

**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): **February 26, 2016**

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
(IRS Employer Identification No.)

1 Cedar Brook Drive, Cranbury, NJ
(Address of Principal Executive Offices)

08512
(Zip Code)

Registrant's telephone number, including area code: **(609) 662-2000**

(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))

Item 2.02. Results of Operations and Financial Condition.

On February 26, 2016, Amicus Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter and full year ended December 31, 2015. A copy of this press release is attached hereto as Exhibit 99.1. The Company will also host a conference call and webcast on February 26, 2016 to discuss its fourth quarter results of operations.

In accordance with General Instruction B.2. of Form 8-K, the information in this Current Report on Form 8-K and the Exhibit 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 a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits: The Exhibit Index annexed hereto is incorporated herein by reference.

SIGNATURES

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: February 26, 2016

By: /s/ Ellen S. Rosenberg
Ellen S. Rosenberg
General Counsel and Corporate Secretary

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EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated February 26, 2016

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**Amicus Therapeutics Announces Full-Year 2015
Financial Results and Corporate Updates**

***Committee for Medicinal Products for Human Use (CHMP) Opinion
on Migalastat for Fabry Disease Likely in March***

Clinical Study Underway to Investigate Novel Enzyme Replacement Therapy for Pompe Disease

CRANBURY, NJ, February 26, 2016 — Amicus Therapeutics (Nasdaq: FOLD), a biotechnology company at the forefront of therapies for rare and orphan diseases, today announced financial results for the full year ended December 31, 2015. The Company also provided program updates and reiterated full-year 2016 net cash spend guidance.

John F. Crowley, Chairman and Chief Executive Officer of Amicus Therapeutics, Inc., stated, “Following our completion of an Oral Explanation at the February CHMP meeting earlier this week, we are likely to receive an Opinion for migalastat at the next CHMP meeting in late March. We continue to believe that the significant body of clinical data for migalastat supports approval in the EU for Fabry patients with amenable mutations. If we receive approval, our international leadership team is fully prepared for product launch. In Pompe disease, we are very pleased now to move our novel ERT into clinical studies. There remains such remarkable need for new treatment options in Pompe and it is a great milestone for us to advance the fight against this devastating disease with our first experimental biologic therapy. We are also very pleased with the significant advancements in our EB program, now firmly under Amicus leadership and with significant resources brought to bear to ensure the successful execution of this Phase 3 EB study. Together, these three lead rare disease programs in Fabry, Pompe, and EB have the potential to deliver significant value to patients and to our shareholders. Today, Amicus is strongly positioned to become one of the world’s leading biotechnology companies focused on rare and devastating diseases.”

2015 Full-Year Financial Results

- Cash, cash equivalents, and marketable securities totaled \$214.0 million at December 31, 2015 compared to \$169.1 million at December 31, 2014.
- Total operating expenses increased to \$130.4 million compared to \$69.9 million for the full year 2014 primarily due to increases in clinical development costs of the Fabry monotherapy program and manufacturing scale-up on the Pompe program.
- Net cash spend was \$91.8 million, below the full-year 2015 guidance range of \$100-110 million.
- Net loss was \$132.1 million, or \$1.20 per share, compared to a net loss of \$68.9 million, or \$0.93 per share, for the full year 2014.

2016 Financial Guidance

Cash, cash equivalents, and marketable securities totaled \$214.0 million at December 31, 2015 compared to \$169.1 million at December 31, 2014. The Company’s balance sheet was strengthened during 2015 with a \$258.8 million public offering. Amicus expects full-year 2016 net cash spend between \$135 million and \$155 million. The current cash position is projected to fund operations into mid-2017.

Program Highlights

Migalastat for Fabry Disease

Migalastat is an oral personalized medicine intended to treat Fabry disease in patients who have amenable genetic mutations. Amicus has built a commercial organization that is prepared to launch migalastat upon approval in the EU and other international territories.

The European Medicines Agency’s (EMA) review of the Marketing Authorisation Application (MAA) for migalastat is currently in progress. Amicus provided an Oral Explanation before the CHMP in February 2016, which included members of the Amicus team and Key Opinion Leaders from the Fabry treatment community. An Oral Explanation is part of the MAA process for many novel orphan drugs, and the Opinion will often follow in a subsequent CHMP meeting. Following the Oral

Explanation, Amicus is likely to receive the Opinion for migalastat at the next CHMP meeting (March 29 — April 1, 2016), which is consistent with prior Company guidance.

