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): **August 5, 2021**

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 August 5, 2021, Amicus Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended June 30, 2021. A copy of this press release is attached hereto as Exhibit 99.1. The Company will host a conference call and webcast on August 5, 2021 to discuss its second 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 August 5, 2021
99.2	August 5, 2021 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: August 5, 2021

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

Amicus Therapeutics Announces Second Quarter 2021 Financial Results and Corporate Updates

2Q21 Total Galafold® (migalastat) Revenue of $77.4M, a 24% increase over 2Q20

On-Track to Achieve Revenue Guidance of $300M-$315M

Completed the Rolling BLA and NDA Submissions to the U.S. FDA for AT-GAA in Pompe Disease

Positive EMA Rapporteur and Co-Rapporteur Meeting Support the MAA Submissions for AT-GAA; Global Submissions On-Track in 2021

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

PHILADELPHIA, PA, Aug. 5, 2021 – Amicus Therapeutics (Nasdaq: FOLD), a patient-dedicated global biotechnology company focused on discovering, developing and delivering novel medicines for rare diseases, today announced financial results for the quarter ended June 30, 2021.

John F. Crowley, Chairman and Chief Executive Officer of Amicus Therapeutics, Inc., stated, "Throughout this year and into the third quarter, the global Amicus team has continued to advance our mission for patients and made significant strides towards achieving our 2021 strategic priorities, including continued commercial execution of Galafold, the completion of our rolling BLA submission with the U.S. FDA and progression of additional global regulatory work for AT-GAA, as well as advancing our industry-leading gene therapy pipeline. Through our efforts, we remain well positioned to deliver on our mission for patients and shareholders, and to continue building Amicus into a leading global rare disease biotechnology company. We are especially excited for and confident in our Pompe program now moving through regulatory reviews around the world and hopeful that it will reach many more people living with Pompe disease as soon as possible."

Corporate Highlights

- **Global revenue for Galafold® (migalastat) in the second quarter of 2021 reached $77.4 million, representing a year-over-year increase of 24.0% from total revenue of $62.4 million in the second quarter of 2020.** Second quarter total revenue benefited from a positive currency impact of $4.3 million. On a constant currency basis, second quarter total revenue was $73.1 million, a growth of 17.2% measured at constant currency exchange rates.
- **Galafold EU label expanded following the European Commission approval for use in adolescents.** Galafold is the first and only oral therapy approved in the EU for the long-term treatment of adolescents with Fabry disease aged 12 to <16 years weighing ≥ 45 kg and who have an amenable mutation.
- **Rolling Biologics License Application (BLA) for cipaglucosidase alfa and the New Drug Application (NDA) for miglustat have been submitted to the U.S. Food and Drug Administration (FDA).**
- **In the European Union, following a positive rapporteur and co-rapporteur meeting, regulators are supportive of Marketing Authorization Application (MAA) submissions for AT-GAA in the second half of this year.**
- **AT-GAA granted positive scientific opinion through the Early Access to Medicines Scheme (EAMS) by the U.K.'s Medicines and Healthcare Products Regulatory Agency (MHRA).** The MHRA's positive scientific opinion recognizes the high unmet medical need and permits eligible adults living with Late-Onset Pompe disease (LOPD) who have received alglucosidase alfa for at least 2 years to switch and have access to AT-GAA prior to marketing authorization in the U.K.
- **Clinical Batten gene therapy programs continue to advance**. The Company continues to follow the first 13 patients with CLN6 and the 4 patients with CLN3 in their respective Phase 1/2 studies. Focus remains on progressing manufacturing, clinical and regulatory activities to enable next clinical studies.

- **Cash position sufficient to achieve self-sustainability without the need for any future dilutive financings.** The Company continues to carefully manage expenses and investments, while executing on the Galafold launch, proceeding with AT-GAA global regulatory submissions and advancing development programs.

