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): **May 9, 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 2.02 Results of Operations and Financial Condition

On May 9, 2022, Amicus Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended March 31, 2022. A copy of this press release is attached hereto as Exhibit 99.1. The Company will host a conference call and webcast on May 9, 2022 to discuss its first quarter results of operations. A copy of the conference call presentation materials is attached hereto as Exhibit 99.2. Both exhibits are incorporated herein by reference.

In accordance with General Instruction B.2. of Form 8-K, the information in this Current Report on Form 8-K and the Exhibits 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 liability of that section, nor shall it be deemed 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 May 9, 2022
99.2	May 9, 2022 Conference Call 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: May 9, 2022

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

Amicus Therapeutics Announces First Quarter 2022 Financial Results

1Q22 Galafold® Revenue Growth of 18.5% to $78.7M

New Composition of Matter Patent for Galafold® Strengthens U.S. Patent Protection into 2038

Advancing U.S. and EU Regulatory Reviews and Launch Preparations for AT-GAA in Pompe Disease

Positive Long-Term Data from Phase 1/2 Study of AT-GAA in Pompe Disease Presented at 2022 MDA Conference

Conference Call and Webcast Today at 8:30 a.m. ET

PHILADELPHIA, PA, May 9, 2022 – Amicus Therapeutics (Nasdaq: FOLD), a patient-dedicated global biotechnology company focused on developing and commercializing novel medicines for rare diseases, today announced financial results for the quarter ended March 31, 2022.

John F. Crowley, Chairman and Chief Executive Officer of Amicus Therapeutics, Inc., stated, "Against a tumultuous market, we at Amicus have a deeply sharpened focus. We continue to ensure that Galafold gets to as many amenable people living with Fabry disease around the world, as seen by the significant first quarter performance of this precision medicine. We are committed to the regulatory approvals of AT-GAA for people living with Pompe disease, first in the United States and then in Europe and beyond. We are well on track with these anticipated approvals and the associated launch preparations, furthering our belief in the potential for this treatment regimen to become the new global standard of care in Pompe disease. And finally, we are laser focused on the financial strength of the business. This is anchored by the continued growth of Galafold and the anticipated approval of AT-GAA, each with strong exclusivity well into the late 2030s. Together this uniquely positions Amicus to deliver substantial value for shareholders and patients ahead."

Corporate Highlights

- **Global revenue for Galafold® (migalastat) in the first quarter of 2022 was $78.7 million.** First-quarter revenue represented a year-over-year increase of 18.5% from total revenue of $66.4 million in the first quarter of 2021. First quarter operational revenue growth measured at constant exchange rates (CER)[1] was 23.5%.
- **Galafold U.S. intellectual property estate strengthened following the issuance of eight new patents this year, including a composition of matter patent**. The Galafold U.S. intellectual property portfolio now includes 35 orange book listed patents, 19 of which provide protection through 2038.
- **Long-term Phase 1/2 data of AT-GAA presented at the 2022 MDA Clinical & Scientific Conference in March.** Study participants treated with AT-GAA for up to 36 months demonstrated persistent and durable effects on six-minute walk test (6MWT) distance, stability or increase in forced vital capacity (FVC), and reductions in biomarkers of muscle damage and disease substrate.
- **AT-GAA regulatory reviews progressing:** In the U.S., the Food and Drug Administration (FDA) has set a Prescription Drug User Fee Act (PDUFA) action date of May 29, 2022, for the New Drug Application (NDA) and July 29, 2022, for the Biologic License Application (BLA), reflective of the two components of AT-GAA. Following a positive late cycle review meeting, the Company continues to expect the FDA to approve the applications together by the July 29, 2022 action date. In the EU, the Committee for Medicinal Products for Human Use (CHMP) positive opinion is expected in late 2022.
- **AT-GAA launch preparations accelerating:** Development of pre-launch activities, targeted investments in additional personnel, and launch inventory build are fully underway as the Company believes AT-GAA has the potential to become the new standard of care treatment regimen for people living with Pompe disease.

- **Multiple expanded access programs in place driving significant enthusiasm for AT-GAA.** In the U.K., under the Early Access to Medicines Scheme (EAMS) multiple physicians have requested access across all the leading Pompe centers in the country.

- **Financial position sufficient to achieve profitability[2] in 2023.** Through careful management of expenses, the Company is on the path to achieve profitability in 2023, as it executes on the global expansion of Galafold and prepares for the global launch of AT-GAA.

- **2022 Environmental, Social, and Governance (ESG) Report published.** The Amicus ESG report highlights its dedication to patients alongside the Company's environmental, social, and governance responsibilities.

First Quarter 2022 Financial Results

- Total revenue in the first quarter 2022 was $78.7 million, a year-over-year increase of 18.5% from total revenue of $66.4 million in the first quarter of 2021. On a constant currency basis, first quarter 2022 total revenue growth was 23.5%. Reported revenue was offset by a negative currency impact of $3.3 million, or 5.0%.
- Cash, cash equivalents, and marketable securities totaled $411.2 million at March 31, 2022, compared to $482.5 million at December 31, 2021.
- Total GAAP operating expenses of $147.1 million for the first quarter 2022 increased as compared to $112.9 million for the first quarter 2021.
- Total non-GAAP operating expenses of $109.0 million for the first quarter of 2022 increased as compared to $90.5 million in the first quarter of 2021, reflecting manufacturing costs to support the AT-GAA launch and non-recurring expenses related to the reprioritization of the gene therapy portfolio.[3]
- Net loss was $85.3 million, or $0.30 per share, compared to a net loss of $65.7 million, or $0.25 per share, for the first quarter 2021.

