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 8, 2021**

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

Delaware	001-33497	71-0869350
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

3675 Market Street, Philadelphia, PA 19104
(Address of Principal Executive Offices, and Zip Code)

215-921-7600
Registrant's Telephone Number, Including Area Code

(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock Par Value $0.01	FOLD	NASDAQ

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). Emerging growth company ☐

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. ☐

Item 8.01 – Other Events

On June 8, 2021, Amicus Therapeutics, Inc. issued a press release announcing the United Kingdom's Medicines and Healthcare Products Regulatory Agency has granted a positive scientific opinion through the Early Access to Medicines Scheme (EAMS) to AT-GAA. A copy of this press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits:

Exhibit No.	Description
99.1	Press Release dated June 8, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

Signature Page

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.

Date: June 8, 2021

AMICUS THERAPEUTICS, INC.
By: /s/ Ellen S. Rosenberg
Name: Ellen S. Rosenberg
Title: Chief Legal Officer and Corporate Secretary

Exhibit 99.1

Amicus Therapeutics Announces United Kingdom's MHRA Grants Early Access to AT-GAA

Permits All Eligible Individuals with Late-Onset Pompe Disease Access to AT-GAA Prior to Marketing Authorization in the UK

Positive Scientific Opinion Under Early Access to Medicines Scheme (EAMS) Recognizes High Unmet Medical Need in ERT Treated Late-Onset Pompe Disease Patients

Positive Scientific Opinion Includes MHRA Review of AT-GAA Phase 3 PROPEL Study Data

Philadelphia, PA, and Marlow, UK – June 8, 2021 (GLOBE NEWSWIRE) -- Amicus Therapeutics (Nasdaq: FOLD), a patient-dedicated global biotechnology company focused on discovering, developing and delivering novel medicines for rare diseases, today announced that the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) has granted a positive scientific opinion through the Early Access to Medicines Scheme (EAMS) to AT-GAA, the Company's investigational two-component therapy for the treatment of Pompe disease. This positive opinion means that eligible adults living with late-onset Pompe disease (LOPD) who have received alglucosidase alfa for at least 2 years can now switch and have access to AT-GAA prior to marketing authorization in the UK.

The EAMS mechanism is intended to provide individuals in the UK who live with a life threatening or seriously debilitating condition early access to innovative and unlicensed medicines for which there is not yet marketing authorization and where there is a clear unmet medical need.

John F. Crowley, Chairman and Chief Executive Officer of Amicus Therapeutics, stated, "We are pleased that the MHRA has recognized the potential of AT-GAA for individuals living with Late-Onset Pompe disease. This positive scientific opinion reaffirms that there is significant unmet medical need in Pompe disease today, and supports our strategy of advancing AT-GAA as quickly as possible to as many patients as possible. We are privileged to offer eligible patients in the UK access to this novel medicine prior to marketing authorization, reinforcing our commitment to people living with Pompe and other rare diseases."

"The EAMS positive scientific opinion from the MHRA is an important development for people living with Late-Onset Pompe disease. Alternative treatment options that have the potential to have a meaningful impact in managing this devastating neuromuscular disease are desperately needed, and this decision will allow eligible patients access to AT-GAA at the earliest opportunity," said Dr. Mark Roberts, Consultant Neurologist at the Greater Manchester Neurosciences Unit at Salford Royal NHS Foundation Trust.

"I am very pleased that the MHRA has granted this positive opinion to AT-GAA in ERT treated late-onset Pompe disease patients," said Allan Muir, Chair of the Board of Trustees of Pompe Support Network. "With significant unmet needs and a lack of treatment choices for people living with Pompe disease in the UK, we are closer to a new option for patients. Amicus has been a true partner for the Pompe community for more than a decade, and I look forward to potentially having a new therapy available in the UK."

The MHRA's decision is based on the evaluation of the effects of AT-GAA in LOPD patients and its safety profile, including data from both the Phase 1/2 and Phase 3 PROPEL study. Results from the global Phase 3 PROPEL clinical study of AT-GAA were presented at the 17th Annual WORLD*Symposium*™ 2021, held virtually February 8-12, 2021.

Marketing Authorization Applications for AT-GAA are expected to be submitted with the UK and EU, respectively, in the second half of 2021. For the full approval in the UK, Amicus will seek inclusion of the treatment population to all ERT-switch patients regardless of length of time on prior ERT, as well as the treatment naïve population. Future studies will also investigate the treatment of patients with Infantile Onset Pompe Disease. Previously, the MHRA has granted the PIM (Priority Innovative Medicines) designation to AT-GAA. Also, the U.S. FDA granted Breakthrough Therapy Designation to AT-GAA for the treatment of LOPD based on clinical efficacy results from the Phase 1/2 clinical study. A rolling Biologics License Application (BLA) for AT-GAA was initiated with the U.S. FDA in the fourth quarter of 2020 and is on track with submission of the final modules in the second quarter of 2021.

About AT-GAA

AT-GAA is an investigational two-component therapy that consists of cipaglucosidase alfa (ATB200), a recombinant human acid alpha-glucosidase (rhGAA) enzyme with optimized carbohydrate structures, particularly bis-phosphorylated mannose-6 phosphate (bis-M6P) glycans, to enhance uptake into cells, administered in conjunction with miglustat (AT2221), a stabilizer of cipaglucosidase alfa. In preclinical studies, AT-GAA was associated with increased levels of the mature lysosomal form of GAA and reduced glycogen levels in muscle, alleviation of the autophagic defect and improvements in muscle strength.

About Pompe Disease

Pompe disease is an inherited lysosomal disorder caused by deficiency of the enzyme acid alpha-glucosidase (GAA). Reduced or absent levels of GAA levels lead to accumulation of glycogen in cells, which is believed to result in the clinical manifestations of Pompe disease. The disease can be debilitating and is characterized by severe muscle weakness that worsens over time. Pompe disease ranges from a rapidly fatal infantile form with significant impacts to heart function to a more slowly progressive, late-onset form primarily affecting skeletal muscle. It is estimated that Pompe disease affects approximately 5,000 to 10,000 people worldwide.

About Amicus Therapeutics

Amicus Therapeutics (Nasdaq: FOLD) is a global, patient-dedicated biotechnology company focused on discovering, developing and delivering novel high-quality medicines for people living with rare metabolic diseases. With a patient focus, 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, and follow us on Twitter and LinkedIn.

Forward Looking Statement

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to top-line data from a global Phase 3 study to investigate AT-GAA for the treatment of Pompe Disease and the potential implications on these data for the future advancement and development of AT-GAA. Words such as, but not limited to, "look forward to," "believe," "expect," "anticipate," "estimate," "intend," "confidence," "encouraged," "potential," "plan," "targets," "likely," "may," "will," "would," "should" and "could," and similar expressions or words identify forward-looking statements. The forward looking statements included in this press release are based on management's current expectations and belief's which are subject to a number of risks, uncertainties and factors, including that the Company will not be able to successfully complete the development of, obtain regulatory approval for, or successfully manufacture and commercialize AT-GAA. In addition, all forward looking statements are subject to the other risks and uncertainties detailed in our Annual Report on Form 10-K for the year ended December 31, 2020 and Quarterly Report on 10-Q for the Quarter ended March 31, 2021. As a consequence, actual results may differ materially from those set forth in this press release. You are cautioned not to place undue reliance on these forward looking statements, which speak only of the date hereof. All forward looking statements are qualified in their entirety by this cautionary statement and we undertake no obligation to revise this press release to reflect events or circumstances after the date hereof.

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