Second Quarter 2021 Financial Results

- Total revenue in the second quarter of 2021 was $77.4 million, a year-over-year increase of 24.0% from total revenue of $62.4 million in the second quarter of 2020. On a constant currency basis, second quarter 2021 total revenue was $73.1 million, representing operational revenue growth measured at constant currency exchange rates of 17.2%. Reported revenue was aided by a positive currency impact of $4.3 million, or 6.8%.
- Cash, cash equivalents, and marketable securities totaled $383.1 million at June 30, 2021, compared to $483.3 million at December 31, 2020.
- Total GAAP operating expenses of $107.9 million for the second quarter of 2021 increased as compared to $107.0 million for the second quarter 2020.
- Total non-GAAP operating expenses of $93.5 million for the second quarter of 2021 decreased as compared to $95.9 million in the second quarter of 2020, reflecting the timing of investments in our pipeline.[1]
- Net loss was $51.2 million, or $0.19 per share, compared to a net loss of $52.5 million, or $0.20 per share, for the second quarter 2020.

[1] 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.

2021 Financial Guidance

- For the full-year 2021, the Company anticipates total Galafold revenue of $300 million to $315 million. Double-digit revenue growth in 2021 is expected to be driven by continued operational growth and commercial execution across all major markets, including the U.S., EU, U.K. and Japan.
- Non-GAAP operating expense guidance for the full-year 2021 is $410 million to $420 million, driven by continued investment in the global Galafold launch, AT-GAA clinical studies and pre-launch activities, and advancing our gene therapy pipeline.[2]
- Based on current operating models, the Company believes that the current cash position and expected future revenues are sufficient to fund the Company's operations and ongoing research programs through to self-sustainability.

[2] 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.

2021 Milestones by Program

Galafold (migalastat) Oral Precision Medicine for Fabry Disease

- Continue revenue growth in 2021
- EU label expanded to cover adolescent population
- Continue geographic expansion
- Registry and other Phase 4 studies

AT-GAA for Pompe Disease

- Completed the BLA and NDA submissions in 3Q21; EU MAA submissions to be completed in 2H2021
- Ongoing supportive studies, including pediatric and extension studies

Gene Therapy Portfolio

- Advance manufacturing activities and regulatory discussions for the CLN6 Batten disease gene therapy program to enable dosing of additional patients with GMP clinical grade material
- Reported initial data from the CLN3 Batten disease gene therapy Phase 1/2 study; advance manufacturing activities and regulatory discussions to enable dosing additional patients with GMP clinical-grade material
- Continue to progress IND-enabling work in both Pompe and Fabry gene therapies
- Disclose additional preclinical data and potential IND candidate declarations across multiple preclinical programs
- Manufacturing advancements and updates across the portfolio

Conference Call and Webcast

Amicus Therapeutics will host a conference call and audio webcast today, August 5, 2021 at 8:30 a.m. ET to discuss the second quarter 2021 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: 7374935.

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 August 5, 2021. Access numbers for this replay are 855-859-2056 (U.S./Canada) and 404-537-3406 (international); conference ID: 7374935.

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, and revenue goals, including as they are 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 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 or to treatment sites. 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, UK, 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, commercialization and manufacturing. Further, the results of earlier preclinical studies and/or clinical trials 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 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, 2020 and Quarterly Report 10-Q for the quarter ended June 30, 2021, 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.

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TABLE 1

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Net product sales	$ 77,413	$ 62,353	$ 143,815	$ 122,878
Cost of goods sold	8,380	6,676	14,919	13,228
Gross profit	69,033	55,677	128,896	109,650
Operating expenses:				
Research and development	63,003	69,611	127,120	158,731
Selling, general, and administrative	42,276	34,657	89,002	74,872
Changes in fair value of contingent consideration payable	1,021	715	1,492	1,646
Depreciation and amortization	1,567	2,039	3,171	3,803
Total operating expenses	107,867	107,022	220,785	239,052
Loss from operations	(38,834)	(51,345)	(91,889)	(129,402)
Other income (expense):				
Interest income	50	865	215	2,380
Interest expense	(8,150)	(3,635)	(16,142)	(7,364)
Other expense	234	5,326	(2,966)	(2,990)
Loss before income tax	(46,700)	(48,789)	(110,782)	(137,376)
Income tax benefit (expense)	(4,525)	(3,703)	(6,107)	(4,064)
Net loss attributable to common stockholders	$ (51,225)	$ (52,492)	$ (116,889)	$ (141,440)
Net loss attributable to common stockholders per common share — basic and diluted	$ (0.19)	$ (0.20)	$ (0.44)	$ (0.55)
Weighted-average common shares outstanding — basic and diluted	266,398,516	257,973,329	265,384,865	257,548,623