2022 Financial Guidance

- For the full-year 2022, the Company anticipates total Galafold revenue of $350 million to $365 million at constant exchange rates[1]. Double-digit revenue growth between 15 and 20% at CER[1] in 2022 is expected to be driven by continued underlying demand from both switch and naïve patients, geographic expansion, the continued diagnosis of new Fabry patients and commercial execution across all major markets, including the U.S., EU, U.K., and Japan. Applying average April 2022 exchange rates, the negative currency impact on full-year 2022 Galafold reported sales would be approximately 6%.
- Non-GAAP operating expense guidance for the full-year 2022 is $470 million to $485 million, driven by continued investment in the global Galafold launch, AT-GAA clinical studies and pre-launch activities, in addition to certain non-recurring costs for manufacturing to support the global launch of AT-GAA and committed obligations for the gene therapy portfolio. In 2023, Amicus expects non-GAAP operating expense levels to come down to a similar level as in 2021.[4]
- Cash, cash equivalents, and marketable securities totaled $411.2 million at March 31, 2022. Based on current operating models, the Company believes that the current and projected cash flows are sufficient to achieve self-sustainability.

Anticipated 2022 Milestones by Program

Galafold (migalastat) Oral Precision Medicine for Fabry Disease
- Sustain double-digit revenue growth in 2022 of $350 million to $365 million at CER
- Continue geographic expansion
- Registry and other Phase 4 studies ongoing

AT-GAA for Pompe Disease
- U.S. Prescription Drug User Fee Act (PDUFA) action date of May 29, 2022 for the NDA and July 29, 2022 for the BLA
- EU Committee for Medicinal Products for Human Use (CHMP) opinion expected in late 2022
- Continue to broaden early access plans in the U.K., Germany, France, Japan, and other countries
- Ongoing supportive studies, including pediatric and extension studies

[1] In order to illustrate underlying performance, Amicus discusses its results in terms of constant exchange rate (CER) growth. This represents growth calculated as if the exchange rates had remained unchanged from those used in the comparative period. Full year 2022 Galafold revenue guidance utilizes the average actual exchange rates for 2021

[2] 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, 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

[3] Full reconciliation of GAAP results to the Company's non-GAAP adjusted measures for all reporting periods appear in the tables to this press release.

[4] A reconciliation of the differences between the non-GAAP expectation and the corresponding GAAP measure is not available without unreasonable effort due to high variability, complexity, and low visibility as to the items that would be excluded from the GAAP measure.

Conference Call and Webcast

Amicus Therapeutics will host a conference call and audio webcast today, May 9, 2022 at 8:30 a.m. ET to discuss the first quarter 2022 financial results and corporate updates. Interested participants and investors may access the conference call by dialing 877-303-5859 (U.S./Canada) or 678-224-7784 (international), conference ID: 7867383.

A live audio webcast and related presentation materials can also be accessed via the Investors section of the Amicus Therapeutics corporate website at ir.amicusrx.com. Web participants are encouraged to register on the website 15 minutes prior to the start of the call. A replay of the call will be available for seven days beginning at 11:30 a.m. ET on May 9, 2022. Access numbers for this replay are 855-859-2056 (U.S./Canada) and 404-537-3406 (international); conference ID: 7867383.

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 Fabry patients may have amenable *GLA* variants, though amenability rates within this range vary by geography. Galafold is approved in over 40 countries around the world, including the U.S., EU, U.K., Japan and others.

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.

EU Important Safety Information

Treatment with Galafold should be initiated and supervised by specialists experienced in the diagnosis and treatment of Fabry disease. Galafold is not recommended for use in patients with a nonamenable mutation.

- Galafold is not intended for concomitant use with enzyme replacement therapy.
- Galafold is not recommended for use in patients with Fabry disease who have severe renal impairment (<30 mL/min/1.73 m2). The safety and efficacy of Galafold in children less than 12 years of age have not yet been established. No data are available.
- No dosage adjustments are required in patients with hepatic impairment or in the elderly population.

- There is very limited experience with the use of this medicine in pregnant women. If you are pregnant, think you may be pregnant, or are planning to have a baby, do not take this medicine until you have checked with your doctor, pharmacist, or nurse.
- While taking Galafold, effective birth control should be used. It is not known whether Galafold is excreted in human milk.
- Contraindications to Galafold include hypersensitivity to the active substance or to any of the excipients listed in the PRESCRIBING INFORMATION.
- Galafold 123 mg capsules are not for children (≥12 years) weighing less than 45 kg.
- It is advised to periodically monitor renal function, echocardiographic parameters and biochemical markers (every 6 months) in patients initiated on Galafold or switched to Galafold.
- OVERDOSE: General medical care is recommended in the case of Galafold overdose.
- The most common adverse reaction reported was headache, which was experienced by approximately 10% of patients who received Galafold. For a complete list of adverse reactions, please review the SUMMARY OF PRODUCT CHARACTERISTICS.
- Call your doctor for medical advice about side effects.

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.

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 metabolic diseases. With extraordinary patient focus, Amicus Therapeutics is committed to advancing and expanding a robust pipeline of cutting-edge, first- or best-in-class medicines for rare metabolic diseases. For more information please visit the company's website at www.amicusrx.com, and follow on Twitter and LinkedIn.