In the U.S., the Company is on track to complete the Integrated Safety Summary across all clinical studies as well as the additional data analyses from existing Phase 3 studies, as requested by the U.S. Food and Drug Administration (FDA). Specifically, the Company has collected and analyzed additional histopathology data and gastrointestinal symptom data, as well as longer-term renal and cardiac data across both Phase 3 clinical studies. The Company expects to meet with the FDA in the second quarter of 2016 to present these data and discuss a potential pathway to submit a New Drug Application (NDA) for migalastat in the U.S.

Anticipated Upcoming Fabry Disease Program Milestones:

- Oral presentations and posters at *WORLDSymposium™* 2016 in San Diego (February 29 — March 3, 2016)
- CHMP Opinion in EU
- FDA meeting and U.S. regulatory update

- Publication of migalastat Fabry Clinical Study 011 in top-tier medical journal

SD-101 for Epidermolysis Bullosa (EB)

SD-101 is a novel, late-stage, proprietary topical treatment and potential first-to-market therapy for EB. This investigational product was granted FDA Breakthrough Therapy designation in 2013 based on results from a Phase 2a study for the treatment of lesions in patients suffering with EB. SD-101 is the first-ever treatment in clinical studies to show improvements in wound closure across all major EB types. SD-101 is currently being investigated in a registration-directed Phase 3 study (SD-005) to support global regulatory submissions. The Company began a rolling NDA submission for SD-101 in the fourth quarter of 2015.

Anticipated 2016 EB Program Milestones:

- Amy Paller, MD, of the Northwestern University Feinberg School of Medicine to present Phase 2b (Study SD-003) data at the American Academy of Dermatology's Annual Meeting in Washington, D.C. on Sunday, March 6 at 2:24pm ET
- Completion of enrollment in Phase 3 study (mid-2016)
- Top-line Phase 3 data (2H16)

ATB200/AT2221 for Pompe Disease

Amicus is currently conducting a global clinical study (ATB200-02) to investigate ATB200/AT2221, a novel treatment paradigm that consists of ATB200, a uniquely engineered recombinant human acid alpha-glucosidase (rhGAA) enzyme with an optimized carbohydrate structure to enhance uptake, co-administered with AT2221, a pharmacological chaperone to improve activity and stability. Up to approximately a dozen clinical sites are expected to participate in this study. The study design is agreed to by both U.S. and EU regulators. Amicus completed Good Manufacturing Practice (GMP) production of ATB200 during 2015 to supply this clinical study in Pompe disease patients.

Anticipated 2016 Pompe Disease Program Milestones:

- Oral presentation and poster at *WORLDSymposium 2016*
- Interim and full data from clinical study ATB200-02

Conference Call and Webcast

Amicus Therapeutics will host a conference call and audio webcast today, February 26, 2016 at 8:30 a.m. ET to discuss full-year 2015 financial results and corporate updates. Interested participants and investors may access the conference call at 8:00 a.m. ET by dialing 877-303-5859 (U.S./Canada) or 678-224-7784 (international) participant code 52850523.

An audio webcast can also be accessed via the Investors section of the Amicus Therapeutics corporate web site at <http://www.amicusrx.com>, and will be archived for 30 days. Web participants are encouraged to go to the web site 15 minutes prior to the start of the call to register, download and install any necessary software. A telephonic replay of the call will be available for seven days beginning at 11:30 a.m. ET today. Access numbers for this replay are 855-859-2056 (U.S./Canada) and 404-537-3406 (international); participant code 52850523.

About Amicus Therapeutics

Amicus Therapeutics (Nasdaq: FOLD) is a biotechnology company at the forefront of therapies for rare and orphan diseases. The Company has a robust pipeline of advanced therapies for a broad range of human genetic diseases. Amicus' lead programs in development include the small molecule pharmacological chaperone migalastat as a monotherapy for Fabry disease, SD-101 for Epidermolysis Bullosa (EB), as well as novel enzyme replacement therapy (ERT) products for Fabry disease, Pompe disease, and other Lysosomal Storage Disorders.

