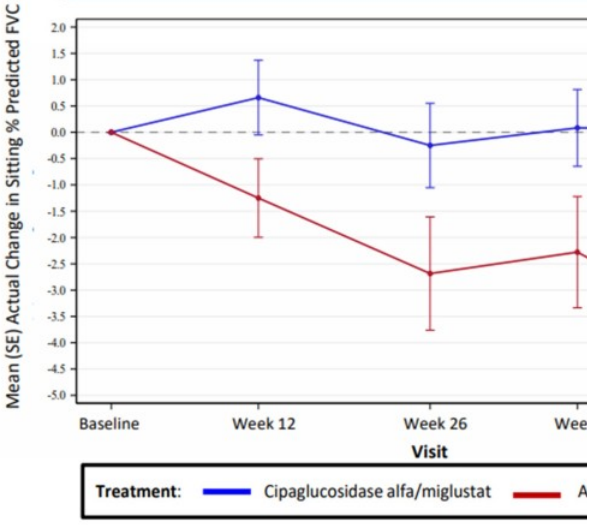
Phase 3 PROPEL Topline Results:
ERT Experienced Population (n=95)

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

6MWD (m): Change from baseline (n=65, n=30)



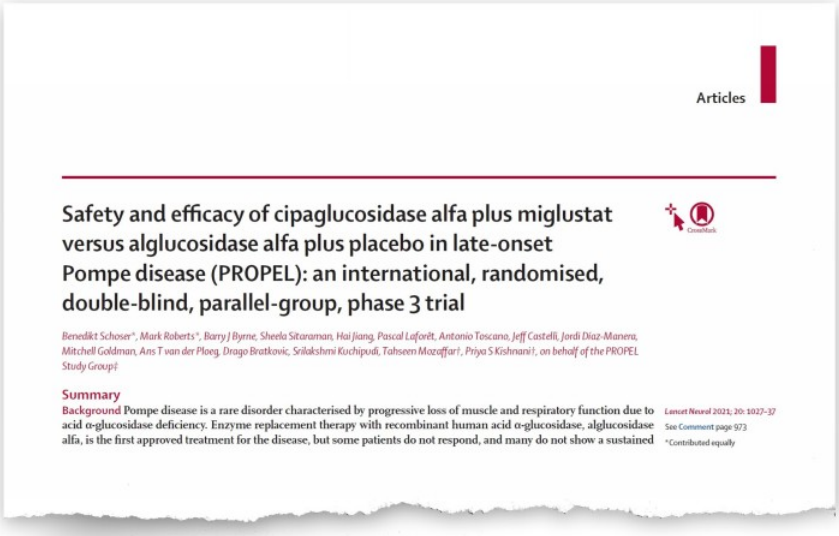
FVC (% predicted): Change from (n=65, n=30)



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 fo Regulatory Submissions of AT-GAA



Articles

Safety and efficacy of cipaglucosidase alfa plus miglustat versus alglucosidase alfa plus placebo in late-onset Pompe disease (PROPEL): an international, randomised, double-blind, parallel-group, phase 3 trial

Benedikt Schoser*, Mark Roberts*, Barry J Byrne, Sheela Sitaraman, Hai Jiang, Pascal Laforêt, Antonio Toscano, Jeff Castelli, Jordi Díaz-Manera, Mitchell Goldman, Ans T van der Ploeg, Drago Bratkovic, Srilakshmi Kuchipudi, Tahseen Mozaffar†, Priya S Kishnani†, on behalf of the PROPEL Study Group‡

Summary

Background Pompe disease is a rare disorder characterised by progressive loss of muscle and respiratory function due to acid α-glucosidase deficiency. Enzyme replacement therapy with recombinant human acid α-glucosidase, alglucosidase alfa, is the first approved treatment for the disease, but some patients do not respond, and many do not show a sustained