Non-GAAP Financial Measures

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

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 relating to preclinical and clinical development of our product candidates, the timing and reporting of results from preclinical studies and clinical trials, the prospects and timing of the potential regulatory approval of our product candidates, commercialization plans, manufacturing and supply plans, financing plans, and the projected revenues and cash position for the Company. The inclusion of forward-looking statements should not be regarded as a representation by us that any of our plans will be achieved. Any or all of the forward-looking statements in this press release may turn out to be wrong and can be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. For example, with respect to statements regarding the goals, progress, timing, and outcomes of discussions with regulatory authorities, and in particular the potential 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 on patient access to commercial or clinical product. In addition to the impact of the COVID-19 pandemic, actual results may differ materially from those set forth in this release due to the risks and uncertainties inherent in our business, including, without limitation: the potential that results of clinical or preclinical studies indicate that the product candidates are unsafe or ineffective; the potential that it may be difficult to enroll patients in our clinical trials; the potential that regulatory authorities, 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 commercializing Galafold in 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 delayed because we identify serious side effects or other safety issues; the potential that we may not be able to manufacture or supply sufficient clinical or commercial products; and the potential that we will need additional funding to complete all of our studies and manufacturing. Further, the results of earlier preclinical studies and/or clinical trials may not be predictive of future results. Statements regarding corporate financial guidance and financial goals and the attainment of such goals. With respect to statements regarding projections of the Company's revenue 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, 2021 and Form 10-Q for the quarter ended March 31, 2022, to be filed today. 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.

CONTACTS:

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

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

FOLD-G

TABLE 1

Amicus Therapeutics, Inc.
Consolidated Statements of Operations
(Unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2022	**2021**
Net product sales	$ 78,715	$ 66,402
Cost of goods sold	7,582	6,539
Gross profit	71,133	59,863
Operating expenses:		
Research and development	81,517	64,117
Selling, general, and administrative	58,116	46,726
Changes in fair value of contingent consideration payable	(1,188)	471
Loss on impairment of assets	6,616	—
Depreciation and amortization	1,411	1,604
Total operating expenses	146,472	112,918
Loss from operations	(75,339)	(53,055)
Other (expense) income:		
Interest income	133	165
Interest expense	(8,147)	(7,992)
Other expense	1,902	(3,200)
Loss before income tax	(81,451)	(64,082)
Income tax expense	(3,809)	(1,582)
Net loss attributable to common stockholders	$ (85,260)	$ (65,664)
Net loss attributable to common stockholders per common share — basic and diluted	$ (0.30)	$ (0.25)
Weighted-average common shares outstanding — basic and diluted	288,481,741	264,369,317

TABLE 2

Amicus Therapeutics, Inc.
Consolidated Balance Sheets
(Unaudited)
(in thousands, except share and per share amounts)

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 233,317	$ 245,197
Investments in marketable securities	177,878	237,299
Accounts receivable	52,421	52,672
Inventories	24,324	26,818
Prepaid expenses and other current assets	30,960	34,848
Total current assets	518,900	596,834
Operating lease right-of-use assets, net	27,509	20,586
Property and equipment, less accumulated depreciation of $20,966 and $19,882 at March 31, 2022 and December 31, 2021, respectively	34,544	42,496
In-process research & development	23,000	23,000
Goodwill	197,797	197,797
Other non-current assets	25,188	24,427
Total Assets	$ 826,938	$ 905,140
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 22,914	$ 21,513
Accrued expenses and other current liabilities	80,379	98,153
Contingent consideration payable	19,151	18,900
Operating lease liabilities	7,255	7,409
Total current liabilities	129,699	145,975
Deferred reimbursements	5,906	5,906
Long-term debt	389,994	389,357
Deferred income taxes	4,930	4,930
Operating lease liabilities	50,457	43,363
Other non-current liabilities	7,335	8,240
Total liabilities	588,321	597,771
Commitments and contingencies		
Stockholders' equity		
Common stock, $0.01 par value, 500,000,000 shares authorized, 280,133,856 and 278,912,800 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	2,809	2,808
Additional paid-in capital	2,617,935	2,595,419
Accumulated other comprehensive (loss) gain:		
Foreign currency translation adjustment	(420)	5,251
Unrealized loss on available-for-sale securities	(608)	(270)
Warrants	83	83
Accumulated deficit	(2,381,182)	(2,295,922)
Total stockholders' equity	238,617	307,369
Total Liabilities and Stockholders' Equity	$ 826,938	$ 905,140

TABLE 3

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

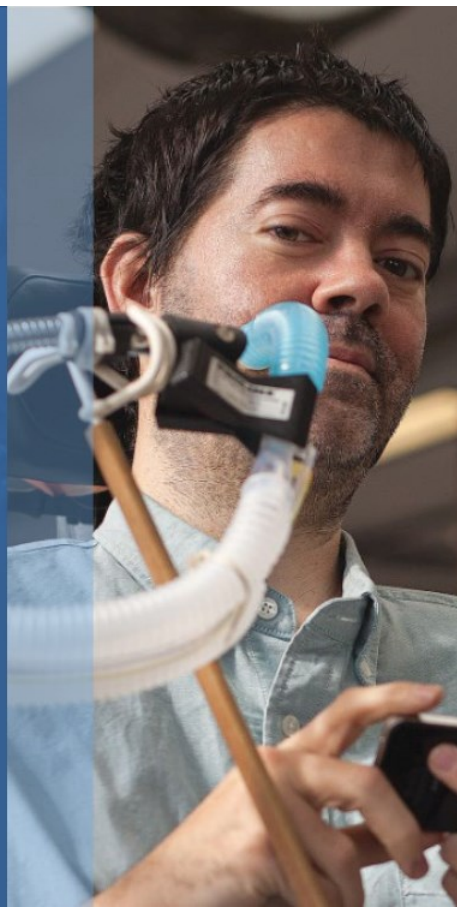
	Three Months Ended March 31,	
	2022	2021
Total operating expenses - as reported GAAP	$ 146,472	$ 112,918
Research and development:		
Share-based compensation	9,365	6,305
Selling, general and administrative:		
Share-based compensation	21,286	14,049
Loss on impairment of assets	6,616	—
Changes in fair value of contingent consideration payable	(1,188)	471
Depreciation and amortization	1,411	1,604
Total operating expense adjustments to reported GAAP	37,490	22,429
Total operating expenses - as adjusted	$ 108,982	$ 90,489

