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): **July 11, 2017**

AMICUS THERAPEUTICS, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	
(State or Other Jurisdiction of Incorporation)	
001-33497	**71-0869350**
(Commission File Number)	(IRS Employer Identification No.)
1 Cedar Brook Drive, Cranbury, NJ	**08512**
(Address of Principal Executive Offices)	(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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company o

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. o

Item 8.01. Other Events.

On July 11, 2017, Amicus Therapeutics, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration (the "U.S. FDA") confirmed that the Company may submit new drug application for migalastat for Fabry Disease in the U.S. A copy of this press release is attached hereto as Exhibit 99.1.

The Company also provided an update on the European launch of Galafold that as of June 30, 2017, there were 151 patients on reimbursed Galafold.

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 July 11, 2017 titled "U.S. FDA Confirms Amicus Therapeutics May Submit New Drug Application for Migalastat for Fabry Disease."

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: July 11, 2017

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release dated July 11, 2017 titled "U.S. FDA Confirms Amicus Therapeutics May Submit New Drug Application for Migalastat for Fabry Disease."

U.S. FDA Confirms Amicus Therapeutics May Submit New Drug Application for Migalastat for Fabry Disease

Data Deemed Sufficient to Support NDA Submission

NDA Submission Targeted for 4Q17

Conference Call Today at 8:30am ET

CRANBURY, NJ, July 11, 2017 — Amicus Therapeutics (Nasdaq: FOLD) plans to submit a new drug application (NDA) to the U.S. FDA for the oral precision medicine migalastat for Fabry disease in the fourth quarter of 2017. Based on a series of discussions with and written communication received from the FDA, the Agency has informed Amicus that it may now submit an NDA for migalastat.

Amicus is preparing the NDA submission under Subpart H, which provides for accelerated approval. Amicus intends to base its NDA on existing data, including reduction in disease-causing substrate (GL-3), as well as the totality of data from completed clinical studies. 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. An additional Phase 3 study previously requested by the Agency to assess Gastrointestinal (GI) symptoms is no longer required prior to an NDA submission.

“This guidance from the FDA marks a tremendous step forward for thousands of people living with Fabry disease in the United States,” stated John F. Crowley, Chairman and Chief Executive Officer of Amicus Therapeutics. “We are moving ahead expeditiously with our NDA submission and accelerating the U.S. pathway for migalastat. Today is a seminal moment in the development of migalastat and a testament to the dedication and perseverance of the patients, physicians and employees who have worked so hard on the development of this precision medicine.”

Jay Barth, M.D., Chief Medical Officer of Amicus Therapeutics, stated, “The data from our clinical trials, including the two largest pivotal studies ever completed in Fabry disease, have already supported approvals for migalastat in the EU, Israel and Switzerland, as well as our pending regulatory submissions in Japan, Canada and Australia. The FDA’s willingness to review migalastat data reflects what we believe is the gold standard in science-based, data-driven, patient-centric therapeutic development. We believe that we have a robust data package for this NDA submission, and we look forward to advancing toward a planned pathway for U.S. approval for migalastat.”

An estimated 3,000 people in the U.S. are currently diagnosed with Fabry disease. The U.S. represents the single largest geography for Amicus to positively impact the lives of people with Fabry who have amenable mutations.

“I am very pleased that Amicus plans to submit the NDA for migalastat in the fourth quarter,” said Jack Johnson, Founder and Executive Director of the Fabry Support & Information Group (FSIG). “With significant unmet needs and a lack of treatment choices for people living with Fabry disease in the U.S., we may be one step closer to a new oral therapy. Amicus has been a true partner for the Fabry community for more than a decade, and I look forward to potentially having a new oral precision medicine available to patients with amenable mutations in the U.S.”

Migalastat is an oral precision medicine intended to treat Fabry disease in patients who have amenable genetic mutations. Migalastat works by stabilizing the body’s own dysfunctional enzyme, so it can clear the accumulated disease substrate in patients who have amenable mutations. An amenable mutation is one that is responsive to therapy with migalastat based on a proprietary *in vitro* assay. Amicus estimates that 35%-50% of Fabry patients globally may have amenable genetic mutations.

The European Commission (EC) has granted full approval for migalastat under the trade name Galafold® as a first line therapy for long-term treatment of adults and adolescents aged 16 years and older with a confirmed diagnosis of Fabry disease and who have an amenable mutation. Marketing applications have also been approved in several countries outside the EU, including Switzerland and Israel. Regulatory submissions are under review in additional countries including Japan, Canada and Australia.