TABLE 2

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

	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 176,538	$ 163,240
Investments in marketable securities	206,530	320,029
Accounts receivable	49,172	46,923
Inventories	24,086	19,556
Prepaid expenses and other current assets	24,176	29,721
Total current assets	480,502	579,469
Operating lease right-of-use assets, less accumulated amortization of $8,150 and $7,574 at June 30, 2021 and December 31, 2020, respectively	22,028	23,296
Property and equipment, less accumulated depreciation of $17,410 and $14,487 at June 30, 2021 and December 31, 2020, respectively	42,365	43,863
In-process research & development	23,000	23,000
Goodwill	197,797	197,797
Other non-current assets	21,200	19,095
Total Assets	$ 786,892	$ 886,520
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 13,762	$ 17,063
Accrued expenses and other current liabilities	71,325	96,841
Contingent consideration payable	19,800	8,900
Operating lease liabilities	7,106	6,872
Total current liabilities	111,993	129,676
Deferred reimbursements	7,406	7,406
Long-term debt	390,434	389,254
Contingent consideration payable	7,517	16,925
Deferred income taxes	4,896	4,896
Operating lease liabilities	44,201	45,604
Other non-current liabilities	6,535	6,379
Total liabilities	572,982	600,140
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.01 par value, 500,000,000 shares authorized, 266,532,536 and 262,063,461 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	2,685	2,650
Additional paid-in capital	2,364,494	2,308,578
Accumulated other comprehensive income (loss):		
Foreign currency translation adjustment	9,255	8,412
Unrealized loss on available-for-sale securities	(173)	(185)
Warrants	—	12,387
Accumulated deficit	(2,162,351)	(2,045,462)
Total stockholders' equity	213,910	286,380
Total Liabilities and Stockholders' Equity	$ 786,892	$ 886,520

TABLE 3

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Total operating expenses - as reported GAAP	**$ 107,867**	**$ 107,022**	**$ 220,785**	**$ 239,052**
Research and development:				
Share-based compensation	3,152	3,362	9,457	8,615
Selling, general and administrative:				
Share-based compensation	8,584	5,046	22,633	12,389
Changes in fair value of contingent consideration payable	1,021	715	1,492	1,646
Depreciation and amortization	1,567	2,039	3,171	3,803
Total operating expense adjustments to reported GAAP	14,324	11,162	36,753	26,453
Total operating expenses - as adjusted	$ 93,543	$ 95,860	$ 184,032	$ 212,599

Exhibit 99.2

Amicus Therapeutics®

2Q21 Financial Results Conference Call & Webcast

August 5, 2021

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 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 presentation 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, and revenue goals, including as they are 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 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 or to treatment sites. 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, UK, 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, commercialization and manufacturing. Further, the results of earlier preclinical studies and/or clinical trials 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 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, 2020, and on Form 10-Q for the quarter ended June 30, 2021, 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.

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.

A RARE COMPANY

A leading fully integrated, global rare disease biotechnology company

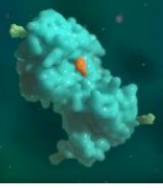
Galafold® (migalastat)
First Oral Precision Medicine for Fabry Disease

Gene Therapy PLATFORM
Protein Engineering & Glycobiology

World Class BIOLOGICS Capabilities

EMPLOYEES in 27 Countries

AT-GAA
Registration in Pompe Disease



GLOBAL COMMERCIAL ORGANIZATION

Robust R&D Engine
50+ Lysosomal Disorders and More Prevalent Rare Diseases

$383M
Cash
as of 6/30/21

Two Clinical-Stage Gene Therapies

2021 Key Strategic Priorities

1. Achieve double-digit Galafold growth and revenue of $300M to $315M
2. Report data from the AT-GAA Phase 3 PROPEL study and complete BLA and MAA filings for regulatory approvals
3. Advance clinical studies, regulatory discussions and scientific data across industry leading gene therapy pipeline
4. Further manufacturing capabilities and capacity to build world-class technical operations to support all gene therapy programs
5. Maintain strong financial position

