

**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): **March 3, 2015**

**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))

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**Item 2.02. Results of Operations and Financial Condition.**

On March 3, 2015, Amicus Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter and full year ended December 31, 2014. A copy of this press release is attached hereto as Exhibit 99.1. The Company will also host a conference call and webcast on March 3, 2015 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.

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**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: March 3, 2015

By: /s/ William D. Baird III  
William D. Baird III  
Chief Financial Officer

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**EXHIBIT INDEX**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated March 3, 2015

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**Amicus Therapeutics Announces Full-Year 2014  
Financial Results and Corporate Updates**

*MAA Submission for Migalastat Monotherapy for Fabry Disease on Track  
for Mid-2015 — FDA Meeting Scheduled in 1Q15 to Discuss U.S. Pathway*

*Next-Generation Pompe ERT Set to Enter Clinic in 2H15*

**CRANBURY, NJ, March 3, 2015** — Amicus Therapeutics (Nasdaq: FOLD), a biopharmaceutical company at the forefront of therapies for rare and orphan diseases, today announced financial results for the full-year ended December 31, 2014. The Company also provided program updates and reiterated full-year 2015 net cash spend guidance.

John F. Crowley, Chairman and Chief Executive Officer of Amicus Therapeutics, Inc., stated, “Our vision at Amicus is very clear: to build one of the most significant and lasting global biotechnology companies in the world, focused on transformational treatments for people living with devastating rare diseases. We will achieve this vision with world-class science and clinical medicine. To augment these areas of expertise we are currently in the process of building a global commercial leadership team. We remain on track for a mid-year marketing application in Europe for migalastat monotherapy for Fabry disease and we look forward to an upcoming meeting with the FDA to discuss a path forward for an NDA submission for migalastat monotherapy in the United States. We continue to believe firmly that the totality of the data with this important new precision medicine-based therapy should be available to Fabry patients in the U.S. as soon as possible. Finally, advancing our next-generation enzyme replacement therapy for people living with Pompe disease is a key priority and that important program remains on track. Indeed, a busy and important set of activities are ahead for the Amicus team this year. We hope that success in these endeavors will enhance the lives of many people living with Fabry and Pompe diseases.”

**Financial Highlights for Full Year Quarter Ended December 31, 2014**

- Cash, cash equivalents, and marketable securities totaled \$169.1 million at December 31, 2014 compared to \$82.0 million at December 31, 2013.
- Total operating expenses increased to \$69.9 million compared to \$64.5 million for the full-year 2013 primarily due to increases in preclinical and clinical development costs on the Fabry monotherapy and Pompe programs.
- Net cash spend was \$53.2 million, below the full-year 2014 guidance range of \$54-59 million.
- Net loss was \$68.9 million, or \$0.93 per share, compared to a net loss of \$59.6 million, or \$1.16 per share, for the full-year 2013.

**2015 Financial Guidance**

Cash, cash equivalents, and marketable securities totaled \$169.1 million at December 31, 2014 compared to \$82.0 million at December 31, 2013. The Company’s balance sheet was strengthened during 2014 with a \$40 million at-the-market (ATM) financing as well as a \$103.5 million public offering. Amicus expects full-year 2015 net cash spend between \$73 million and \$83 million. The current cash position is projected to fund operations into 2017.

**Program Highlights**

**Fabry Franchise**

Amicus is preparing to submit marketing applications for the oral pharmacological chaperone migalastat HCl (“migalastat”) as a precision medicine, orally bioavailable monotherapy for Fabry patients who have amenable mutations. Positive Phase 3 data in both treatment-naïve and ERT-switch patients have shown that treatment with migalastat has resulted in reductions in disease substrate, stability of kidney function, reduction in cardiac mass, and a positive impact in patient-reported outcomes in patients with amenable mutations. These results were recently featured in an oral presentation and 4 posters at *WORLDSymposium™* 2015 in February. For all other Fabry patients who do not have amenable mutations and cannot take monotherapy, Amicus is advancing migalastat in combination with ERT.

