

**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): **June 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))

Item 8.01. Other Events.

On June 3, 2015, Amicus Therapeutics, Inc. (the "Company") issued a press release announcing the submission of a marketing authorization application for full approval of Fabry Monotherapy Galafold™ (Migalastat) in the European Union. A copy of this press release is attached hereto as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits.

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

Exhibit No.	Description
99.1	Press Release dated June 3, 2015 titled "Amicus Therapeutics Submits Marketing Authorization Application (MAA) for Full Approval of Fabry Monotherapy Galafold™ (Migalastat) in European Union."

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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: June 3, 2015

By: /s/ WILLIAM D. BAIRD III
Name: William D. Baird III
Title: Chief Financial Officer

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EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release dated June 3, 2015 titled "Amicus Therapeutics Submits Marketing Authorization Application (MAA) for Full Approval of Fabry Monotherapy Galafold™ (Migalastat) in European Union."



Amicus Therapeutics Submits Marketing Authorization Application (MAA) for Full Approval of Fabry Monotherapy Galafold™ (Migalastat) in European Union

MAA Submission Under “Accelerated Assessment”

Brand Name Galafold™ Approved by Regulatory Authorities in EU and U.S.

CRANBURY, NJ June 3, 2015 — Amicus Therapeutics (Nasdaq: FOLD), a biopharmaceutical company at the forefront of therapies for rare and orphan diseases, has submitted a marketing authorization application (MAA) to request full approval of the oral small molecule pharmacological chaperone Galafold (migalastat HCl) for Fabry patients who have amenable genetic mutations. The brand name Galafold has been approved by both the European Medicines Agency (EMA) as well as the U.S. Food and Drug Administration (FDA).

“This filing represents the single greatest milestone in the history of Amicus,” stated John F. Crowley, Chairman and Chief Executive Officer of Amicus Therapeutics. “The MAA submission for Galafold is the first marketing application for Amicus. This comprehensive regulatory submission is the result of the tireless efforts of so many Amicus employees, investigators, consultants and, most importantly, the Fabry patients who have volunteered to participate in our clinical trials over the years. Our goal now is crystal clear: to bring this novel small molecule, orally bioavailable personalized medicine to as many people living with this devastating genetic disease as quickly as possible. We could not be more proud of our team and thankful to the entire Fabry community as we are today.”

As previously announced, Galafold is the first investigational Fabry drug to be granted Accelerated Assessment in the EU. Under Accelerated Assessment, the Committee for Medicinal Products for Human Use (CHMP) may shorten the MAA review period from 210 days, under standard review, to 150 days under Accelerated Assessment. The CHMP opinion is then reviewed by the European Commission, which generally issues a final decision on EU approval within three months. The MAA submission will be reviewed in the Centralized Procedure, which if authorized, provides a marketing license valid in all 28 EU member states. Once authorized, Amicus would then begin the country-by-country reimbursement approval process.

Amicus also plans to conduct a pre-NDA meeting with the US FDA and to submit a New Drug Application (NDA) for Galafold in the United States under Subpart H⁽¹⁾ in the second half of 2015.

Approximately 90 individuals around the world are currently being treated with Galafold as their only therapy for Fabry disease in ongoing long-term extension studies. Amicus previously reported positive Phase 3 data for Galafold in both treatment naïve (Study 011, or FACETS) and enzyme replacement therapy (ERT) switch patients (Study 012, or ATTRACT). Results from these studies have shown that treatment with Galafold has resulted in reductions in disease substrate, stability of kidney function, reduction in cardiac mass, and a positive impact on patient-reported outcomes in patients with amenable mutations.

Today approximately 5,000 to 10,000 individuals are diagnosed with Fabry disease, however, an estimated 40% to 50% of diagnosed patients are not currently on treatment. If approved, Amicus estimates that 30% to 50% of Fabry patients may benefit from Galafold on the basis of their genotype. Based on third party research, the Company also projects a 10% annual growth rate in diagnosis that is expected to continue.

About Fabry Disease

Fabry disease is an inherited lysosomal storage disorder caused by deficiency of an enzyme called alpha-galactosidase A (alpha-Gal A). 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 Gb3). 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. This

accumulation of GL-3 is believed to cause the various symptoms of Fabry disease, including pain, kidney failure, and increased risk of heart attack and stroke.

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 disorders. Amicus’ lead programs in development include the small molecule pharmacological chaperone Galafold™ (migalastat HCl) for Fabry disease, as well as next-generation enzyme replacement therapy (ERT) products for Fabry disease, Pompe disease, and MPS I.

(1)CFR - Code of Federal Regulations Title 21, www.fda.gov

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 Amicus’ candidate drug products, the timing and reporting of results from preclinical studies and clinical trials evaluating Amicus’ candidate drug products 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 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.

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