Galafold® (migalastat) Global Launch…

…taking a leadership role in the treatment of Fabry disease

"We push ideas as far and as fast as possible"
- Amicus Belief Statement

Galafold Snapshot (as of June 30, 2021)

Galafold is an orally delivered small molecule precision medicine with a unique mechanism of action for Fabry patients with amenable variants that replaces the need for intravenously delivered ERT

One of the Most Successful Rare Disease Launches

Galafold is indicated for adults with a confirmed diagnosis of Fabry Disease and an amenable mutation/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.

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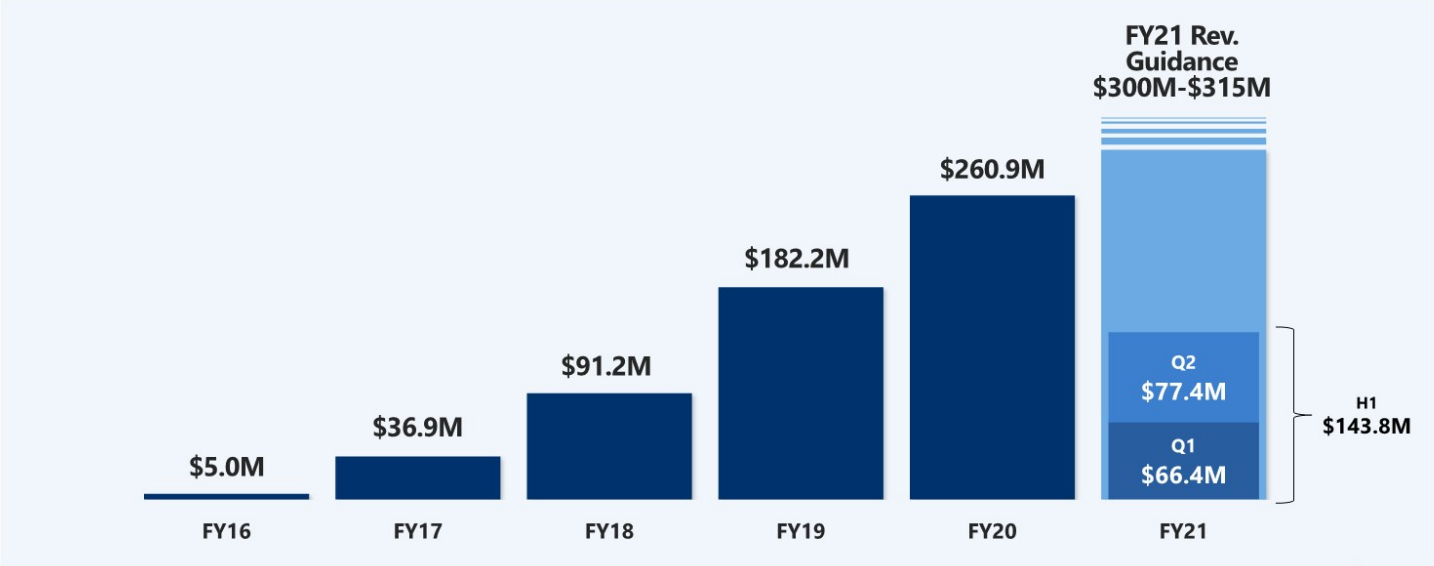
Galafold Success and FY21 Revenue Guidance

Galafold momentum remains on track to achieve full year 2021 revenue guidance



Outlook for 2021

Continued double-digit Galafold revenue growth to $300M-$315M in 2021

- Global demand remains strong with 1H21 revenue growth rate of 17% and continued growth anticipated in 2021 and beyond
- Net new international patients in June was the second-best month since launch
- In 2021, project double-digit revenue growth with net new patient starts expected to be greater than in 2020
- Expanded EU label following the European Commission approval for use in adolescents
- COVID continues to impact time between patient identification and treatment initiation
- Expect higher patient adds and revenue growth in the second half of 2021 as COVID impact eases
- Continue to see >90% compliance and adherence rates globally