Amicus Therapeutics®

1Q22 Financial Results Conference Call & Webcast

At the Forefront of Therapies for Rare Diseases

May 9, 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 development of our prod 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 candida commercialization plans, manufacturing and supply plans, financing plans, and the projected revenues and cash position for the Company. The inclusion of forward-looking statements sho 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 presentation may turn out to be wrong and can be affec 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 discussions with regulatory authorities, and in particular the potential goals, progress, timing, and results of preclinical studies and clinical trials, and revenue goals, including as they impacted by COVID-19 related disruption, are based on current information. The potential impact on operations and/or revenue from the COVID-19 pandemic is inherently unknown 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 imp 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-pa business closures and resource allocations, manufacturing and supply chain disruptions and limitations on patient access to commercial or clinical product or to treatment sites. In addition the impact of the COVID-19 pandemic, actual results may differ materially from those set forth in this release due to the risks and uncertainties inherent in our business, including, with limitation: the potential that results of clinical or preclinical studies indicate that the product candidates are unsafe or ineffective; the potential that it may be difficult to enroll patients in clinical trials; the potential that regulatory authorities, including the FDA, EMA, and PMDA, may not grant or may delay approval for our product candidates; the potential that we may not successful in commercializing Galafold in Europe, U.K., Japan, the U.S. and other geographies or our other product candidates if and when approved; the potential that preclinical and clin studies could be delayed because we identify serious side effects or other safety issues; the potential that we may not be able to manufacture or supply sufficient clinical or commercial produ and the potential that we will need additional funding to complete all of our studies, commercialization and manufacturing. Further, the results of earlier preclinical studies and/or clinical tr may not be predictive of future results. With respect to statements regarding corporate financial guidance and financial goals and the attainment of such goals and statements regard projections of the Company's revenue 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, forward-looking statements are subject to other risks detailed in our Annual Report on Form 10-K for the year ended December 31, 2021, and on Form 10-Q for the quarter ended March 2022, to be filed today. 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 quali 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.

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 w supplemental information relating to operating performance and trends that facilitate comparisons between periods and with respect to projected information. These adjusted finan 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 cert 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 th 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-GA 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 t 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 potentia unpredictable, impact on our future GAAP results.

A Rare Company

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

Galafold® (migalastat)

First Oral Precision Medicine for Fabry Disease

Gene Therapy PLATFORM

Leveraging Experience in Protein Engineering & Glycobiology

World-Class CLINICAL DEVELOPMENT Capabilities

PROFITABILI
expected in
2023

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

$411M
Cash
as of 3/31/2

2022 Strategic Priorities to Drive Value

1. Double-digit Galafold growth (15-20%) with revenue of $350M to $365M at CER[1]
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]2022 Galafold revenue guidance is based on the average exchange rates for 2021

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 self-sustainability and profitability in 2023

Amicus Therapeutics®

Galafold Success (as of March 31, 2022)

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

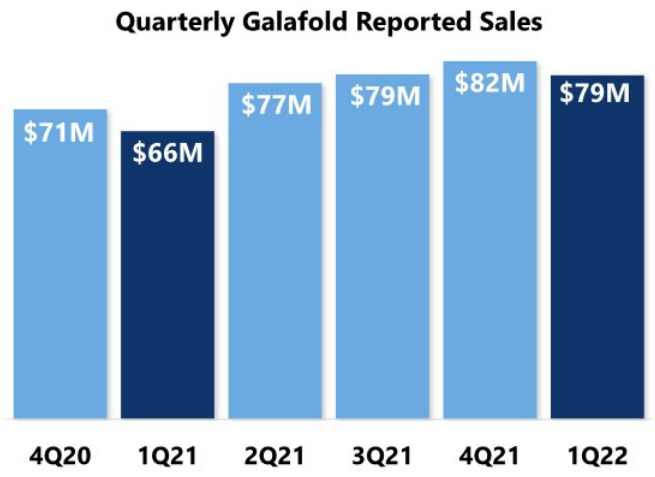
Galafold is first and only approved oral treatment option with a unique mechanism of action for Fabry patients with amenable variants

- **$78.7M +18.5% YoY** 1Q22 Galafold Revenue
- **1,384** Amenable Mutations Included in EU Label
- **$350M-$365M** 2022 Galafold Revenue Guidance at CER
- **Continued Geographic Expansion in 2022**
- **350** Amenable Variants in U.S. Label
- **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://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 Quarterly Trends

Q1 Reported Revenue Growth of +18.5% to $79M - Operational Growth of +23.5% at CER



- Global mix of switch (~55%) and previously untreated patients (~45%)
- Compliance and adherence over 90%+
- Continue to support diagnostic initiatives to drive a shorter pathway to diagnosis
- Expect non-linear quarterly growth to continue due to uneven ordering patterns
- Distribution of Galafold sales by quarter in past 3 years:

	Q1	Q2	Q3	Q4
3 Year Avg.	21%	25%	26%	28%

Galafold Success and FY22 Revenue Guidance

Galafold Momentum on Track to Achieve Full-Year 2022 Revenue Guidance 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:

1Q operational revenue growth of +24%

Near-term growth to $500M driven by:

Continued penetration into existing markets

Expansion into new geographies

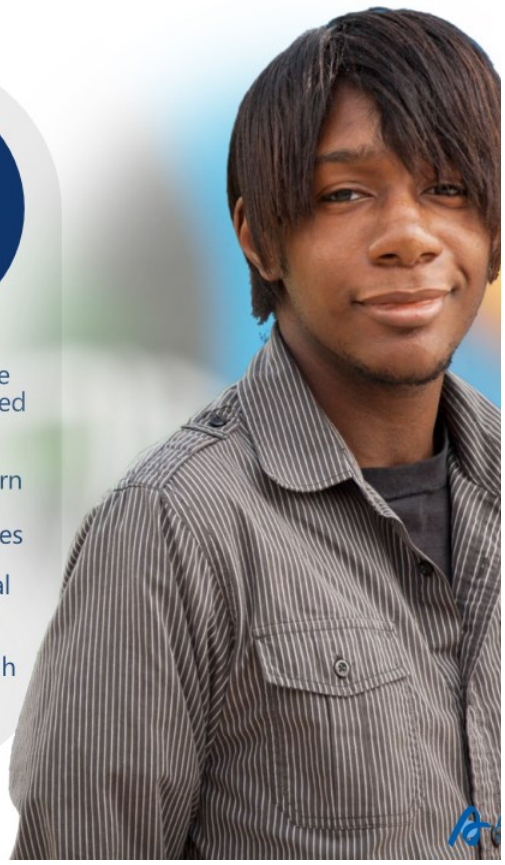
Broadening of labels

Long-term growth towards peak sales potential driven by:

Penetration of the diagnosed untreated population

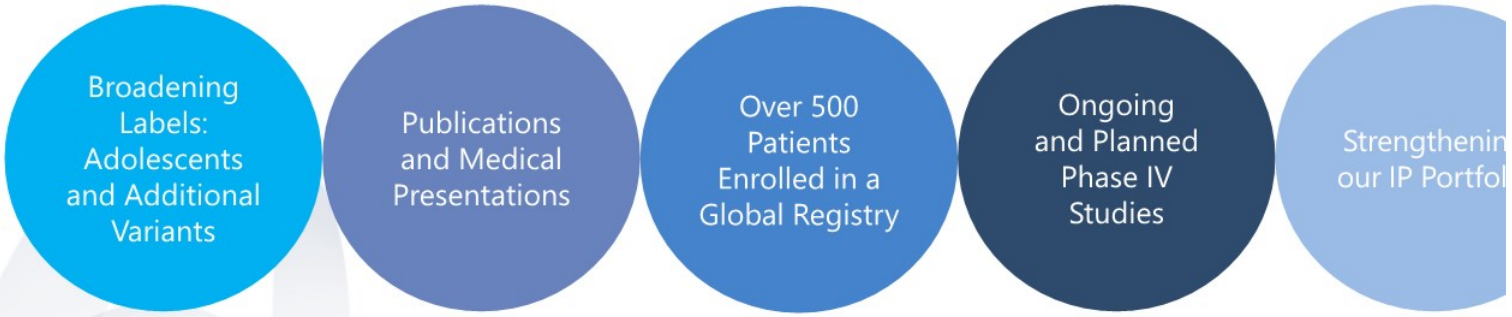
Increase in newborn screening and diagnostic initiatives

Strong intellectual property 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 Enzyme G

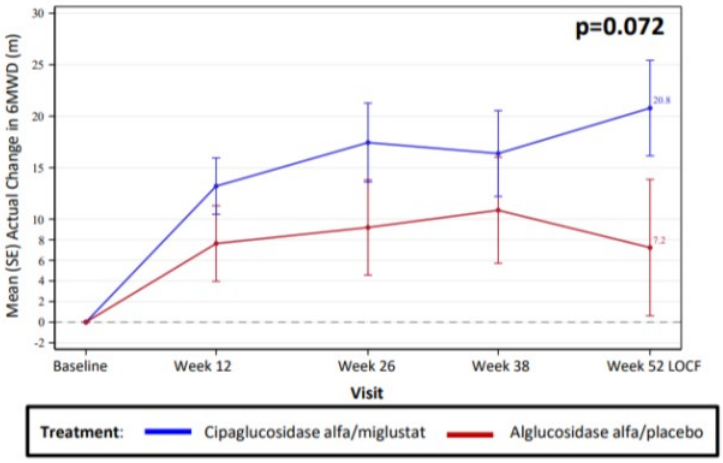
- Estimated incidence of ~1:28,000 ; newborn screening suggests significant underdiagnosis
- Age of onset ranges from infancy to adulthood
- Majority of patients on current standard of care decline after ~2 years
- Respiratory and cardiac failure are leading causes of morbidity and mortality
- Deficiency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

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

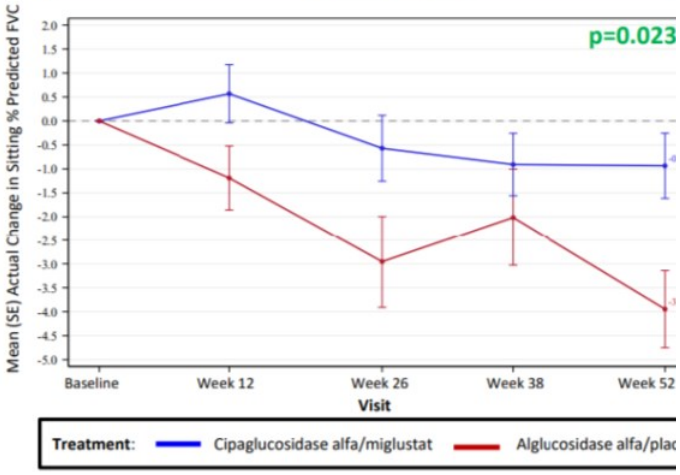
Phase 3 PROPEL Study Results
Overall Population (n=122*)

