

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 8, 2024

AMICUS THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-33497
(Commission
File Number)

71-0869350
(I.R.S. Employer
Identification No.)

47 Hulfish Street, Princeton, New Jersey 08542
(Address of Principal Executive Offices, and Zip Code)

609-662-2000
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 8, 2024, Amicus Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended June 30, 2024. A copy of this press release is attached hereto as Exhibit 99.1. The Company will host a conference call and webcast on August 8, 2024 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 8, 2024
99.2	August 8, 2024 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 8, 2024

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



Amicus Therapeutics Announces Second Quarter 2024 Financial Results and Corporate Updates

Q2 2024 Total Revenue of \$126.7M, a 34% Increase Year-over-Year

Galafold® Q2 Revenue of \$110.8M, up 17% Year-over-Year

Pombiliti® + Opfolda® Q2 Revenue of \$15.9M, up 44% from Q1 2024

*Raising 2024 Total Revenue Growth Guidance to 26%-31% at CER
and 2024 Galafold Growth Guidance to 14%-18% at CER*

Narrowing non-GAAP Operating Expense Guidance to \$345M to \$360M

Non-GAAP Profitability Achieved in Q2 and H1 2024 with Acceleration Expected in H2

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

PRINCETON, NJ, August 8, 2024 – 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 second quarter ended June 30, 2024.

“In the first half of 2024 we demonstrated strong commercial execution, leading to robust revenue growth and achieving non-GAAP profitability for the period,” said Bradley Campbell, President and Chief Executive Officer of Amicus Therapeutics, Inc. “We are very pleased with the continued global uptake of Galafold and sustained patient demand leading to the increase of our 2024 guidance. The commercial launch of Pombiliti and Opfolda is performing exceptionally well with a steady addition of new patients in each of the approved markets. Looking ahead, we remain confident in our ability to deliver significant revenue growth, accomplish our objective of achieving full-year non-GAAP profitability and continuing to deliver on our mission for people living with rare diseases.”

Financial and Corporate Highlights:

- **Total revenue in the second quarter 2024** was \$126.7 million, a year-over-year increase of 34% from total revenue of \$94.5 million in the second quarter 2023. On a constant currency basis (CER)¹, second quarter 2024 total revenue growth was 36%. Given strong performance in the first half of 2024, the Company is raising its full year 2024 total revenue growth guidance to 26% to 31% on a constant currency basis (CER)¹.

(in thousands)	Three Months Ended June 30,		Year over Year % Growth		Six Months Ended June 30,		Year over Year % Growth	
	2024	2023	Reported	at CER ¹	2024	2023	Reported	at CER ¹
Galafold®	\$ 110,817	\$ 94,331	17%	19%	\$ 210,176	\$ 180,443	16%	17%
Pombiliti® + Opfolda®	\$ 15,852	\$ 172	n/a	n/a	\$ 26,896	\$ 330	n/a	n/a
Net Product Revenues	\$ 126,669	\$ 94,503	34%	36%	\$ 237,072	\$ 180,773	31%	32%

- **Galafold (migalastat) net product sales** were \$110.8 million in the second quarter 2024, a year-over-year increase of 17%, or 19% at constant exchange rates¹, reflecting continued strong demand. As a result of strong performance in the first half 2024, the company is raising its revenue growth guidance for Galafold to 14% to 18% on a constant currency basis (CER)¹.
- **Pombiliti (cipaglucosidase alfa-atga) + Opfolda (miglustat) net product sales** were \$15.9 million in the second quarter 2024, a 44% increase from the first quarter of 2024. As of the end of July, 186 patients have been treated or are scheduled to be treated with commercial product in five markets (USA, Germany, UK, Spain and Austria). Given strong launch momentum, the company is well on-track to achieve full year 2024 revenue guidance for Pombiliti + Opfolda of \$62 million to \$67 million on a constant currency basis (CER)¹.