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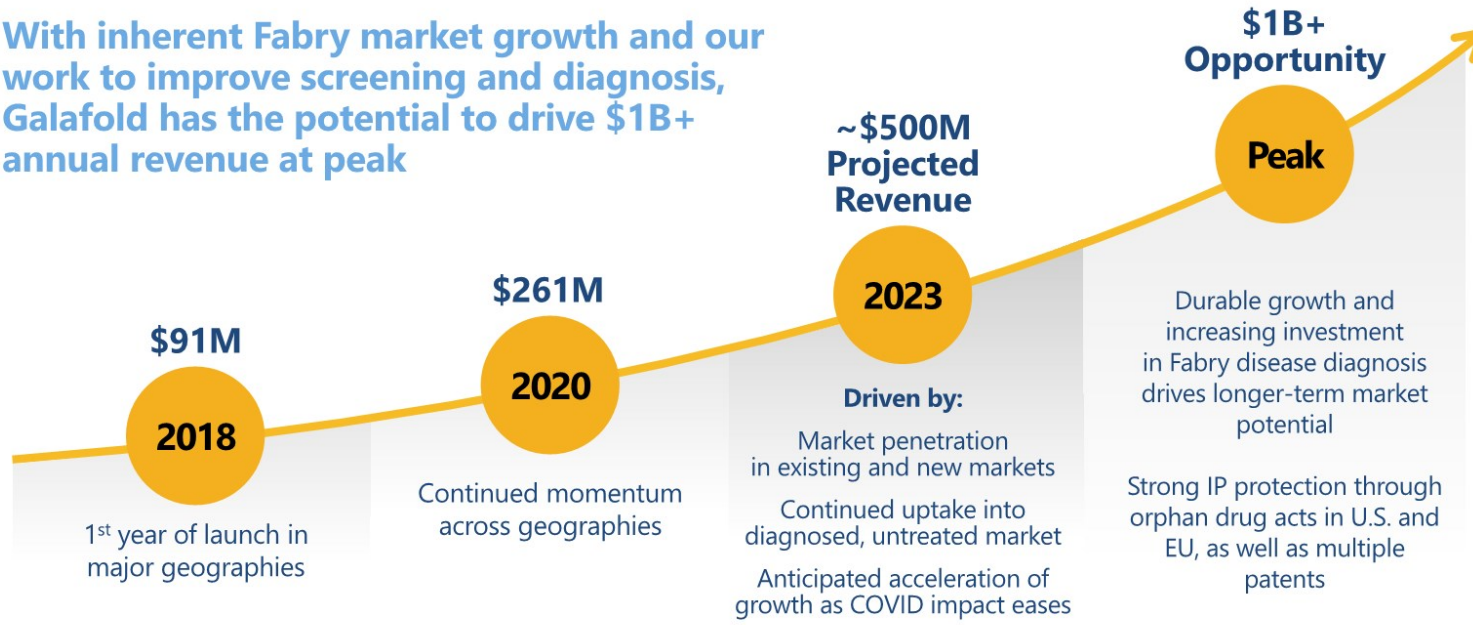
Galafold Opportunity

With inherent Fabry market growth and our work to improve screening and diagnosis, Galafold has the potential to drive $1B+ annual revenue at peak