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

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



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

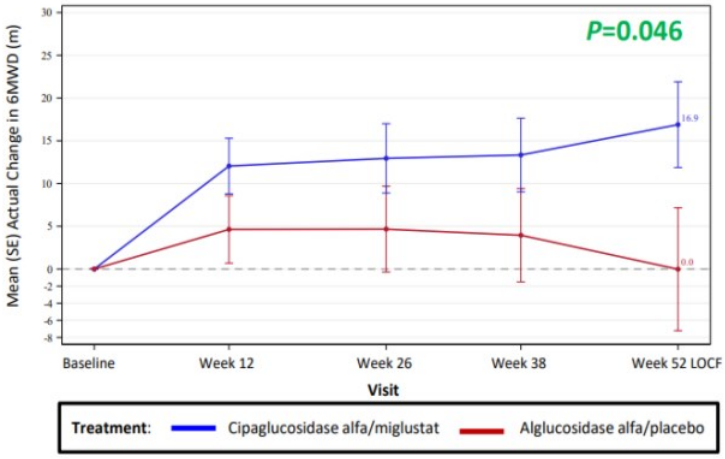


6MWD=6-minute walk distance;; FVC=forced vital capacity; SE=standard error. P values are nominal 2-sided; FVC data normally distributed and P value is from ANCOVA. 6MWD data not normally distributed and P value is for nonparametric ANCOVA;
*Results exclude one outlier subject

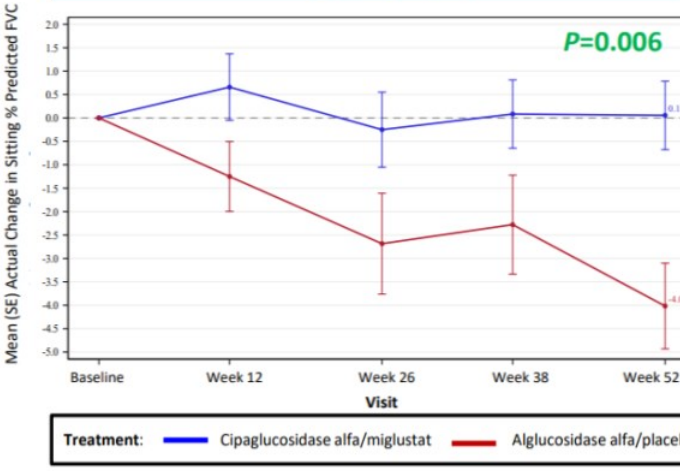
Phase 3 PROPEL Study Results
ERT-Experienced Population (n=95)

Results in the Large Pre-specified Subgroup of ERT-Experienced Patients with High Clinical Unm Need Showed Meaningful Improvement for Both 6MWD and FVC

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



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

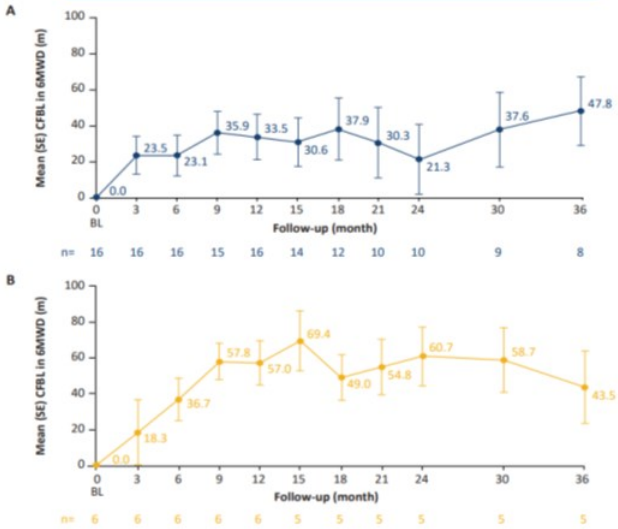


6MWD=6-minute walk distance;; FVC=forced vital capacity; SE=standard error. P values are nominal 2-sided; FVC data normally distributed and P value is from ANCOVA. 6MWD data not normally distributed and P value is for nonparametric ANCOVA;
*Results exclude one outlier subject

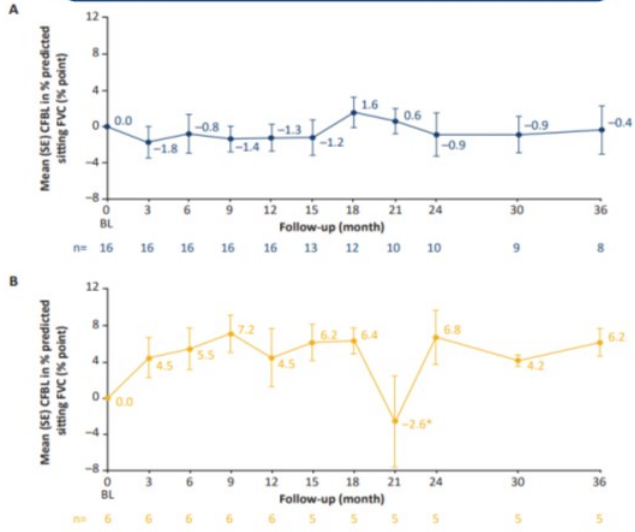
Long-Term Data from Phase 1/2 Clinical Study (ATB200-02)

Persistent and Durable Improvements in Motor and Respiratory Function and Reductions in Biomarkers of Muscle Damage and Disease Substrate Observed in Patients out to 36 Months

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



CFBL in FVC in (A) ERT-Experienced and (B) 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).