- **Swissmedic in Switzerland approved Pombiliti + Opfolda on July 4th** as a long-term enzyme replacement therapy and enzyme stabilizer for adults with late-onset Pompe disease. Additional regulatory reviews are ongoing in Australia and Canada.
- **Total GAAP operating expenses** of \$100.4 million for the second quarter 2024 decreased by 4% as compared to \$104.2 million for the second quarter 2023. **Total non-GAAP operating expenses** of \$82.1 million for the second quarter 2024 decreased by 2% as compared to \$84.0 million for the second quarter 2023. Given our continued financial discipline in the first half of 2024, the Company enhances its non-GAAP Operating Expense guidance³ to \$345 million to \$360 million.
- **GAAP net loss** was \$15.7 million, or \$0.05 per share, for the second quarter 2024, and was reduced compared to a net loss of \$43.2 million, or \$0.15 per share, for the second quarter 2023.
- **Non-GAAP net income** was \$18.5 million, or \$0.06 per share, for the second quarter 2024, compared to a non-GAAP net loss of \$20.3 million, or \$0.07 per share, for the second quarter 2023². Non-GAAP profitability was also achieved in the first half 2024. The Company expects non-GAAP profitability to accelerate in the second half 2024.
- **Cash, cash equivalents, and marketable securities** totaled \$260.1 million at June 30, 2024, compared to \$286.2 million at December 31, 2023.

2024 Financial Guidance:

	Previous		Updated
Total Revenue Growth ¹	25% to 30%	→	26% to 31%
Galafold Revenue Growth ¹	13% to 17%	→	14% to 18%
Pombiliti + Opfolda Revenue ¹	\$62M to \$67M	→	\$62M to \$67M
Non-GAAP Operating Expense ³	\$345M to \$365M	→	\$345M to \$360M

Amicus is focused on the following key strategic priorities in 2024:

- Delivering double-digit Galafold revenue growth
- Executing multiple successful launches of Pombiliti + Opfolda
- Advancing ongoing studies to support medical and scientific leadership in Fabry and Pompe diseases
- Achieving full-year non-GAAP profitability⁴

¹ At constant exchange rates (CER). In order to illustrate underlying performance, Amicus discusses its results in terms of CER growth. This represents growth calculated as if the exchange rates had remained unchanged from those used in the comparative period. Full-year revenue guidance utilizes actual exchange rate as of December 31, 2023.

² Full reconciliation of GAAP results to the Company's non-GAAP adjusted measures for the reporting period(s) appear in the tables to this press release.

³ 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.

⁴ Based on projections of Amicus' non-GAAP Net (Loss) Income under current operating plans, which includes successful Pombiliti + Opfolda launch and continued Galafold growth. Amicus defines non-GAAP Net (Loss) Income as GAAP Net (Loss) 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, restructuring charges and income taxes.

Conference Call and Webcast

Amicus Therapeutics will host a conference call and audio webcast today, August 8, 2024, at 8:30 a.m. ET to discuss the second quarter 2024 financial results and corporate updates. Participants and investors interested in accessing the call by phone will need to register using the [online registration form](#). After registering, all phone participants will receive a dial-in number along with a PIN number to access the event.

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. An archived webcast and accompanying slides will be available on the Company's website shortly after the conclusion of the live event.

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 people living with Fabry disease may have amenable *GLA* variants, though amenability rates within this range vary by geography. Galafold is approved in more than 40 countries around the world, including the U.S., EU, U.K., and Japan.

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>

About Pombiliti + Opfolda

Pombiliti + Opfolda, is a two-component therapy that consists of cipaglucosidase alfa-atga, a bis-M6P-enriched rhGAA that facilitates high-affinity uptake through the M6P receptor while retaining its capacity for processing into the most active form of the enzyme, and the oral enzyme stabilizer, miglustat, that's designed to reduce loss of enzyme activity in the blood.