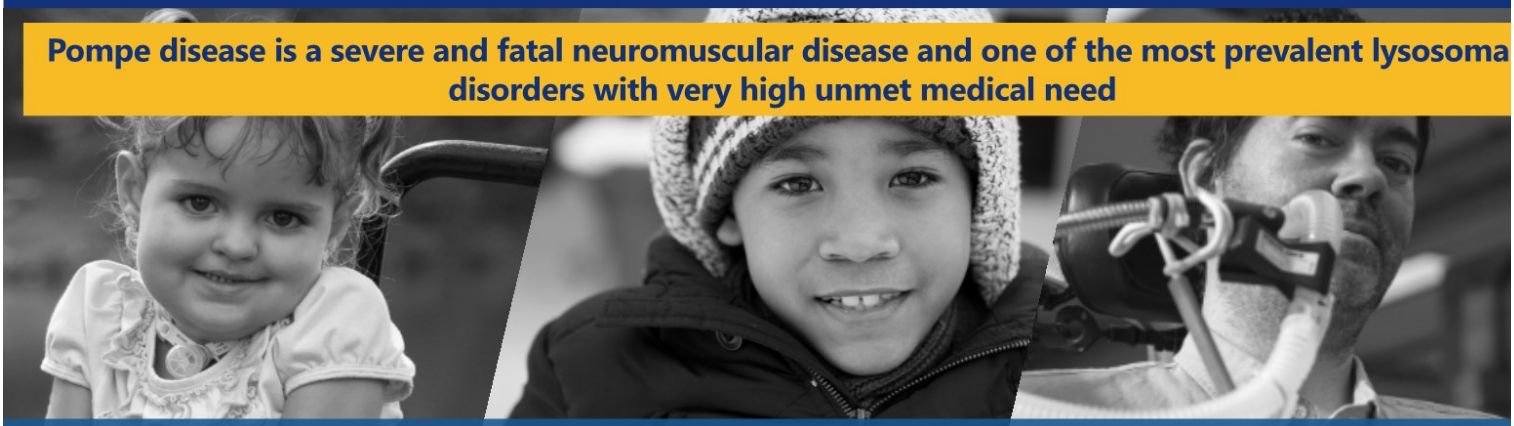


AT-GAA: Next Potential Standard of Care for Pompe Disease

"We encourage and embrace constant innovation"
- Amicus Belief Statement

Pompe Disease Overview

Pompe disease is a severe and fatal neuromuscular disease and one of the most prevalent lysosoma disorders with very high unmet medical need



- 5,000 – 10,000+ patients diagnosed WW[1]; newborn screening suggests underdiagnosis
- Age of onset ranges from infancy to adulthood
- 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 glycogen accumulation and cellular dysfunction
- Symptoms include muscle weakness, respiratory failure and cardiomyopathy
- ~$1.1B+ global Pompe ERT sales[2]

1. National Institute of Neurological Disorders and Stroke (NIH). 2. Based on year ending June 30, 2021. Source: Sanofi Press Releases

Phase 3 PROPEL Study

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 in both the overall and ERT experienced populations

		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 ($P<0.05$)

Note: * Nominal P-value <0.05; based on LOCF means

Source: Presented at the *16th International Congress on Neuromuscular Diseases (ICNMD)* May 2021.

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AT-GAA: Next Steps

- Completed rolling BLA and NDA submissions to the U.S. FDA
- Positive EMA rapporteur and co-rapporteur meeting supportive of MA submissions
- Granted positive scientific opinion through the Early Access to Medicines Scheme (EAMS) by the United Kingdom's MHRA
- 150+ patients worldwide now being treated with AT-GAA including adults, adolescents and infants
- Pediatric study for adolescents aged 12 to <18 with late-onset Pompe disease ongoing
- Clinical study for Pompe patients with infantile-onset disease expected to begin this year
- Expanded access program for infantile and adult-onset patients open and has enrolled multiple patients with Pompe. Further expanded access for all Pompe patients being considered.