Lancet Neurol 2021; 20: 1027–37
See Comment page 973
*Contributed equally

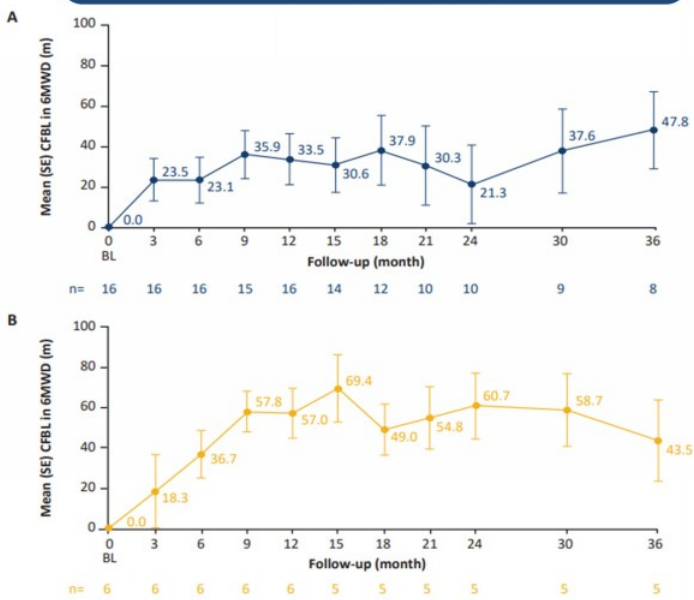
- Peer-reviewed results from PROPE that treatment with AT-GAA provi clinically meaningful improvemen standard of care, including ERT-ex patients with high unmet need
- The authors deemed AT-GAA to p differentiated mechanism of actio potential alternative treatment op people living with late-onset Pom

Schoser et al. 2021, The Lancet Neurology, Volume 20, Issue12, P1027-1037

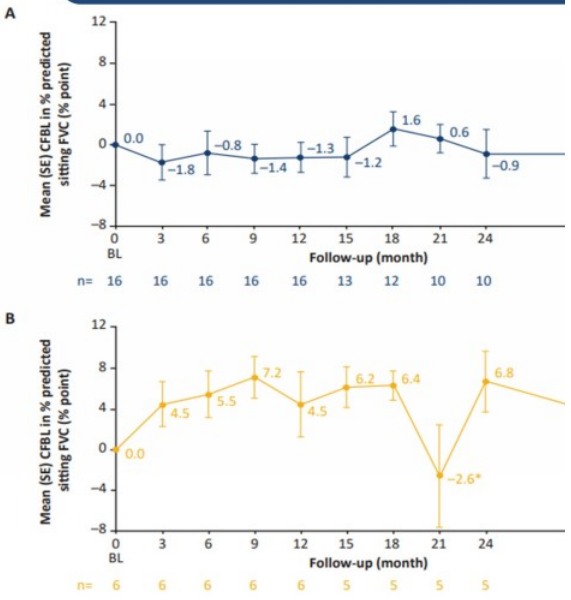
Long-Term Data from Phase 1/2 Clinical Study (ATB200-02)

Persistent and Durable Improvements in Motor and Respiratory Function and Redu
Biomarkers of Muscle Damage and Disease Substrate Observed in Patients out to 3

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



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

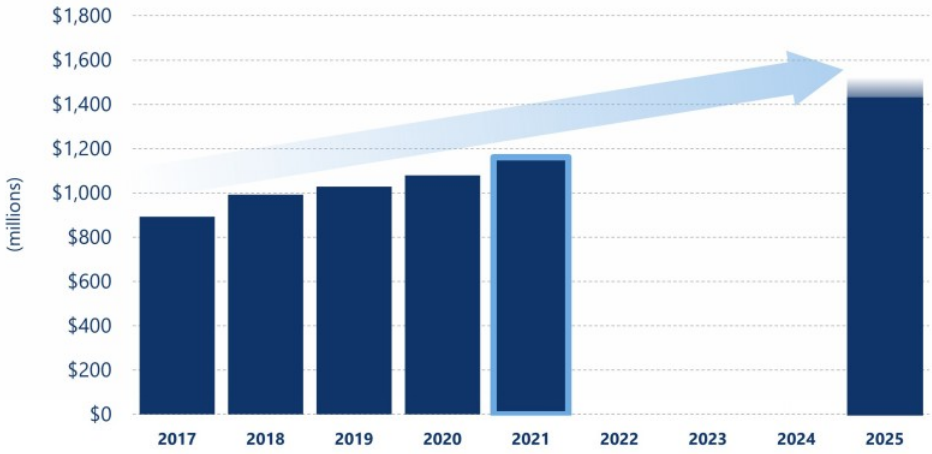


NOTE: * One patient in the ERT-naïve cohort experienced a large drop in % predicted FVC at month 21, which returned to previous levels at the following visit (month 24).