U.S. INDICATIONS AND USAGE

POMBILITI in combination with OPFOLDA is indicated for the treatment of adult patients with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) weighing ≥40 kg and who are not improving on their current enzyme replacement therapy (ERT).

SAFETY INFORMATION

HYPERSENSITIVITY REACTIONS INCLUDING ANAPHYLAXIS: Appropriate medical support measures, including cardiopulmonary resuscitation equipment, should be readily available. If a severe hypersensitivity reaction occurs, POMBILITI should be discontinued immediately and appropriate medical treatment should be initiated. **INFUSION-ASSOCIATED REACTIONS (IARs):** If severe IARs occur, immediately discontinue POMBILITI and initiate appropriate medical treatment. **RISK OF ACUTE CARDIORESPIRATORY FAILURE IN SUSCEPTIBLE PATIENTS:** Patients susceptible to fluid volume overload, or those with acute underlying respiratory illness or compromised cardiac or respiratory function, may be at risk of serious exacerbation of their cardiac or respiratory status during POMBILITI infusion. See PI for complete Boxed Warning. **CONTRAINDICATION:** POMBILITI in combination with Opfolda is contraindicated in pregnancy. **EMBRYO-FETAL TOXICITY:** May cause embryo-fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception during treatment and for at least 60 days after the last dose. **Adverse Reactions:** Most common adverse reactions ≥ 5% are headache, diarrhea, fatigue, nausea, abdominal pain, and pyrexia. Please see full PRESCRIBING INFORMATION, including BOXED WARNING, for POMBILITI (cipaglucosidase alfa-atga) [LINK](#) and full PRESCRIBING INFORMATION for OPFOLDA (miglustat) [LINK](#).



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 diseases. With extraordinary patient focus, Amicus Therapeutics is committed to advancing and expanding a pipeline of cutting-edge, first- or best-in-class medicines for rare diseases. For more information, please visit the company's website at www.amicusrx.com, and follow on [X](#) 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 use these non-GAAP measures as key performance measures for the purpose of evaluating operational performance and cash requirements internally. 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 and profitability 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 Statement

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 pricing and reimbursement authorities, are based on current information. 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 may not grant or may delay approval for our product candidates; the potential that required regulatory inspections may be delayed or not be successful and delay or prevent product approval; the potential that we may not be successful in negotiations with pricing and reimbursement authorities; the potential that we may not be successful in commercializing Galafold and/or Pombiliti and Opfoda in Europe, the UK, the US and other geographies; 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, the manufacturing, and commercialization of our products. With respect to statements regarding corporate financial guidance and financial goals and the expected attainment of such goals and projections of the Company's revenue, non-GAAP profitability 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, 2023, and on Form 10-Q for the quarter ended June 30, 2024, 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.

CONTACT:

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TABLE 1

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Net product sales	\$ 126,669	\$ 94,503	\$ 237,072	\$ 180,773
Cost of goods sold	11,261	9,114	24,828	16,056
Gross profit	115,408	85,389	212,244	164,717
Operating expenses:				
Research and development	24,683	35,149	53,012	76,648
Selling, general, and administrative	73,576	65,423	161,605	139,380
Changes in fair value of contingent consideration payable	—	337	—	588
Restructuring charges	—	—	6,045	—
Loss on impairment of assets	—	1,134	—	1,134
Depreciation and amortization	2,182	2,206	4,336	3,463
Total operating expenses	100,441	104,249	224,998	221,213
Income (loss) from operations	14,967	(18,860)	(12,754)	(56,496)
Other expense:				
Interest income	1,370	1,737	2,910	3,936
Interest expense	(12,512)	(12,492)	(24,948)	(24,336)
Other expense	(3,717)	(10,902)	(8,683)	(16,840)
Income (loss) before income tax	108	(40,517)	(43,475)	(93,736)
Income tax expense	(15,805)	(2,715)	(20,641)	(2,428)
Net loss attributable to common stockholders	\$ (15,697)	\$ (43,232)	\$ (64,116)	\$ (96,164)
Net loss attributable to common stockholders per common share — basic and diluted	\$ (0.05)	\$ (0.15)	\$ (0.21)	\$ (0.33)
Weighted-average common shares outstanding — basic and diluted	303,773,922	292,797,002	303,336,787	292,071,201

