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): **May 3, 2021**

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

Delaware
(State or Other Jurisdiction of Incorporation)

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 May 3, 2021, Amicus Therapeutics, Inc. issued a press release announcing the completion of a successful Type B Pre-Biologics License Application ("BLA") meeting with the U.S. Food and Drug Administration for AT-GAA (cipaglucosidase alfa co-administered with miglustat), its investigational two-component therapy for the treatment of Pompe disease. A copy of this press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits:

Exhibit No.	Description
99.1	Press Release dated May 3, 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.

AMICUS THERAPEUTICS, INC.

Date: May 3, 2021

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

Exhibit 99.1

Amicus Therapeutics Announces Successful Pre-BLA Meeting with U.S. FDA for AT-GAA for the Treatment of Pompe Disease

Existing Data Support Regulatory Submissions

Submissions to Seek Approval in both ERT Naïve and ERT Switch Pompe Patients

Completion of Rolling Biologics License Application On-Track by end of 2Q21

PHILADELPHIA - May 3, 2021 (GLOBE NEWSWIRE) -- Amicus Therapeutics (NASDAQ:FOLD) today announced the completion of a successful Type B Pre-Biologics License Application (BLA) meeting with the U.S. Food and Drug Administration (FDA) for AT-GAA (cipaglucosidase alfa co-administered with miglustat), its investigational two-component therapy for the treatment of Pompe disease. Based on this formal pre-BLA meeting and the final written communication received from the FDA, Amicus intends to complete the rolling BLA submission for cipaglucosidase alfa and submit a New Drug Application for miglustat.

Amicus intends to base its filings on the evaluation of the effects of AT-GAA in late-onset Pompe patients and its safety profile, which will include data from both the Phase 1/2 and Phase 3 PROPEL studies as well as data from the open label extension study. As part of the rolling BLA, Amicus previously submitted the nonclinical component of the cipaglucosidase alfa BLA and is on-track to submit all of the remaining modules of the BLA by the end of the second quarter, including the chemistry, manufacturing and controls (CMC) and clinical sections.

"This meeting with the FDA marks a step forward for thousands of people living with Pompe disease in the United States," said John F. Crowley, Chairman and Chief Executive Officer of Amicus Therapeutics. "This is an important moment in the development of AT-GAA and a testament to the dedication and perseverance of the patients, physicians and employees who have worked so hard on the development of this investigational medicine. We are moving ahead expeditiously with our submission and all the work necessary to ensure that AT-GAA gets to as many people living with Pompe disease as quickly as possible."

Jeff Castelli, Ph.D., Chief Development Officer of Amicus Therapeutics, stated, "We believe the data from our clinical trials, including the largest pivotal study ever completed in Pompe disease, have shown clinically meaningful improvements. The AT-GAA development program reflects what we believe is the highest standard in science-based, data-driven, patient-centric therapeutic development. We are confident that we have a robust data package for this regulatory submission, and we look forward to advancing toward its review as soon as possible."

The U.S. represents the single largest geography for Amicus to positively impact the lives of people with Pompe disease.

AT-GAA is an investigational two-component therapy that consists of cipaglucosidase alfa (ATB200), a unique enzyme replacement therapy with optimized carbohydrate structures, administered in conjunction with miglustat (AT2221), an orally administered stabilizer of cipaglucosidase alfa.

Previously, the U.S. FDA granted Breakthrough Therapy Designation to AT-GAA for the treatment of late-onset Pompe disease (LOPD) based on clinical efficacy results from the Phase 1/2 clinical study. A rolling BLA for AT-GAA was initiated with the U.S. FDA in the fourth quarter of 2020. Marketing Authorization Applications for AT-GAA are expected to be submitted with the European Medicines Agency (EMA) in the second half 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, the potential implications on these data for the future advancement and development of AT-GAA, and anticipated regulatory submissions. There can be no assurance that the FDA will accept a BLA submission or if accepted will grant approval for 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. 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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