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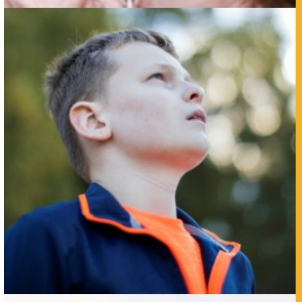
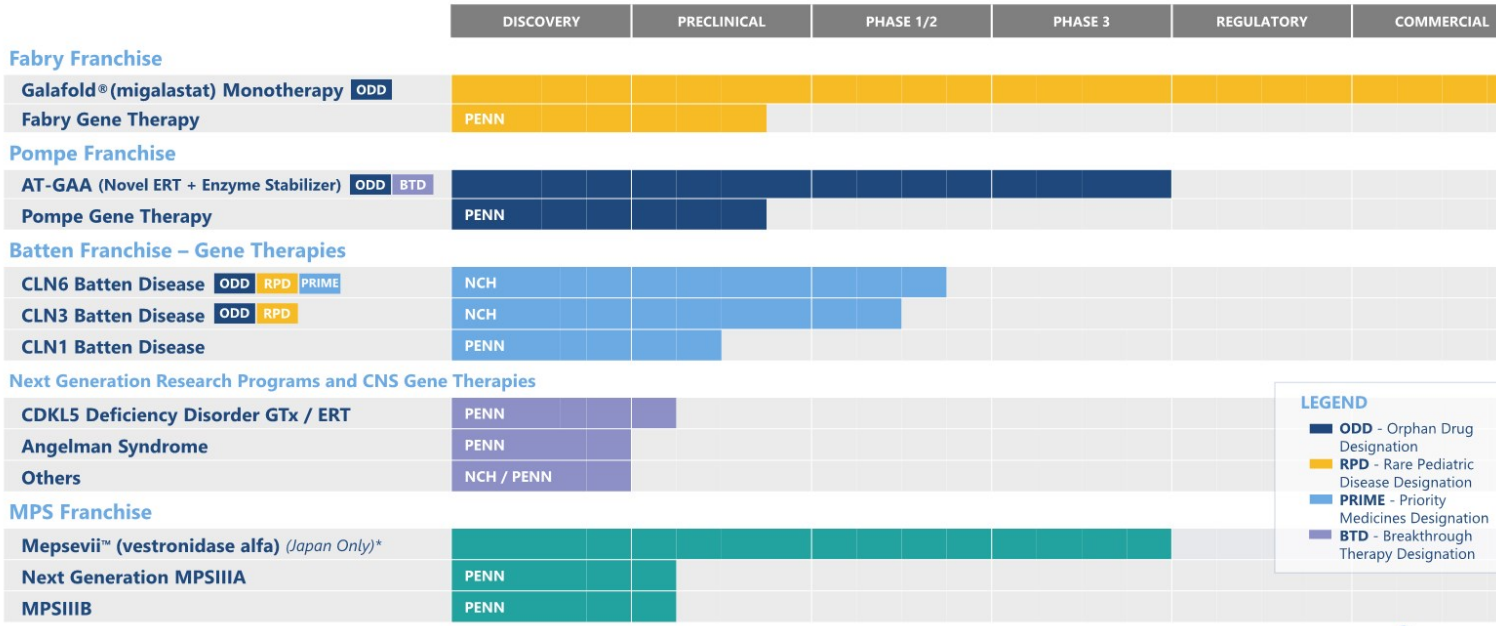


Next Generation Gene Therapy Platform

"We have a duty to obsolete our own technologies"
- Amicus Belief Statement

Next Generation Gene Therapy Platform

A RARE PORTFOLIO



*Exclusive license from Ultragenyx for Japanese rights to Mepsevii™, investigator-sponsored trial in Japan underway

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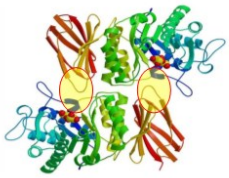
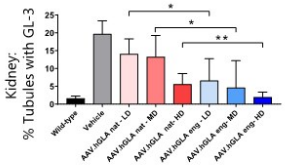
Amicus Protein Engineering Expertise & Technologies for Gene Therapy

Differentiated gene therapy approach for greater potency and optimized cross correction through transgene engineering for stability and targeting

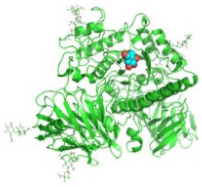
Fabry Gene Therapy

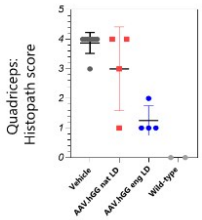




- Proprietary AAV capsid
- Pantropic capsid and ubiquitous promoter
- Engineered hGLA transgene at dimer interface designed for improved stability and optimized cross correction
- Preclinical data demonstrate robust substrate reduction across all Fabry disease relevant tissues, including first evidence of dorsal root ganglia storage reduction
- IND expected in 2H2022

Pompe Gene Therapy





- Proprietary AAV capsid
- Pantropic capsid and ubiquitous promoter
- Engineered hGAA transgene with cell receptor binding motif designed for improved uptake and optimized cross correction
- Preclinical data demonstrate robust glycogen reduction in all key Pompe disease tissues, including reduction in neurons of central nervous system
- IND enabling work underway