TABLE 2

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

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 209,335	\$ 246,994
Investments in marketable securities	50,727	39,206
Accounts receivable	85,174	87,632
Inventories	81,320	59,696
Prepaid expenses and other current assets	35,145	49,533
Total current assets	461,701	483,061
Operating lease right-of-use assets, net	22,611	26,312
Property and equipment, less accumulated depreciation of \$27,844 and \$25,429 at June 30, 2024 and December 31, 2023, respectively	31,161	31,667
Intangible assets, less accumulated amortization of \$4,147 and \$2,510 at June 30, 2024 and December 31, 2023, respectively	18,853	20,490
Goodwill	197,797	197,797
Other non-current assets	17,361	18,553
Total Assets	\$ 749,484	\$ 777,880
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 32,057	\$ 15,120
Accrued expenses and other current liabilities	127,897	144,245
Operating lease liabilities	8,112	8,324
Total current liabilities	168,066	167,689
Long-term debt	388,939	387,858
Operating lease liabilities	47,007	48,877
Other non-current liabilities	12,949	13,282
Total liabilities	616,961	617,706
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.01 par value, 500,000,000 shares authorized, 296,428,877 and 293,594,209 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	2,923	2,918
Additional paid-in capital	2,868,925	2,836,018
Accumulated other comprehensive income (loss):		
Foreign currency translation adjustment	8,991	5,429
Unrealized loss on available-for-sale securities	(197)	(188)
Warrants	71	71
Accumulated deficit	(2,748,190)	(2,684,074)
Total stockholders' equity	132,523	160,174
Total Liabilities and Stockholders' Equity	\$ 749,484	\$ 777,880

TABLE 3

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Total operating expenses - as reported GAAP	\$ 100,441	\$ 104,249	\$ 224,998	\$ 221,213
Research and development:				
Stock-based compensation	3,061	4,117	7,932	12,607
Selling, general and administrative:				
Stock-based compensation	13,136	12,460	39,068	38,864
Loss on impairment of assets	—	1,134	—	1,134
Changes in fair value of contingent consideration payable	—	337	—	588
Restructuring Charges	—	—	6,045	—
Depreciation and amortization	2,182	2,206	4,336	3,463
Total operating expense adjustments to reported GAAP	18,379	20,254	57,381	56,656
Total operating expenses - as adjusted	\$ 82,062	\$ 83,995	\$ 167,617	\$ 164,557

TABLE 4

Amicus Therapeutics, Inc.
Reconciliation of Non-GAAP Financial Measures
(in thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2024	2023	2024	2023
GAAP net loss	\$ (15,697)	\$ (43,232)	\$ (64,116)	\$ (96,164)
Share-based compensation	16,197	16,577	47,000	51,471
Changes in fair value of contingent consideration payable	—	337	—	588
Depreciation and amortization	2,182	2,206	4,336	3,463
Loss on impairment of assets	—	1,134	—	1,134
Restructuring charges	—	—	6,045	—
Income tax expense	15,805	2,715	20,641	2,428
Non-GAAP net income (loss)	\$ 18,487	\$ (20,263)	\$ 13,906	\$ (37,080)
Non-GAAP net income (loss) attributable to common stockholders per common share — basic and diluted	\$ 0.06	\$ (0.07)	\$ 0.05	\$ (0.13)
Weighted-average common shares outstanding — basic and diluted	303,773,922	292,797,002	303,336,787	292,071,201