Conference Call and Webcast
Amicus Therapeutics will host a conference call and webcast today, July 11, 2017 at 8:30 a.m. ET. Interested participants and investors may access the conference call by dialing 877-303-5859 (U.S./Canada) or 678-224-7784 (international); conference ID 52498209. An audio webcast can also be accessed via the Investors section of the Amicus Therapeutics corporate web site at http://ir.amicusrx.com/events.cfm, 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 nine 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); conference ID 52498209.

About Galafold™ and Amenable Mutations
Galafold® (migalastat) is a first-in-class chaperone therapy approved in the European Union as a monotherapy for Fabry disease in patients with amenable mutations. Galafold works by stabilizing the body’s own dysfunctional enzyme, so it can clear the accumulation of disease substrate in patients who have amenable mutations. A proprietary *in vitro* assay (Galafold Amenability Assay) was used to classify more than 800 known *GLA* mutations as “amenable” or “not amenable” to treatment with Galafold. The EU label includes 331 *GLA* mutations that have been identified and determined to be amenable based on the Galafold Amenability Assay, which represent between 35% and 50% of the currently diagnosed Fabry population.

Healthcare providers in the EU may access the website www.Galafoldamenabilitytable.com to quickly and accurately identify which mutations are categorized as “amenable” or “not amenable” to Galafold. Amicus expects to submit additional updates to the EU label as additional *GLA* mutations are identified and tested in the Galafold Amenability Assay.

EU Important Safety Information

Treatment with Galafold should be initiated and supervised by specialists experienced in the diagnosis and treatment of Fabry disease. Galafold is not recommended for use in patients with a non-amenable mutation.

- Galafold is not intended for concomitant use with enzyme replacement therapy.
- Galafold is not recommended for use in patients with Fabry disease who have severe renal impairment (<30 mL/min/1.73 m^2). The safety and efficacy of Galafold in children 0—15 years of age have not yet been established.
- No dosage adjustments are required in patients with hepatic impairment or in the elderly population.
- There is very limited experience with the use of this medicine in pregnant women. If you are pregnant, think you may be pregnant, or are planning to have a baby, do not take this medicine until you have checked with your doctor, pharmacist, or nurse.
- While taking Galafold, effective birth control should be used. It is not known whether Galafold is excreted in human milk.
- Contraindications to Galafold include hypersensitivity to the active substance or to any of the excipients listed in the PRESCRIBING INFORMATION.
- It is advised to periodically monitor renal function, echocardiographic parameters and biochemical markers (every 6 months) in patients initiated on Galafold or switched to Galafold.
- OVERDOSE: General medical care is recommended in the case of Galafold overdose.
- The most common adverse reaction reported was headache, which was experienced by approximately 10% of patients who received Galafold. For a complete list of adverse reactions, please review the SUMMARY OF PRODUCT CHARACTERISTICS.
- Call your doctor for medical advice about side effects.

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.

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 is 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_3). 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 may lead to organ damage regardless of the time of symptom onset.

About Amicus Therapeutics

Amicus Therapeutics (Nasdaq: FOLD) is a global 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) and biologic products for Fabry disease, Pompe disease, and other rare and devastating diseases.

Forward-Looking Statements

This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 relating to the clinical development, regulatory approval pathway, and prospects and timing of regulatory submission and approval of our product candidates for the treatment of Fabry disease. Any express or implied statements contained in this press release that are not statements of historical fact, including interpretation of guidance given by the U.S. FDA may be deemed forward-looking statements. The inclusion of forward-looking statements should not be regarded as a representation by us that any of our plans will be achieved in a timely manner or at all. 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, 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, changes in FDA guidance for regulatory approval, risks regarding the FDA’s interpretation of our clinical trial results, including the risk that results from completed clinical trials that supported approval by regulators in other jurisdictions will not be sufficient for U.S. FDA purposes, the risk that the FDA will require additional studies or data, the risk that the timing of an NDA will be delayed or not be accepted by the FDA, the potential that regulatory authorities, including the FDA, EMA, and PMDA, may not grant or may delay approval for our product candidate and the potential that we may not be successful in commercializing our product candidates for Fabry disease in Europe or any other country in which approval is ultimately obtained, if any. 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, 2016 and the Quarterly Report for the quarter ended March 31, 2017. The FDA guidance described in this release was given as of a specific date and the FDA could change its position on the clinical end points or other standards for review and/or approval. 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.

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