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, products, the prospects and timing of the potential regulatory approval of our product candidates, commercialization plans, financing plans and the projected cash position for the Company. Such forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. 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 the expected timing of the EMA's final decision with respect to regulatory approval of migalastat in the European Union, 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 pre-clinical 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 EMA, may not grant or may delay approval for our product candidates; the potential that we may not be successful in commercializing our 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; and the potential that we will need additional funding to complete all of our studies. Further, the results of earlier preclinical studies and/or clinical trials may not be predictive of future results. With respect to statements regarding projections of the Company's 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, 2014 and Form 10-Q for the quarter ended June 30, 2015. 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:

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TABLE 1

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

	Years Ended December 31,		
	2015	2014	2013
Revenue:			
Research revenue	\$ —	\$ 1,224	\$ 363
Total revenue	<u>—</u>	<u>1,224</u>	<u>363</u>
Operating Expenses:			
Research and development	76,943	47,624	41,944
General and administrative	47,269	20,717	18,893
Changes in fair value of contingent consideration payable	4,377	100	—
Restructuring charges	15	(63)	1,988
Depreciation and amortization	1,833	1,547	1,719
Total operating expenses	<u>130,437</u>	<u>69,925</u>	<u>64,544</u>
Loss from operations	<u>(130,437)</u>	<u>(68,701)</u>	<u>(64,181)</u>
Other income (expenses):			
Interest income	929	223	174
Interest expense	(1,578)	(1,484)	(46)
Loss on extinguishment of debt	(952)	—	—
Change in fair value of warrant liability	—	—	908
Other expense	(80)	(77)	—
Loss before income tax benefit	<u>(132,118)</u>	<u>(70,039)</u>	<u>(63,145)</u>
Income tax benefit	<u>—</u>	<u>1,113</u>	<u>3,512</u>
Net loss attributable to common stockholders	<u>\$ (132,118)</u>	<u>\$ (68,926)</u>	<u>\$ 59,633)</u>
Net loss attributable to common stockholders per common share — basic and diluted	<u>\$ (1.20)</u>	<u>\$ (0.93)</u>	<u>\$ (1.16)</u>
Weighted-average common shares outstanding — basic and diluted	<u>109,923,815</u>	<u>74,444,157</u>	<u>51,286,059</u>

TABLE 2

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

	December 31,	
	2015	2014
Assets:		
Current assets:		
Cash and cash equivalents	\$ 69,485	\$ 24,074
Investments in marketable securities	144,548	127,601
Prepaid expenses and other current assets	2,568	2,902
Total current assets	<u>216,601</u>	<u>154,577</u>
Investments in marketable securities	—	17,464
Property and equipment, less accumulated depreciation and amortization of \$13,353 and \$11,520 at December 31, 2015 and 2014, respectively	6,178	2,811
In-process research & development	486,700	23,000
Goodwill	197,797	11,613
Other non-current assets	1,108	502
Total Assets	<u>\$ 908,384</u>	<u>\$ 209,967</u>
Liabilities and Stockholders' Equity		

Current liabilities:

Accounts payable and accrued expenses	\$ 32,216	\$ 16,345
Contingent consideration payable, current portion	41,400	—
Current portion of secured loan	—	3,840
Total current liabilities	73,616	20,185
Deferred reimbursements	35,756	36,620
Secured loan, less current portion	—	10,510
Due to related party	41,601	—
Contingent consideration payable	232,677	10,700
Deferred tax liability	176,219	9,186
Other non-current liability	681	588
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$.01 par value, 250,000,000 shares authorized, 125,027,034 shares issued and outstanding at December 31, 2015 Common stock, \$.01 par value, 125,000,000 shares authorized, 95,556,277 shares issued and outstanding at December 31, 2014,	1,306	1,015
Additional paid-in capital	917,454	568,743
Accumulated other comprehensive income	(115)	(132)
Warrants	8,755	—
Accumulated deficit	(579,566)	(447,448)
Total stockholders' equity	347,834	122,178
Total Liabilities and Stockholders' Equity	\$ 908,384	\$ 209,967