AT THE FOREFRONT OF
THERAPIES FOR RARE DISEASES

2Q24 Results Conference Call & Webcast

August 8, 2024



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 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 pricing and reimbursement authorities, are based on current information. 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 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 may not grant or may delay approval for our product candidates; the potential that required regulatory inspections may be delayed or not be successful and delay prevent product approval; the potential that we may not be successful in negotiations with pricing and reimbursement authorities; the potential that we may not be successful commercializing Galafold® and/or Pombiliti® and Opfolda® in Europe, the UK, the US and other geographies; 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, the manufacturing, and commercialization of our products. With respect to statements regarding corporate financial guidance and financial goals and the expected attainment of such goals and projections of the Company's revenue, non-GAAP profitability 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, 2023, and on Form 10-Q for the quarter ended June 30, 2024, 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 a 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 and 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 biotech company projected to deliver 2024 total revenue growth of 26%-31%¹



2024 Strategic Priorities

A Transformative
Year Ahead for
Amicus

- 1 Galafold[®] revenue growth of 11-16% at CER¹, now raised to 14%
- 2 Execute multiple successful launches of Pombiliti[®] + Opfolda[®]
- 3 Advance ongoing studies to support medical and scientific leadership in Fabry and Pompe diseases
- 4 Achieve non-GAAP profitability for the full year

Galafold[®] (*migalastat*)

Continued Growth

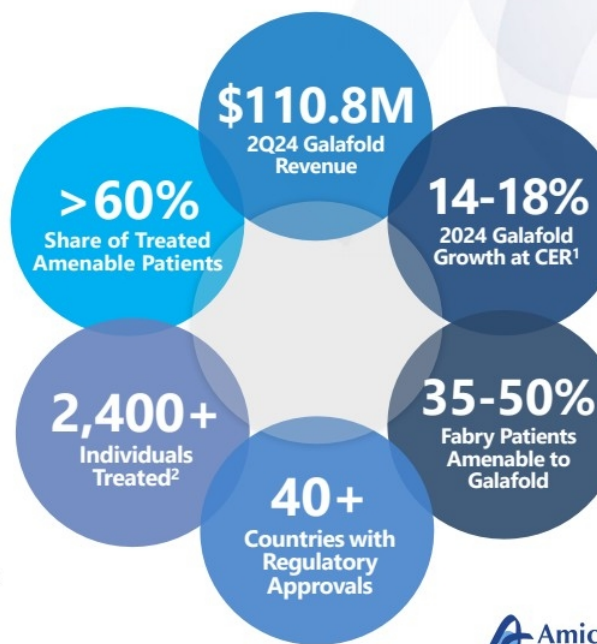
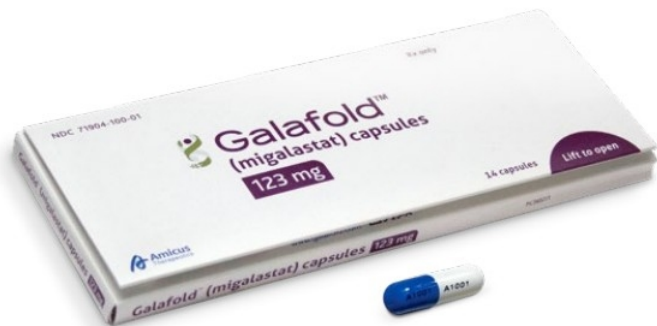
Building a leadership position
in the treatment of Fabry disease