Global Pompe Market

Global Pompe Disease Market Growth Continues to be Driven by the Diagnosis of Ne
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 2025[1]



- Pompe Disease believed to be underdiagnosed
  - Newborn screening studies Pompe to be more prevalen literature suggest (~1:10,000
  - Newborn screening already 27 U.S. states with 9 additio pursuing NBS implementati disease

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

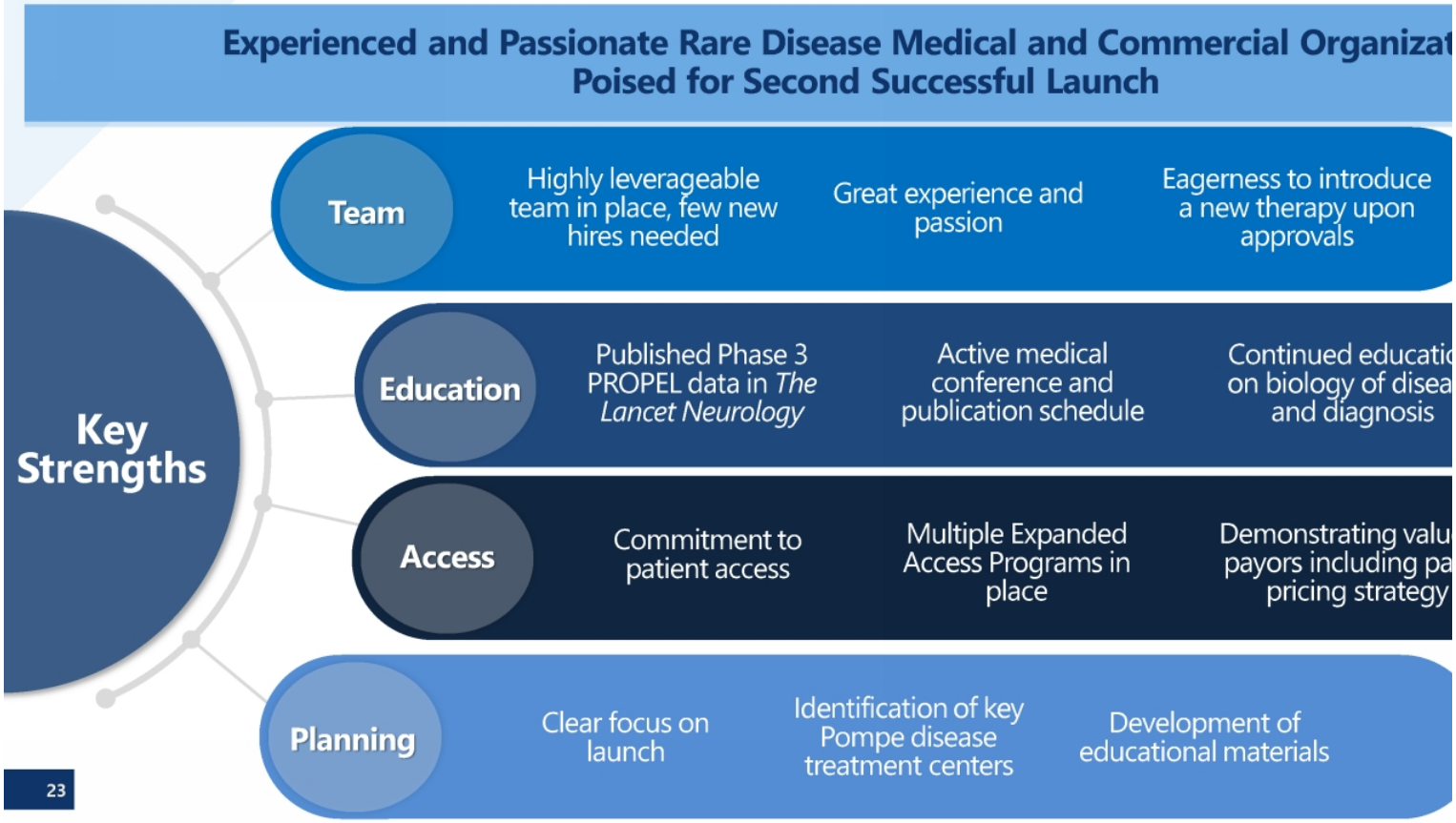
AT-GAA: Key Takeaways

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

- U.S. Regulatory status update:
  - U.S. PDUFA date 2H2022[1] subject to completion of a manufacturing inspection, which has not yet been scheduled
  - Negotiations substantially complete for draft label
- International Regulatory status update:
  - CHMP opinion expected 4Q2022
  - Planning for additional regulatory submissions
- Multiple expanded access mechanisms in place, including in the U.S., U.K., Germany, France, Japan, and others
  - First reimbursed access through the French compassionate access program
- 175+ 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 PDUFA date of October 29, 2022 for cipaglucosidase alfa BLA; The Company expects the FDA to approve the NDA and BLA applications together

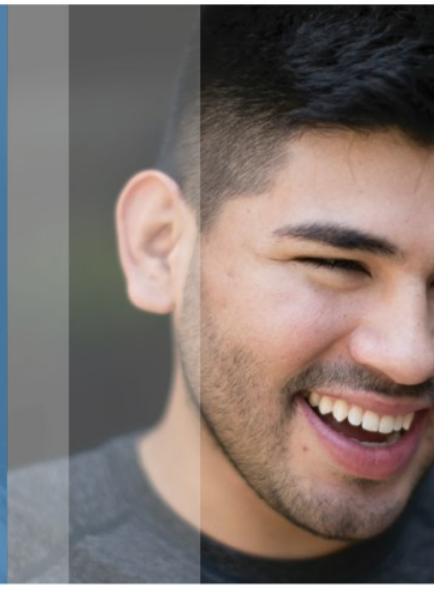
AT-GAA Launch Preparations



Amicus Therapeutics®

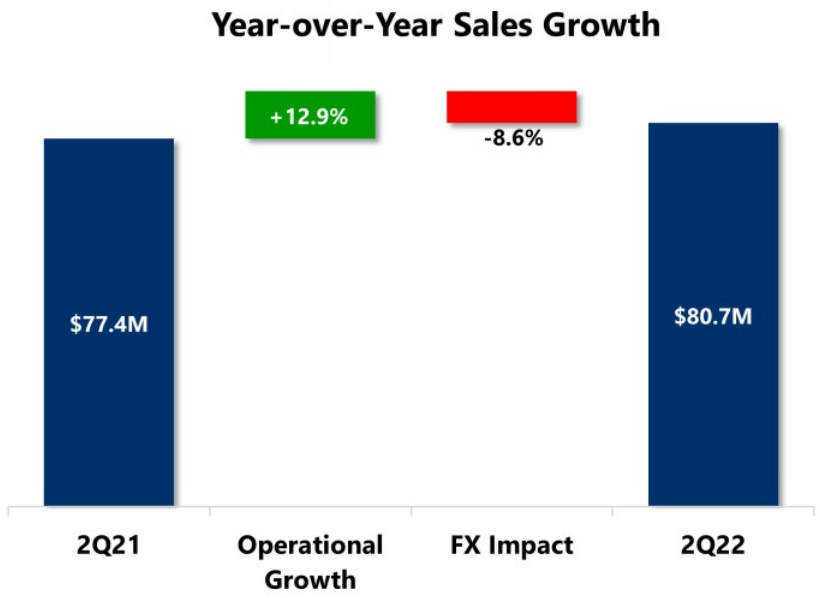
Financial & Operational Strategy

… maintaining a strong financial outlook



Revenue Performance

Q2 Revenue Growth of +4.3% to $80.7M resulting from Strong Operational Growth of +12.9% at CER Offset by Negative FX impact of



