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): **August 10, 2018**

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 August 10, 2018, Amicus Therapeutics, Inc. (the "Company") issued a press release announcing that Galafold™ (migalastat) has been approved by the U.S. Food and Drug Administration for the treatment of certain adult patients with Fabry disease. A copy of this press release is attached as Exhibit 99.1. The Company will host a conference call on August 13, 2018 to discuss the approval.

Item 9.01Financial Statements and Exhibits

(d) Exhibits:

Exhibit No.	Description
99.1	Press Release dated August 10, 2018 titled "FDA Approves Galafold™ (migalastat) for the Treatment of Certain Adult Patients with 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: August 10, 2018

By: /s/ Ellen S. Rosenberg

Name: Ellen S. Rosenberg

Title: General Counsel and Corporate Secretary

Exhibit 99.1

FDA Approves Galafold™ (migalastat) for the Treatment of Certain Adult Patients with Fabry Disease

First Precision and First Oral Medicine for Fabry Disease Approved for 348 Amenable GLA Variants

Galafold is the First New Treatment Option for Fabry Disease in the U.S. in 15+ Years

Amicus Therapeutics to Host Conference Call on August 13 at 8 a.m. ET

CRANBURY, N.J., August 10, 2018 – Amicus Therapeutics (Nasdaq: FOLD) today announced that the U.S. Food and Drug Administration (FDA) has granted accelerated approval of Galafold™ (migalastat) 123 mg capsules. Galafold is an oral, precision medicine for the treatment of adults with a confirmed diagnosis of Fabry disease and an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data.

Galafold was approved under the Subpart H Accelerated Approval pathway based on reduction in kidney interstitial capillary cell globotriaosylceramide (KIC GL-3) substrate. As a condition of accelerated approval, Amicus Therapeutics will continue to study Galafold in a confirmatory Phase 4 program. Galafold is a capsule taken once every other day, at the same time of day. The FDA has approved Galafold for 348 amenable GLA variants. Galafold is the first oral medicine for Fabry disease, and the first new therapy approved to treat Fabry disease in the United States in more than 15 years.

John F. Crowley, Chairman and Chief Executive Officer of Amicus Therapeutics, Inc., stated, "This FDA approval of Galafold is a transformative moment for people in the U.S. living with Fabry disease, as it gives adult patients with amenable GLA variants a new treatment option for the first time in more than 15 years. The Fabry disease community has had an active voice in every stage of development of this medicine. We are grateful to this wonderful and passionate community, particularly the patients and physicians who have made this research possible through their participation in the clinical trials, as well as to the U.S. regulators and our ever-persistent and dedicated Amicus team. This achievement highlights our company's mission, which is focused on transforming the lives of people living with rare diseases. With our new and highly motivated U.S. leadership team, we are poised to make Galafold available to as many appropriate patients as possible."

Fabry disease is a rare, progressive genetic disorder characterized by a defective gene (GLA) that causes an enzyme deficiency. This enzyme is responsible for breaking down disease substrate that, when deficient in patients with Fabry disease, builds up in the kidneys, which is one of the organ systems impacted by Fabry disease. In the U.S., it is estimated that more than 3,000 people are living with Fabry disease, and an estimated more than 50 percent of these diagnosed patients are currently untreated. Globally, it is estimated that 35 to 50 percent of Fabry disease patients may have an amenable GLA variant.

"People with rare diseases often have limited treatment options, so research leading to new therapies is critical. As a physician and researcher, I treated the first patient ever to receive Galafold in a clinical trial. Today, many years later, I am pleased that more patients will have access to this precision medicine," said Raphael Schiffmann, M.D., M.H.Sc., Director, Baylor Scott & White Research Institute, Kimberly H. Courtwright and Joseph W. Summers Institute of Metabolic Disease – Dallas.

The FDA approval was based on data from a Phase 3 pivotal Fabry disease study in treatment-naïve patients (Study 011, or FACETS), which demonstrated the efficacy of Galafold, including a reduction in the amount of damaging disease substrate accumulated in the kidney capillaries. The most common side effects related to Galafold were headache, nasopharyngitis, urinary tract infection, nausea and pyrexia.

"Today is a long-awaited day of celebration for all of us living with and advocating for people with Fabry disease, especially those who have participated in the development of Galafold in the United States," said

Jack Johnson, Founder and Executive Director, Fabry Support & Information Group. "With the FDA approval of Galafold, certain members of the U.S. Fabry disease patient community finally have a second treatment option. Through their unwavering commitment and scientific innovation, Amicus has provided a much-needed new treatment option for many Fabry patients."

