

**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): **April 1, 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 April 1, 2016, Amicus Therapeutics, Inc. (the "Company") issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

**Item 8.01. Other Events.**

The information set forth in Item 2.02 is incorporated in this Item 8.01 by reference.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits:

<b>Exhibit No.</b>	<b>Description</b>
99.1	Press Release, dated April 1, 2016

**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: April 1, 2016

By: /s/ ELLEN S. ROSENBERG  
Name:

**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
99.1	Press Release, dated April 1, 2016



## Amicus Therapeutics Receives Positive CHMP Opinion for Approval of Migalastat in Patients with Fabry Disease in European Union

### *Broad Label for All Fabry Patients with an Amenable Genetic Mutation*

*Conference Call Today at 12:30 pm ET*

**CRANBURY, NJ, April 1, 2016** — Amicus Therapeutics (Nasdaq: FOLD), a biotechnology company at the forefront of rare and orphan diseases, today announced that the European Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion to approve the oral small molecule pharmacological chaperone migalastat as a first line therapy for Fabry disease in all patients who have an amenable genetic mutation. A final decision from the European Commission (EC) is expected in the second quarter of 2016, after which the Company will begin the country-by-country reimbursement processes. The label approved by the CHMP includes 269 Fabry causing mutations which represent up to half of all patients with Fabry disease.

“This positive CHMP opinion for migalastat is a huge milestone for the Fabry community and a significant step towards our vision to become a leading global biotechnology company focused on rare and devastating diseases,” said John F. Crowley, Chairman and Chief Executive Officer of Amicus Therapeutics, Inc. “Oral migalastat represents a groundbreaking approach to personalized medicine. We are very pleased that the CHMP has adopted a positive opinion to approve migalastat with a broad label that includes all 269 amenable mutations screened through our Amenability Assay, as well as a fully searchable Amenability website for physicians. These amenable genetic mutations are represented in an estimated 35% to 50% of the diagnosed Fabry population today, which is a significant opportunity for Amicus to deliver a therapy option for many patients in need. We are grateful for the ongoing support from the Fabry community to advance migalastat, in particular those patients who participated in the clinical studies of migalastat and their families. Our world-class commercial and business leadership team is already in place in key launch countries in Europe, and we look forward to a final EC decision in the coming months. We are fully prepared and sharply focused on the launch of migalastat to complete our transformation into a global commercial organization.”

“As a treating physician, and principal investigator for France in the clinical studies of migalastat over the past decade, I believe that the positive CHMP opinion is a significant milestone toward providing a novel personalized medicine for people affected by Fabry disease,” said Prof. Dominique P. Germain, MD, PhD, Division of Medical Genetics at the University of Versailles and Assistance Publique - Hôpitaux de Paris. “Migalastat is an oral pharmacological chaperone with a unique mechanism of action that has the potential to address unmet medical needs and may shift the treatment standard for Fabry patients who have amenable genetic mutations. An approval by the European Commission will allow many Fabry patients across Europe to access this novel treatment, a paradigm of precision medicine.”

The proposed full indication for migalastat is for long-term treatment of adults and adolescents aged 16 years and older with a confirmed diagnosis of Fabry disease (alpha-galactosidase A deficiency) and who have an amenable mutation. The CHMP Summary of Opinion includes information about the benefits of migalastat and can be found at [http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004059/smops/Positive/human\\_smop\\_000952.jsp&mid=WC0b01ac058001d127](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004059/smops/Positive/human_smop_000952.jsp&mid=WC0b01ac058001d127).

A copy of the European Medicine Agency’s (EMA) press release can be found at [http://www.ema.europa.eu/ema/index.jsp?curl=pages/news\\_and\\_events/news/2016/04/news\\_detail\\_002502.jsp&mid=WC0b01ac058004d5c1](http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2016/04/news_detail_002502.jsp&mid=WC0b01ac058004d5c1).

The CHMP based its opinion on clinical data from Phase 3 pivotal studies in both treatment naïve (Study 011, or FACETS) and enzyme replacement therapy (ERT) switch patients (Study 012, or ATTRACT), as well as ongoing long-term extension studies.

Based on the positive CHMP opinion, the company expects to increase net cash spend in support of commercialization activities. This increase in net cash spend on a go-forward basis is expected to be 10-15% over the company’s initial full-year 2016 net cash spend guidance of between \$135 million and \$155 million. The company’s first quarter 2016 net cash spend is expected to be consistent with the company’s assumptions in determining its initial full-year 2016 net cash spend guidance and further information will be provided in the company’s first quarter earnings release.

The CHMP is a scientific committee composed of representatives from the 28-member states of the EU, and Iceland and Norway. The committee reviews medical product applications on their scientific and clinical merit and provides advice to the EC, which has the authority to approve medicines for the EU. The EC, which generally follows the recommendation of the CHMP, is expected to make its final decision in the second quarter of 2016.

### **Conference Call and Webcast**

Amicus Therapeutics will host a conference call and audio webcast today, April 1, 2016 at 12:30 p.m. ET to discuss the positive CHMP opinion. Interested participants and investors may access the conference call at 12:30 p.m. ET by dialing 877-303-5859 (U.S./Canada) or 678-224-7784 (international).

An audio webcast and slide presentation 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 3:30 p.m. ET today. Access numbers for this replay are 855-859-2056 (U.S./Canada) and 404-537-3406 (international); conference ID: 83075996.

### **About Amenable Mutations**

A proprietary *in vitro* assay (Migalastat Amenability Assay) was used to classify more than 800 known GLA mutations as “amenable” or “not amenable” to treatment with migalastat, which will be categorized in the label. Upon final EC adoption, the GLA mutations will also be accessible by healthcare providers through a website.

The current labeling includes all 269 GLA mutations that have been identified and determined to be amenable based on the Migalastat Amenability Assay. These 269 mutations represent between 35% and 50% of the currently diagnosed Fabry population. Amicus expects to submit updates to the label as additional GLA mutations are identified and tested in the Migalastat Amenability Assay.

### **About Fabry Disease**

Fabry disease is an inherited lysosomal storage disorder caused by deficiency of an enzyme called alpha-galactosidase A (alpha-Gal A), which are the result of mutations in the GLA gene. The primary biological function of alpha-Gal A is to degrade specific lipids in lysosomes, including globotriaosylceramide (referred to here as GL-3 and also known as Gb<sub>3</sub>). Lipids that can be degraded by the action of alpha-Gal A are called “substrates” of the enzyme. Reduced or absent levels of alpha-Gal A activity lead to the accumulation of GL-3 in the affected tissues, including the central nervous system, heart, kidneys, and skin. Progressive accumulation of GL-3 is believed to lead to the morbidity and mortality of Fabry disease, including pain, kidney failure, heart disease, and stroke. The symptoms can be severe, differ from patient to patient, and begin at an early age. All Fabry disease is progressive and leads to organ damage regardless of the time of symptom onset.

### **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, 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. 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 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 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

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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, 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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