AT-GAA: Key Takeaways

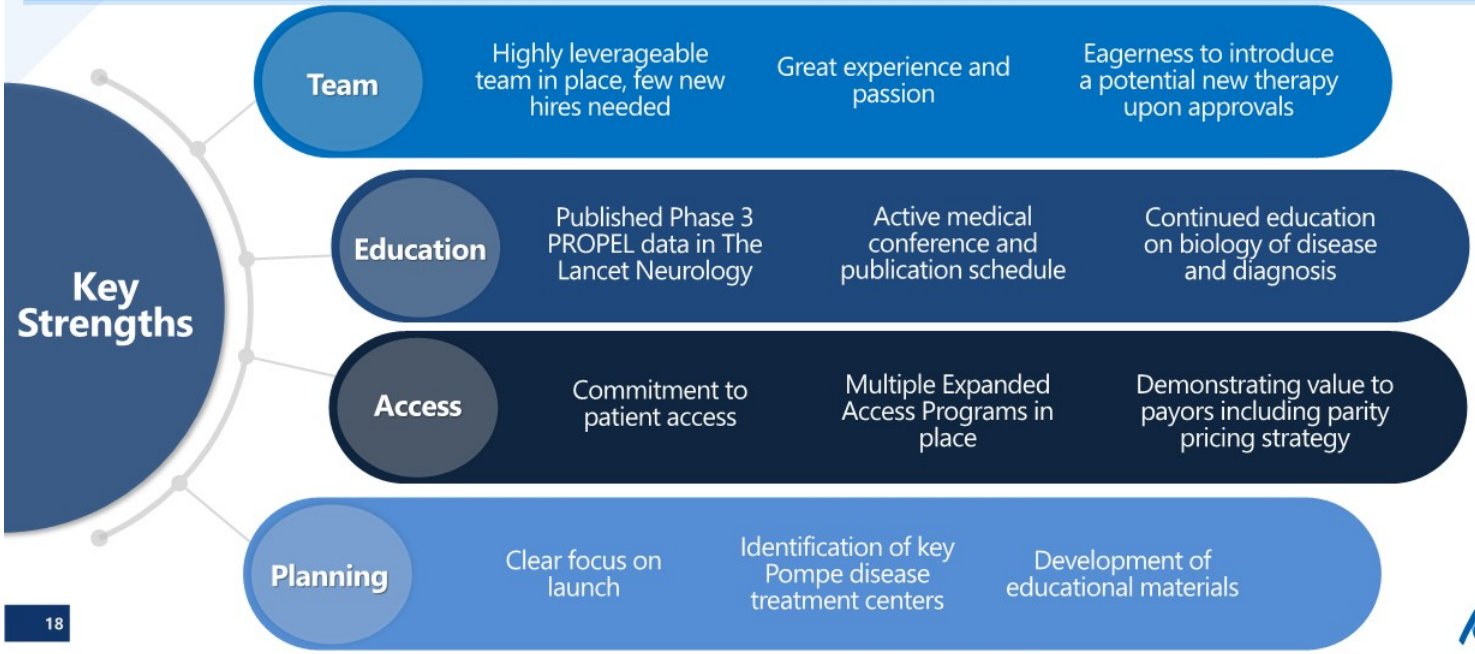
Focused on Advancing AT-GAA to as Many Patients as Possible through Global Regulatory Pathways and Expanded Access Mechanisms

- Regulatory status update:
  - U.S. PDUFA date mid 2022[1]
  - CHMP opinion late 2022
  - Planning for additional regulatory submissions
- Multiple expanded access mechanisms in place, including in the U.K., Germany, France, Japan, and others
- 150+ people living with Pompe disease are on AT-GAA today across our clinical extension studies and expanded access programs
- Ongoing supportive studies:
  - Late-Onset Pompe Disease (LOPD) in children and adolescents aged 0 to <18
  - Infantile-Onset Pompe Disease (IOPD)

[1]FDA PDUFA date of May 29, 2022 for miglustat NDA and July 29, 2022 for cipaglucosidase alfa BLA

Launch Preparations

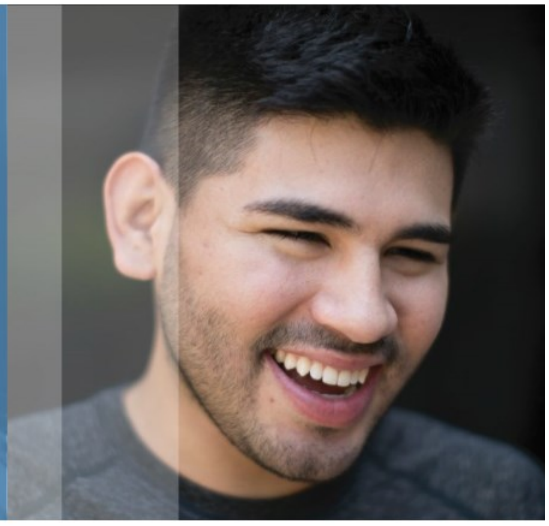
Experienced and Passionate Rare Disease Medical and Commercial Organization Poised for Second Successful Launch