 Amicus
Therapeutics

Galafold is the only approved oral treatment option in Fabry disease

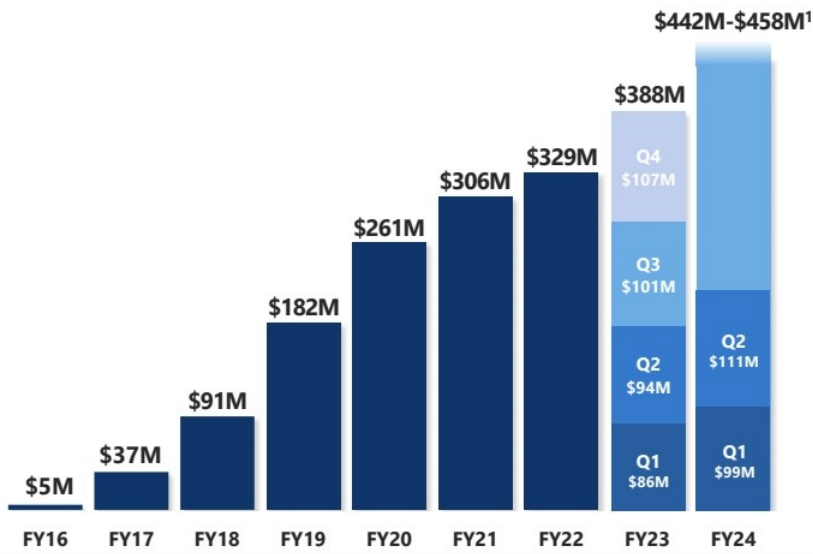
A unique mechanism of action for Fabry patients with amenable variants



Galafold is indicated for adults with a confirmed diagnosis of Fabry disease and an amenable variant. The most common adverse reactions reported with Galafold (≥10%) were headache, nasopharyngitis, urinary tract infection, nausea, and pyrexia. For additional information about Galafold, including the full U.S. Prescribing Information, please visit <https://www.amicusrx.com/pi/Galafold.pdf>. For further important safety information for Galafold, including posology and method of administration, special warnings, drug interactions, and adverse drug reactions, please see the European SmPC for Galafold available from the EMA website at www.ema.europa.eu.

Galafold Performance

Q2 2024 Galafold reported revenue of \$110.8M (+19% growth at CER)



- Global mix of switch (~42%) and previously untreated patients (~58%)²
- Expect non-linear quarterly growth to continue due to uneven ordering patterns and FX fluctuations

Raising FY 2024 Galafold growth guidance to 14%-18% at CER

Key Growth Drivers for 2024

Highest patient demand in last four years lays strong foundation for continued double-digit Galafold growth in 2024

- Expanding market through uptake in naïve population as well as geographic and label expansion
- Increasing patient identification through ongoing medical education, screening, and improved diagnostics
- Driving market share of treated amenable patients through excellent execution
- Maintaining >90% adherence and compliance through HCP and patient education and support

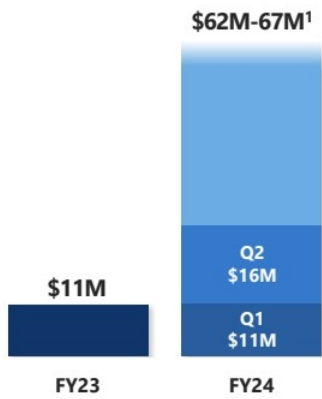
Pombiliti[®] (*cipaglucosidase alfa-atga*)
+
Opfolda[®] (*miglustat*)

Potential to establish a new standard of care
for people living with late-onset Pompe disease



Pombiliti + Opfolda Performance

Q2 2024 revenue of \$15.9M, up +44% from Q1, provides strong foundation for H2 2024



Pombiliti[®]
(cipaglucosidase alfa-atga)
+
Opfolda[®]
(miglustat) 65 mg capsules



Guiding to \$62M to \$67M in FY 2024 Pombiliti + Opfolda Revenue at CER

Successful Global Launch of Pombiliti + Opfolda Underway

Focus in 2024 is on maximizing the number of patients on therapy by year end



Patient Demand

As of end of July 2024

186 patients have been treated or scheduled to be treated with commercial product