- Significant currency exposure a Galafold revenue generated ou
- Applying average July 2022 exc the negative FX impact on full-y Galafold® reported sales would approximately -9%, or ~$26 mi

Financial Outlook and Path to Profitability

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

Sustain Galafold Revenue Growth

$159.4M 1H2022 revenue, +17.8% YoY Operational Growth

2022 Galafold revenue guidance of **$350M-$365M at CER,** +15-20% YoY Growth

Secure Approvals of AT-GAA

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

Deliver Financial

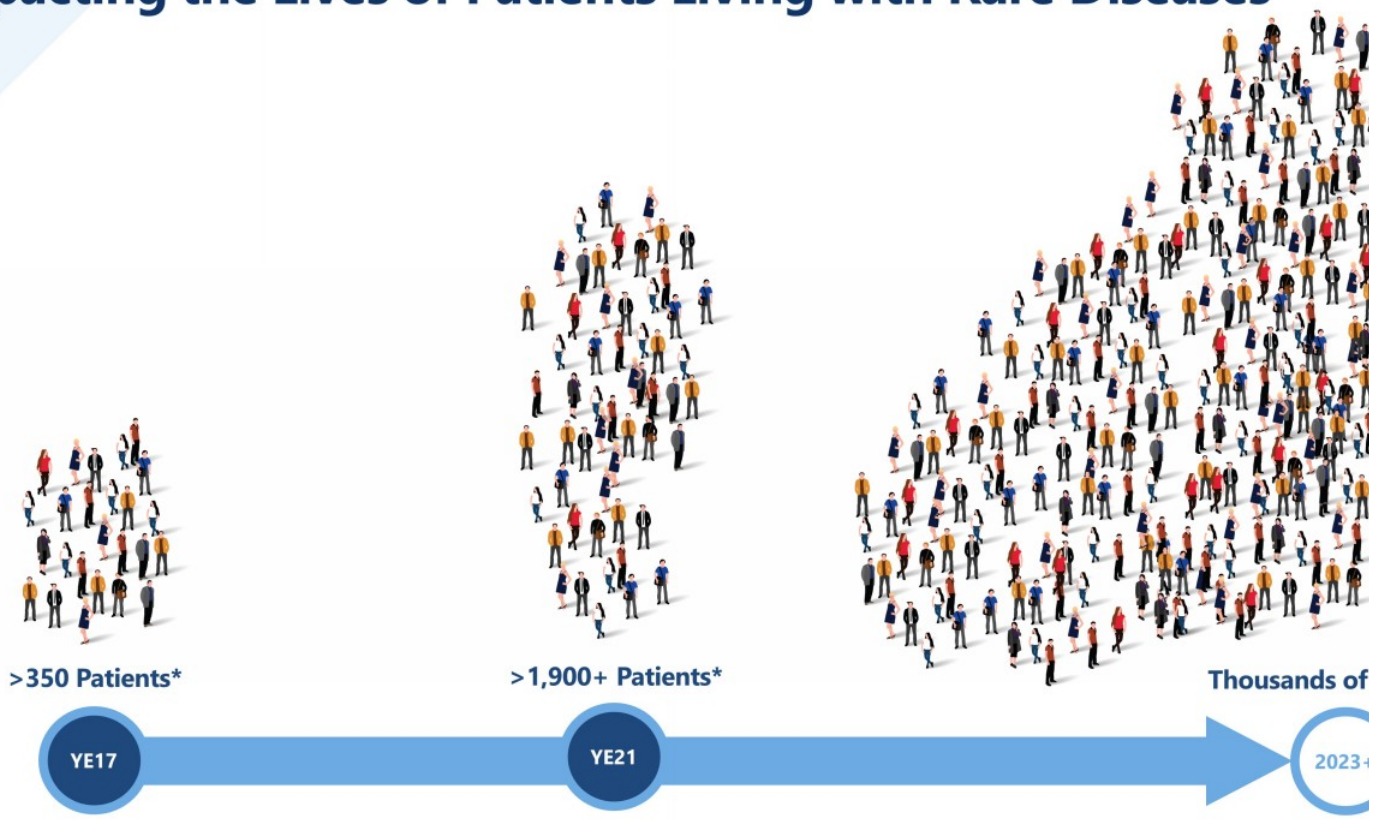
Focused on expense man

2022 non-GAA expense gui **$470M-$**

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.