Amicus Therapeutics will launch Galafold immediately, and will begin shipping to a limited distribution network in the coming week. Amicus Assist, a service that will provide product assistance and support to patients to help gain access to Amicus Therapeutics' medications, will also be initiated immediately; for more information please call +1-833-AMICUS-A (+1-833-264-2872). With today's approval, patients in 20 countries worldwide have reimbursable access to Galafold. Galafold is approved in Australia, Canada, European Union, Israel, Japan, South Korea, Switzerland and the U.S. Galafold is pending approval in Taiwan.

Conference Call and Webcast
Amicus Therapeutics will host a conference call and audio webcast Monday, August 13, 2018, at 8:00 a.m. ET to discuss the FDA approval. Interested participants and investors may access the conference call by dialing +1-877-303-5859 (U.S./Canada) or +1-678-224-7784 (international), conference ID: 9782489.

An audio webcast can also be accessed via the Investors section of the Amicus Therapeutics corporate website at http://ir.amicusrx.com/, and will be archived for 30 days. Web participants are encouraged to go to the website 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 12:00 p.m. ET on August 13, 2018. Access numbers for this replay are +1-855-859-2056 (U.S./Canada) and +1-404-537-3406 (international); conference ID: 9782489.

About Galafold
Galafold™ (migalastat) 123 mg capsules is an oral pharmacological chaperone of alpha-Galactosidase A (alpha-Gal A) for the treatment of Fabry disease in adults who have amenable GLA variants. In these patients, Galafold works by stabilizing the body's own dysfunctional enzyme so that it can clear the accumulation of disease substrate. Globally, Amicus Therapeutics estimates that approximately 35 to 50 percent of Fabry patients may have amenable GLA variants, though amenability rates within this range vary by geography. Galafold is approved in Australia, Canada, European Union, Israel, Japan, South Korea, Switzerland and the U.S.

INDICATIONS AND USAGE
Galafold is indicated for the treatment of adults with a confirmed diagnosis of Fabry disease and an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data.

This indication is approved under accelerated approval based on reduction in kidney interstitial capillary cell globotriaosylceramide (KIC GL-3) substrate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

U.S. IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS
The most common adverse reactions reported with Galafold (≥10%) were headache, nasopharyngitis, urinary tract infection, nausea and pyrexia.

USE IN SPECIFIC POPULATIONS
There is insufficient clinical data on Galafold use in pregnant women to inform a drug-associated risk for major birth defects and miscarriage. Advise women of the potential risk to a fetus.

It is not known if Galafold is present in human milk. Therefore, the developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Galafold and any potential adverse effects on the breastfed child from Galafold or from the underlying maternal condition.

Galafold is not recommended for use in patients with severe renal impairment or end-stage renal disease requiring dialysis.

The safety and effectiveness of Galafold have not been established in pediatric patients.

To report Suspected Adverse Reactions, contact Amicus Therapeutics at 1-877-4AMICUS or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

For additional information about Galafold, including the full U.S. Prescribing Information, please visit https://www.amicusrx.com/pi/galafold.pdf.

About Fabry Disease
Fabry disease is a rare, progressive genetic disorder characterized by a defective gene (GLA) that causes an enzyme deficiency. This enzyme is responsible for breaking down disease substrate that, when deficient in patients with Fabry disease, builds up in the kidneys, which is one of the organ systems impacted by Fabry disease.

About Amicus Therapeutics
Amicus Therapeutics (Nasdaq: FOLD) is a global, patient-centric biotechnology company focused on discovering, developing and delivering novel high-quality medicines for people living with rare metabolic diseases. The cornerstone of the Amicus portfolio is Galafold, an oral precision medicine for people living with Fabry disease who have amenable GLA variants. The lead biologics program in the Amicus Therapeutics pipeline is AT-GAA, an investigational therapy for Pompe disease. Amicus Therapeutics is committed to advancing and expanding a robust pipeline of cutting-edge, first- or best-in-class medicines for rare metabolic diseases. For more information please visit the company's website at www.amicusrx.com.

Forward-Looking Statements
This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 relating to approval and commercialization plans for Galafold in the United States. 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, 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 we may not be successful in commercializing Galafold in the United States, the potential that public and commercial payors will not reimburse Galafold, the potential that we may not be able to manufacture or supply sufficient commercial products; and the potential that we will need additional funding to complete all of our commercialization and manufacturing activities. 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, 2017 as well as our Quarterly Report on Form 10-Q for the quarter ended June 30, 2018 filed August 7, 2018 with the Securities and Exchange Commission. 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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