~174 patients on treatment

Very positive feedback from real-world experience



KOL Outreach

Increasing depth and breadth of prescribers

Global number of prescribers increased 50% in Q2

Ongoing disease education

Building the body of real-world evidence



Access and Reimbursement

Positive interactions with global payors

Time through U.S. insurance process accelerating

Country-by-country reimbursement process underway

Multiple launches expected in H2 2024

Regulatory and Clinical Updates

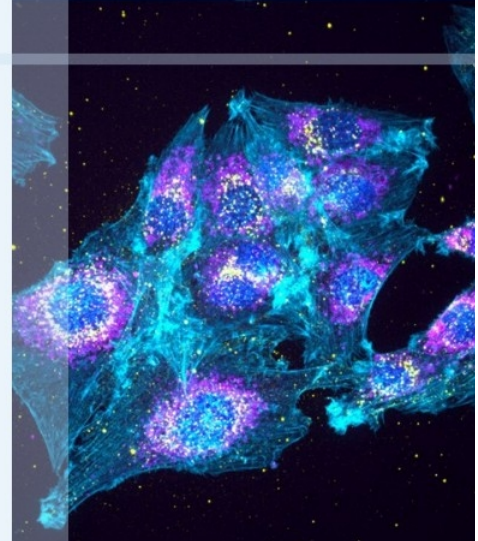
Continuing to build the body of evidence and expand commercial access

- Switzerland's Swissmedic approved Pombiliti + Opfolda on July 4, 2024
- > 10 reimbursement dossiers and multiple regulatory submissions throughout 2024
- Ongoing clinical studies in children with late-onset Pompe disease (LOPD) and infantile-onset Pompe disease (IOPD)
- Amicus registry for Pompe disease to continue generating evidence on differentiated MOA and long-term effect



Corporate Outlook

Delivering on our mission for patients
and shareholders



Q2 2024 Select Financial Results

Q2 2024 revenue of \$126.7M, up 34% and net loss reduced

<i>(in thousands, except per share data)</i>	Q2'24		H1'24	
	Jun. 30, 2024	Jun. 30, 2023	Jun. 30, 2024	Jun. 30, 2023
GAAP net product sales	\$ 126,669	\$ 94,503	\$ 237,072	\$ 180,773
GAAP cost of goods sold	11,261	9,114	24,828	16,056
GAAP operating expenses	100,441	104,249	224,998	221,213
Non-GAAP operating expenses	82,062	83,995	167,617	164,557
GAAP net loss	(15,697)	(43,232)	(64,116)	(96,164)
Non-GAAP net income (loss)	18,487	(20,263)	13,906	(37,080)
GAAP net loss per share	\$ (0.05)	\$ (0.15)	\$ (0.21)	\$ (0.33)
Non-GAAP net income (loss) per share	\$ 0.06	\$ (0.07)	\$ 0.05	\$ (0.13)

Updated Full-Year 2024 Guidance

	Updated Guidance	Previous Guidance
Total Revenue Growth¹	26% to 31%	25% to 30%
Galafold Revenue Growth¹	14% to 18%	13% to 17%
Pombiliti + Opfoda Revenue¹	\$62M to \$67M	\$62M to \$67M
Non-GAAP Operating Expense	\$345M to \$360M	\$345M to \$365M

Guiding to full-year 2024 non-GAAP profitability

Positioned for Significant Value Creation in 2024

Unlocking the value of two unique commercial therapies in sizeable and growing markets



Accelerating
total revenue
growth



Delivering
full-year
non-GAAP¹
profitability



Clear line of
sight to
generating
positive
cashflow

Ultimate Measure of Success: Impacting the Lives of People Living with Rare Diseases



>350 Patients*

YE17



>2,600 Patients*

YE23



Many Thousands of Patients*

2024+

Appendix



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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Total operating expenses - as reported GAAP	\$ 100,441	\$ 104,249	\$ 224,998	\$ 221,213
Research and development:				
Stock-based compensation	3,061	4,117	7,932	12,607
Selling, general and administrative:				
Stock-based compensation	13,136	12,460	39,068	38,864
Loss on impairment of assets	—	1,134	—	1,134
Changes in fair value of contingent consideration payable	—	337	—	588
Restructuring Charges	—	—	6,045	—
Depreciation and amortization	2,182	2,206	4,336	3,463
Total operating expense adjustments to reported GAAP	18,379	20,254	57,381	56,656
Total operating expenses - as adjusted	\$ 82,062	\$ 83,995	\$ 167,617	\$ 164,557