Note: Data from studies in KO GLA and GAA mice

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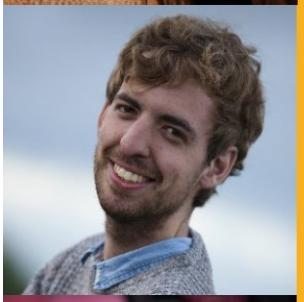
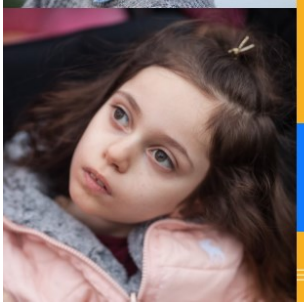




Financial Summary

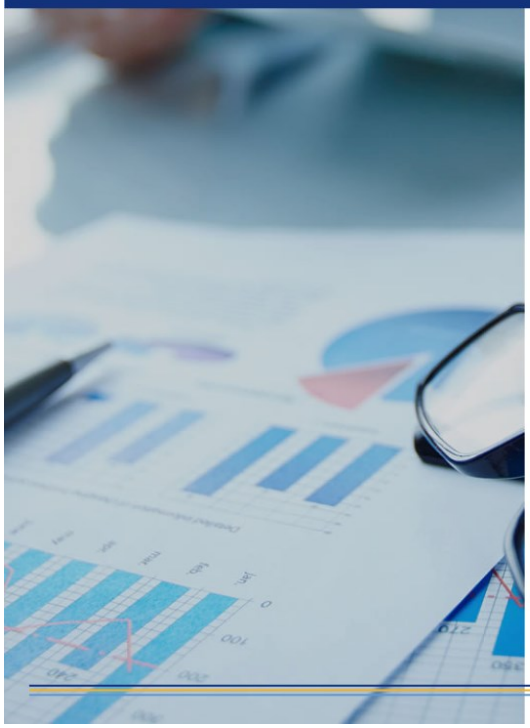
"We are business led and science driven"
- Amicus Belief Statement

2Q21 Select Financial Results

2Q21 revenue of $77.4M and growth rate of 24% primarily from global Galafold sales

(in thousands, except per share data)	Jun. 30, 2021	Jun. 30, 2020
Product Revenue	$77,413	62,353
Cost of Goods Sold	8,380	6,676
R&D Expense	63,003	69,611
SG&A Expense	42,276	34,657
Changes in Fair Value of Contingent Consideration	1,021	715
Depreciation and Amortization	1,567	2,039
Loss from Operations	(38,834)	(51,345)
Income Tax Expense	(4,525)	(3,703)
Net Loss	(51,225)	(52,492)
Net Loss Per Share	(0.19)	(0.20)

Financial Outlook: Key Takeaways



- Reaffirming full-year Galafold revenue guidance of $300 million to $315 million
- Non-GAAP operating expense guidance for 2021 is expected to remain flat at $410 million to $420 million
  - Driven by disciplined expense management and continued investment in the global Galafold launch, AT-GAA clinical studies and pre-launch activities and progressing the gene therapy pipeline
- Current cash position is sufficient to achieve self-sustainability without the need for any future dilutive financing

Closing Remarks

"We believe in our future to build long-term value for our stakeholders"
- Amicus Belief Statement

Thank You

"Our passion for making a difference unites us"

-Amicus Belief Statement

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Appendix

Reconciliation

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Total operating expenses - as reported GAAP	**$ 107,867**	**$ 107,022**	**$ 220,785**	**$ 239,052**
Research and development:				
Share-based compensation	3,152	3,362	9,457	8,615
Selling, general and administrative:				
Share-based compensation	8,584	5,046	22,633	12,389
Changes in fair value of contingent consideration payable	1,021	715	1,492	1,646
Depreciation and amortization	1,567	2,039	3,171	3,803
Total operating expense adjustments to reported GAAP	14,324	11,162	36,753	26,453
Total operating expenses - as adjusted	$ 93,543	$ 95,860	$ 184,032	$ 212,599