Anticipated 2015 Fabry Franchise Milestones:

- FDA meeting to review totality of migalastat monotherapy data and discuss regulatory approval pathway (1Q15)
- Migalastat monotherapy MAA submission (mid-2015)
- Initiation of longer-term Phase 2 study of oral migalastat co-administered with currently marketed ERTs (2H15)
- Internal development underway of next-generation ERT (bio-better Fabry ERT cell line for co-formulation with migalastat)

**Next-Generation ERT for Pompe Disease (ATB200 + Chaperone)**

Amicus is leveraging its biologics capabilities and CHART™ (Chaperone-Advanced Replacement Therapy) platform to develop a next-generation Pompe ERT. This ERT consists of a uniquely engineered recombinant human acid alpha-glucosidase (rhGAA) enzyme (designated ATB200) with an optimized carbohydrate structure to enhance uptake, administered in combination with a pharmacological chaperone to improve activity and stability. In preclinical studies, ATB200 demonstrated greater tissue enzyme levels and further substrate reduction compared to the current approved ERT for Pompe disease (alglucosidase alfa), which were further improved with the addition of a chaperone. Clinical studies of pharmacological chaperones in combination with currently marketed ERTs have established initial human proof-of-concept that a chaperone can stabilize enzyme activity and potentially improve ERT tolerability. An oral presentation and 2 posters highlighting these preclinical results were presented at *WORLDSymposium* 2015 in February.

Anticipated 2015 Pompe Program Milestones:

- Completion of GMP batch of ATB200 (1Q15)

- Completion of IND-enabling toxicology studies (mid-2015)
- Pre-IND meeting (mid-2015)
- Clinical study initiation (2H15)

### **Conference Call and Webcast**

Amicus Therapeutics will host a conference call and audio webcast today, March 3, 2015 at 5:00 p.m. ET to discuss full-year 2014 financial results and program updates. Interested participants and investors may access the conference call at 5:00 p.m. ET by dialing 877-303-5859 (U.S./Canada) or 678-224-7784 (international).

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 8:00 p.m. ET today. Access numbers for this replay are 855-859-2056 (U.S./Canada) and 404-537-3406 (international); participant code 94757702.

### **About Amicus Therapeutics**

Amicus Therapeutics (Nasdaq:FOLD) is a biopharmaceutical company at the forefront of therapies for rare and orphan diseases. The Company is developing novel, first-in-class treatments for a broad range of human genetic diseases, with a focus on delivering new benefits to individuals with lysosomal storage diseases. Amicus' lead programs in development include the small molecule pharmacological chaperone migalastat as a monotherapy for Fabry disease, as well as next-generation enzyme replacement therapy (ERT) products for Fabry disease, Pompe disease, and MPS-1.

### **Forward-Looking Statements**

This press release contains, and the accompanying conference call will contain, "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 relating to preclinical and clinical development of Amicus' candidate drug products, the timing and reporting of results from preclinical studies and clinical trials evaluating Amicus' candidate drug products, financing plans, and the projected cash position for the Company. Words such as, but not limited to, "look forward to," "believe," "expect," "anticipate," "estimate," "intend," "potential," "plan," "targets," "likely," "may," "will," "would," "should" and "could," and similar expressions or words identify forward-looking statements. 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 Amicus that any of its plans will be achieved. Any or all of the forward-looking statements in this press release may turn out to be wrong. They can be affected by inaccurate assumptions Amicus 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 the potential goals, progress, timing and results of preclinical studies and clinical trials, actual results may differ materially from those set forth in this release due to the risks and uncertainties inherent in the business of Amicus, 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 may not grant or may delay approval for our product candidates; the potential that preclinical and clinical studies could be delayed because we identify serious side effects or other safety issues; the potential that we will need additional funding to complete all of our studies and, our dependence on third parties in the conduct of our clinical studies. Further, the results of earlier preclinical studies and/or clinical trials may not be predictive of future results. With

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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. 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 Amicus undertakes no obligation to revise or update this news release to reflect events or circumstances after the date hereof. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.

