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): **October 28, 2022**

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 7.01 – Regulation FD Disclosure.

On October 28, 2022, Amicus Therapeutics, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration (FDA) has deferred action on the Biologics License Application (BLA) for cipaglucosidase alfa, the biologic component of AT-GAA. Due to restrictions on travel related to COVID 19, the FDA was unable to conduct the required inspection of the WuXi Biologics manufacturing site in China during the review cycle. A copy of this press release is attached hereto as Exhibit 99.1 and incorporated herein by reference. The information in this Item 7.01, including Exhibit 99.1, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Act, or otherwise subject to the liabilities of that Section. The information in this Item 7.01, including Exhibit 99.1, shall not be incorporated by reference into any registration statement or other document pursuant to the Act.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits:

Exhibit No.	Description
99.1	Press Release dated October 28, 2022
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: October 28, 2022

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

U.S. FDA Defers Action on Filing for AT-GAA in Late-onset Pompe Disease

FDA Issues Deferred Action Letter on AT-GAA Regulatory Filing Due to the Inability to Conduct Required Manufacturing Site Inspection Prior to the PDUFA Action Date

Company is Now Actively Engaged with the Agency to Develop Plans and Logistics for a Pre-Approval Inspection

PHILADELPHIA, PA, October 28, 2022 – Amicus Therapeutics (Nasdaq: FOLD) today announced that the U.S. Food and Drug Administration (FDA) has deferred action on the Biologics License Application (BLA) for cipaglucosidase alfa, the biologic component of AT-GAA. Due to restrictions on travel related to COVID 19, the FDA was unable to conduct the required inspection of the WuXi Biologics manufacturing site in China during the review cycle. As a result, the FDA is deferring action on the application until the manufacturing site inspection is complete. The Company continues to expect the FDA to approve the two components of AT-GAA, including the BLA and New Drug Application (NDA) for miglustat, together.

The sole reason cited in the FDA-issued letter for the deferred action was the Agency's inability to complete the manufacturing facility inspection. While both applications remain under review, the FDA has not provided anticipated action date(s) as they continue to monitor the public health situation and travel restrictions in China. However, the Company is now actively engaged with the FDA on developing plans and logistics for a pre-approval inspection plan.

Under FDA guidance relating to pre-approval inspections during the COVID-19 pandemic, the Agency may defer action on a pending application when a facility inspection is necessary but cannot be completed by the PDUFA goal date due to travel restrictions, provided that no deficiencies have been identified and the application otherwise satisfies the requirements for approval.[1]

"We are now one step away from the necessary approvals for AT-GAA in the U.S. We continue to believe this is a question of 'when' not 'if' AT-GAA will be approved and we will continue to work with great urgency to support the FDA's completion of the final plant inspection necessary for approval so that this important new treatment option is made available for people living with Pompe disease in the United States," said Bradley Campbell, President and Chief Executive Officer at Amicus Therapeutics, Inc. "We are also very pleased with the progress of the regulatory review in the EU and look forward to a Committee for Medicinal Products for Human Use ("CHMP") opinion by the end of the year. We remain committed to bringing AT-GAA to as many people living with Pompe disease around the world as quickly as possible."

Previously, the FDA granted Breakthrough Therapy Designation to AT-GAA for the treatment of late-onset Pompe disease based on clinical efficacy results from the Phase 1/2 clinical study. In the European Union, where a pre-approval inspection is not required, the regulatory review is on track and the Committee for Medicinal Products for Human Use (CHMP) opinion is expected before year end.

About AT-GAA

AT-GAA is an investigational two-component therapy that consists of cipaglucosidase alfa (ATB200), a unique 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.

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 diseases. With extraordinary patient focus, Amicus Therapeutics is committed to advancing and expanding a robust pipeline of cutting-edge, first- or best-in-class medicines for rare diseases. For more information please visit the company's website at www.amicusrx.com, and follow on Twitter and LinkedIn.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to expectations regarding the FDA regulatory process, and the outcome of the FDA's review and FDA's ability to conduct a manufacturing site inspection. There can be no assurance that the FDA will grant approval for AT-GAA or the timing of any such approval. 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, 2021 and Quarterly Report 10-Q for the quarter ended June 30, 2022. 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.

References

1. U.S. Food and Drug Administration. Manufacturing, Supply Chain, and Drug Inspections - COVID-19. Available at: https://www.fda.gov/drugs/coronavirus-covid-19-drugs/manufacturing-supply-chain-and-drug-inspections-covid-19 Last accessed: October 2022.

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