Amicus Therapeutics®

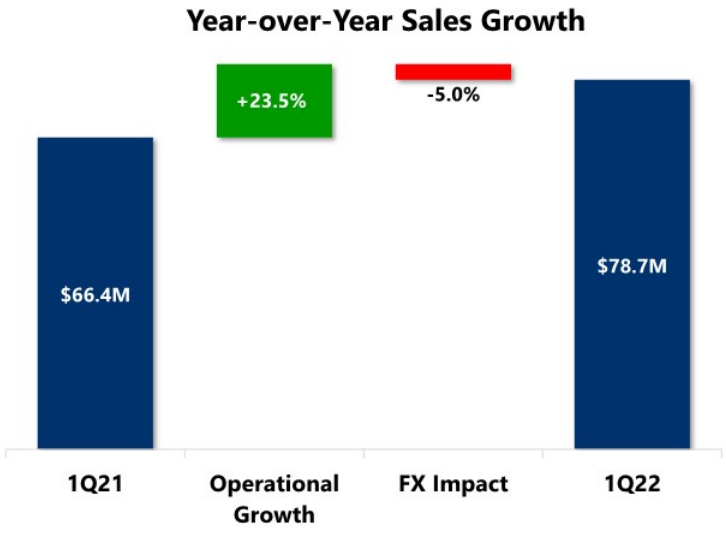
Financial & Operational Strategy

... maintaining a strong financial outlook



Revenue Performance

Q1 Revenue Growth of +18.5% to $79M resulting from Strong Operational Growth of +23.5% at CER Offset by Negative FX impact of -5.0%



- Significant currency exposure as 69% of Galafold revenue generated outside the U.
- Applying average April 2022 exchange rate the negative FX impact on full-year 2022 Galafold® reported sales would be approximately -6%

1Q2022 Select Financial Results

1Q22 OpEX Increase Reflects Manufacturing Costs to Support AT-GAA Launch and Non-Recurring Expenses Related to the Reprioritization of the Gene Therapy Portfolio

(in thousands, except per share data)	Mar. 31, 2022	Mar. 31, 2021
Product Revenue	$78,715	$66,402
Cost of Goods Sold	7,582	6,539
R&D Expense	81,517	64,117
SG&A Expense	58,116	46,726
Changes in Fair Value of Contingent Consideration	(1,188)	471
Loss on Impairment of Assets	6,616	–
Depreciation and Amortization	1,411	1,604
Loss from Operations	(75,339)	(53,055)
Income Tax Expense	(3,809)	(1,582)
Net Loss	(85,260)	(65,664)
Net Loss Per Share	(0.30)	(0.25)

Financial Outlook and Path to Profitability

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

Sustain Galafold Revenue Growth

$79M 1Q2022 revenue, +24% 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 on Financial Goals

Focused on prudent expense management

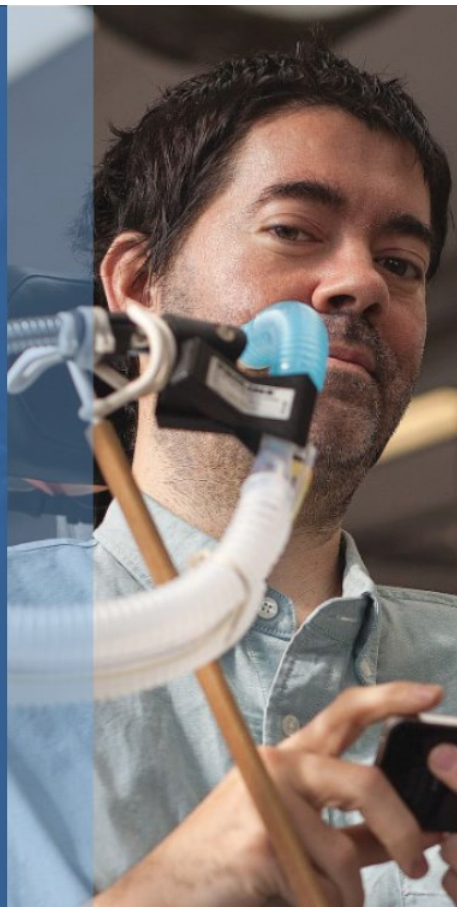
2022 Non-GAAP operating expense guidance of **$470M-$485M**

Achieve profitability[1] in 2023

[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 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.

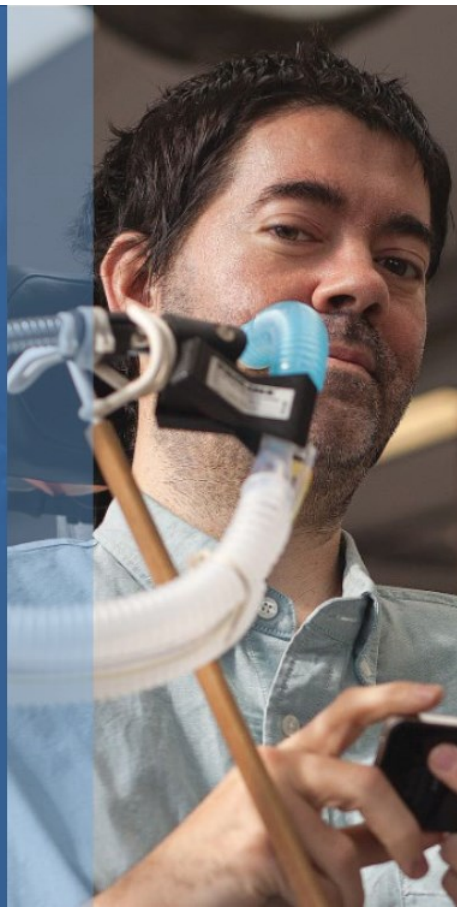
Amicus Therapeutics®

Thank You



Amicus Therapeutics®

Appendix



Appendix

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

	Three Months Ended March 31,	
	2022	**2021**
Total operating expenses - as reported GAAP	**$ 146,472**	**$ 112,918**
Research and development:		
Share-based compensation	9,365	6,305
Selling, general and administrative:		
Share-based compensation	21,286	14,049
Loss on impairment of assets	6,616	—
Changes in fair value of contingent consideration payable	(1,188)	471
Depreciation and amortization	1,411	1,604
Total operating expense adjustments to reported GAAP	37,490	22,429
Total operating expenses - as adjusted	**$ 108,982**	**$ 90,489**