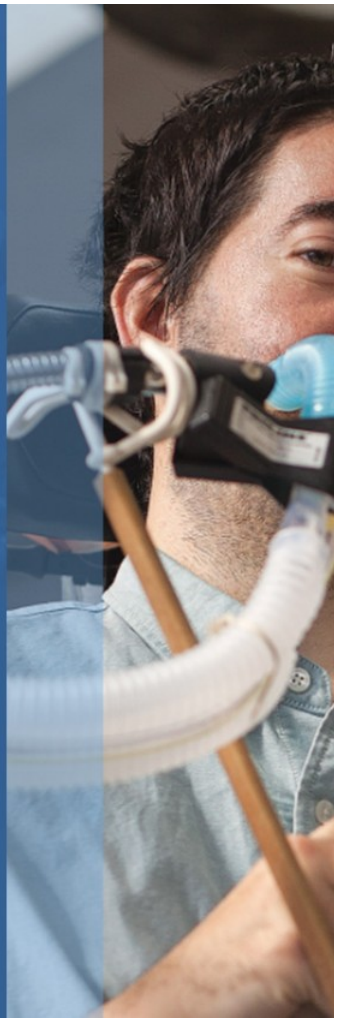
True Measure of Success: Impacting the Lives of Patients Living with Rare Diseases



*Clinical & commercial, all figures approximate

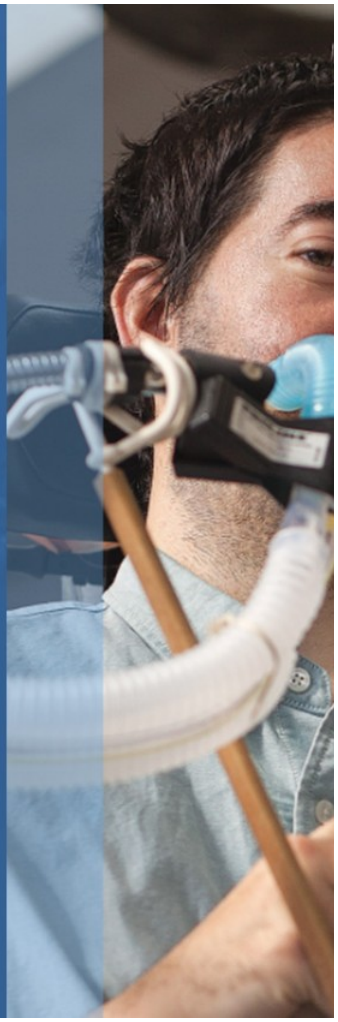
Amicus Therapeutics®

Thank You



Amicus Therapeutics®

Appendix



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

Expanded Access through 2021:
52 patients / **18** 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 society.

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
496

% female employees
58%

% Hiring Slate Diversity **82%**

Board of Directors

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

Director Diversity
3 Female
2 Veteran Status
1 African American

80% **Board Independence**

60% **Overall Board Diversity**

Environmental Management

Eco-friendly decision-mak has unearthed economic efficiencies while continuir bolster our standing as a g corporate citizen.

Employee Recru Engagement, ar

Leverage employee capab provide a culture that driv ultimately attracts, energiz talent

Pulse surveys reveal empl ***satisfaction*** *in their job, and what they contrib*

Care

Reimagined perform to measure the wh those who role-m

Appendix

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Total operating expenses - as reported GAAP	**$ 133,147**	**$ 107,867**	**$ 279,619**	**$ 220,**
Research and development:				
Share-based compensation	4,379	3,152	13,744	9,
Selling, general and administrative:				
Share-based compensation	8,084	8,584	29,370	22,
Loss on impairment of assets	—	—	6,616	
Changes in fair value of contingent consideration payable	115	1,021	(1,073)	1,
Depreciation and amortization	1,334	1,567	2,745	3,
Total operating expense adjustments to reported GAAP	13,912	14,324	51,402	36,
Total operating expenses - as adjusted	$ 119,235	$ 93,543	$ 228,417	$ 184,