Amicus Therapeutics, Inc.
Reconciliation of Non-GAAP Financial Measures
(in thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
GAAP net loss	\$ (15,697)	\$ (43,232)	\$ (64,116)	\$ (96,164)
Share-based compensation	16,197	16,577	47,000	51,471
Changes in fair value of contingent consideration payable	—	337	—	588
Depreciation and amortization	2,182	2,206	4,336	3,463
Loss on impairment of assets	—	1,134	—	1,134
Restructuring charges	—	—	6,045	—
Income tax expense	15,805	2,715	20,641	2,428
Non-GAAP net income (loss)	<u>\$ 18,487</u>	<u>\$ (20,263)</u>	<u>\$ 13,906</u>	<u>\$ (37,080)</u>
Non-GAAP net income (loss) attributable to common stockholders per common share — basic and diluted	\$ 0.06	\$ (0.07)	\$ 0.05	\$ (0.13)
Weighted-average common shares outstanding — basic and diluted	303,773,922	292,797,002	303,336,787	292,071,201

Environmental, Social, & Governance (ESG) Snapshot

Who We Serve

- Programs we invest in have 3 key characteristics:
- Address a rare genetic disease
 - First-in-class or best-in-class
 - Impart meaningful benefit for patients



Pledge for a Cure

Designate a portion of product revenue back into R&D for that specific disease until there is a cure.

Pricing PROMISE

Committed to never raising the annual price of our products more than consumer inflation.

Charitable Giving

(as of December 31, 2023)

Contributions allocated:

\$1,980,516 U.S.

\$706,417 Intl.

Expanded Access through July 2024:

39 patients / **16** countries

Amicus-supported community programs:

37

Volunteer hours (U.S.):

511

Environmental Management

Committed to producing transformative medicines for people living with rare diseases while practicing environmental responsibility and adhering to sustainability best practices in our operations.

Our mission is to drive sustainability with our partners by incorporating environmental and sustainability principles into all our commercial relationships

0% Amicus-owned Direct Manufacturing and Related Scope 1 and Scope 2 Emissions

(as of December 31, 2023)

Global Employees % Female Employees

517

58%

(as of June 30, 2024)

Board of Directors

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

Director Diversity

3 Female
1 Veteran Status
1 African American

89%

Board Independence

56%

Overall Board Diversity

Diversity, Equity, & Inclusion (DEI)

Pledge to support a more inclusive culture to improve our employees, our communities, and society.

We have embedded DEI into our units, our Belief Statement, and Focused B

Employee Recruitment, Engagement, & Retention

Leverage employee capabilities and expertise to promote a culture that drives performance and ultimately attracts, energizes, and retains critical talent.

Amicus is Certified as a **Great Place to Work** U.S., U.K., Italy, Germany, Spain, France, and J

Career Development

90% Employees say Amicus is a great place compared to 57% of employees at a top U.S.-based company

FX Sensitivity and Galafold Distribution of Quarterly Sales

Impact from Foreign Currency Q2 2024:

Currency Variances: USD/	Q2 2023	Q2 2024	YoY Variance
EUR	1.089	1.076	(1.1%)
GBP	1.251	1.262	0.8%
JPY	0.007	0.006	(11.9%)

Distribution of Galafold Revenue by Quarter over Past 5 Years:

	Q1	Q2	Q3	Q4
5 Year Avg.	22%	24%	26%	28%

Full-year 2024 Revenue Sensitivity

Given the high proportion of Amicus revenue Ex-US (>60%), a change in exchange rates of +/- 5% compared to year-end 2023 rates could lead to a ~\$15M move in global reported revenues in 2024.

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