#### **CONTACTS:**

##### **Investors/Media:**

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##### **Media:**

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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 December 31,

Twelve Months  
Ended December 31,

	2014	2013	2014	2013
<b>Revenue:</b>				
Research revenue	\$ —	\$ 324	\$ 1,224	\$ 363
Total revenue	<u>—</u>	<u>324</u>	<u>1,224</u>	<u>363</u>
<b>Operating Expenses:</b>				
Research and development	15,605	9,120	47,624	41,944
General and administrative	5,518	4,605	20,717	18,893
Change in fair value of contingent consideration	500	—	100	—
Restructuring charges	11	1,988	(63)	1,988
Depreciation and amortization	363	401	1,547	1,719
Total operating expenses	<u>21,997</u>	<u>16,114</u>	<u>69,925</u>	<u>64,544</u>
Loss from operations	(21,997)	(15,790)	(68,701)	(64,181)
<b>Other income (expenses):</b>				
Interest income	90	27	223	174
Interest expense	(378)	(20)	(1,484)	(46)
Change in fair value of warrant liability	—	34	—	908
Other (expense)	(47)	—	(77)	—
Loss before tax benefit	<u>(22,332)</u>	<u>(15,749)</u>	<u>(70,039)</u>	<u>(63,145)</u>
Benefit from income taxes	1,113	3,512	1,113	3,512
Net loss attributable to common stockholders	<u>\$ (21,219)</u>	<u>\$ (12,237)</u>	<u>\$ (68,926)</u>	<u>\$ (59,633)</u>
Net loss attributable to common stockholders per common share				
— basic and diluted	<u>\$ (0.24)</u>	<u>\$ (0.22)</u>	<u>\$ (0.93)</u>	<u>\$ (1.16)</u>
Weighted-average common shares outstanding — basic and diluted	<u>86,952,485</u>	<u>56,173,260</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, 2014	December 31, 2013
<b>Assets:</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 24,074	\$ 43,640
Investments in marketable securities	127,601	38,360
Receivable due from collaboration agreements	—	1,083
Prepaid expenses and other current assets	2,902	5,195
Total current assets	<u>154,577</u>	<u>88,278</u>
Investments in marketable securities	17,464	—
Property and equipment, less accumulated depreciation and amortization of \$11,520 and \$9,973 at December 31, 2014 and 2013, respectively	2,811	4,120
In-process research & development	23,000	23,000
Goodwill	11,613	11,613
Other non-current assets	502	552
<b>Total Assets</b>	<u>\$ 209,967</u>	<u>\$ 127,563</u>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current liabilities:</b>		
Accounts payable and accrued expenses	\$ 16,345	\$ 10,162
Current portion of secured loan	3,840	299
Total current liabilities	<u>20,185</u>	<u>10,461</u>
Deferred reimbursements, less current portion	36,620	36,677
Secured loan, less current portion	10,510	14,174
Contingent consideration payable	10,700	10,600
Deferred tax liability	9,186	9,186
Other non-current liability	588	714
<b>Commitments and contingencies</b>		
<b>Stockholders' equity:</b>		
Common stock, \$.01 par value, 125,000,000 shares authorized, 95,556,277 shares issued and outstanding at December 31, 2014, 61,975,416 shares issued and outstanding at December 31, 2013	1,015	679
Additional paid-in capital	568,743	423,593
Accumulated other comprehensive income	(132)	1
Deficit accumulated during the development stage	<u>(447,448)</u>	<u>(378,522)</u>
Total stockholders' equity	<u>122,178</u>	<u>45,751</u>
<b>Total Liabilities and Stockholders' Equity</b>	<u>\$ 209,967</u>	<u>\$ 127,563</u>

