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 27, 2023**

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 June 27, 2023, Amicus Therapeutics, Inc. (the "Company") issued a press release announcing European Commission approval of Opfolda® (miglustat) for late-onset Pompe disease. 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	June 27, 2023 Press Release
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 27, 2023

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 Approval and Launch of New Pompe Disease Therapy in the European Union

Pombiliti® (cipaglucosidase alfa) + Opfolda® (miglustat) Now Approved in the European Union for Adults with Late-onset Pompe Disease (LOPD)

PHILADELPHIA, PA, June 27, 2023 – Amicus Therapeutics (Nasdaq: FOLD), a patient-dedicated global biotechnology company focused on developing and commercializing novel medicines for rare diseases, today announced that the European Commission (EC) has granted approval for Opfolda® (miglustat) 65mg capsules, an enzyme stabilizer of cipaglucosidase alfa, a long-term enzyme replacement therapy for adults with late-onset Pompe disease. Pombiliti® (cipaglucosidase alfa) was previously approved by the EC in March 2023. Pompe disease is an inherited lysosomal disorder caused by deficiency of the enzyme acid α-glucosidase (GAA). Amicus plans to immediately launch Pombiliti + Opfolda in Germany and is commencing reimbursement processes with healthcare authorities in other European countries.

“Late-onset Pompe disease is a rare, neuromuscular disorder that can have devastating consequences for patients and their families. The European Commission approval for Pombiliti and Opfolda is the realization of the work of so many individuals and teams dedicated to the mission of improving the lives of people living with Pompe disease. We look forward to bringing this much needed, new treatment to all adults living in the EU with late-onset Pompe disease,” said John F. Crowley, Executive Chairman of Amicus Therapeutics, Inc.

"We are extremely pleased with the EC approval of Pombiliti and Opfolda, and are grateful to the Pompe community around the world who have helped advance this therapy. Given the strength of the label and our launch readiness, we believe Pombiliti and Opfolda has the potential to become the next standard of care in for this devastating condition by showing that improvement is possible for people living with late-onset Pompe disease,” said Bradley Campbell, President and Chief Executive Officer of Amicus Therapeutics, Inc.

Pombiliti + Opfolda is a unique two-component therapy. Pombiliti (cipaglucosidase alfa), is a bis-M6P-enriched rhGAA enzyme, designed for increased uptake into muscle cells. Once in the cell, Pombiliti can be processed into its most active and mature form to break down glycogen. Opfolda (miglustat) is an enzyme stabilizer designed to stabilize the enzyme in the blood. The EC approval was based on clinical data from the Phase 3 pivotal study (PROPEL), the only trial in LOPD to study the real-world population of both ERT-naïve and ERT-experienced participants in a controlled setting.

“This significant milestone marks the beginning of broad access to Pombiliti and Opfolda for the LOPD community in Europe, where there is a high medical need for novel treatment options,” said Prof. Benedikt Schoser, Professor of Neurology at Ludwig-Maximilians-University of Munich LMU Department of Neurology. “In clinical studies, Pombiliti and Opfolda have exhibited clinically meaningful and positive changes in the key mobility and respiratory manifestations of this challenging disease. The EC approval and indication reflect the hope for the potential of this innovative therapy for people living with Pompe disease.”

“The Pompe community is greatly appreciative of Amicus’ long-standing commitment to develop a treatment option to address the continuing unmet needs of people living with late-onset disease. Each person deserves alternatives to help them best manage their condition,” said Tiffany House, President, International Pompe Association.

In the U.K., the Medicines and Healthcare products Regulatory Agency (MHRA) regulatory approval is expected in the third quarter of 2023. The U.S. Food & Drug Administration’s review is ongoing, and the Company expects approval in the third quarter of 2023. The FDA previously granted Breakthrough Therapy designation for Pombiliti + Opfolda.

About Pombiliti® + Opfolda®

Pombiliti + Opfolda, is a two-component therapy that consists of cipaglucosidase alfa, a bis-M6P-enriched rhGAA that facilitates high-affinity uptake through the M6P receptor while retaining its capacity for processing into the most active form of the enzyme, and the oral enzyme stabilizer, miglustat, that’s designed to reduce loss of enzyme activity in the blood. In clinical studies, Pombiliti + Opfolda was associated with demonstrated improvements in both musculoskeletal and respiratory measures.

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 lead to accumulation of glycogen in cells, which is believed to result in the clinical manifestations of Pompe disease. Pompe disease ranges from a rapidly deteriorating infantile form with significant impact to heart function, to a more slowly progressive, late-onset form primarily affecting skeletal muscle and progressive respiratory involvement. Late-onset Pompe disease can be severe and debilitating with progressive muscle weakness throughout the body that worsens over time, particularly skeletal muscles and muscles controlling breathing.

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 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.

Important Safety Information

Pombiliti (cipaglucosidase alfa) Important Safety Information

Posology and Method of Administration: Pombiliti must be used in combination with miglustat 65 mg hard capsules. The recommended dose of Pombiliti is 20 mg/kg of body weight every other week. The Pombiliti infusion should start 1 hour after taking miglustat capsules. ***Paediatric population:*** The safety and efficacy of Pombiliti in combination with miglustat therapy in paediatric patients less than 18 years old have not yet been established. No data are available. ***Contraindications*****:** Life-threatening hypersensitivity to the active substance, or to any of the excipients. Contraindication to miglustat. ***Anaphylaxis and infusion-associated reactions (IARs):*** Serious anaphylaxis and IARs have occurred in some patients during infusion and following infusion with Pombiliti. Premedication with oral antihistamine, antipyretics, and/or corticosteroids may be administered to assist with signs and symptoms related to IARs experienced with prior enzyme replacement therapy (ERT) treatment. Reduction of the infusion rate, temporary interruption of the infusion, symptomatic treatment with oral antihistamine, or antipyretics, and appropriate resuscitation measures should be considered to manage serious IARs. If anaphylaxis or severe allergic reactions occur, infusion should be immediately paused, and appropriate medical treatment should be initiated. The current medical standards for emergency treatment of anaphylactic reactions are to be observed and cardiopulmonary resuscitation equipment should be readily available. The risks and benefits of re-administering Pombiliti following anaphylaxis or severe allergic reaction should be carefully considered, and appropriate resuscitation measures made available. ***Risk of acute cardiorespiratory failure in susceptible patients:*** Patients with acute underlying respiratory illness or compromised cardiac and/or respiratory function may be at risk of serious exacerbation of their cardiac or respiratory compromise during infusions. Appropriate medical support and monitoring measures should be readily available during Pombiliti infusion. ***Immune complex-related reactions:*** Immune complex-related reactions have been reported with other ERTs in patients who had high IgG antibody titres, including severe cutaneous reactions and nephrotic syndrome. If immune complex-related reactions occur, discontinuation of the administration of Pombiliti should be considered and appropriate medical treatment should be initiated. The risks and benefits of re-administering Pombiliti following an immune complex-related reaction should be reconsidered for each individual patient. ***Contraception in females:*** Reliable contraceptive measures must be used by women of childbearing potential during treatment with Pombiliti in combination with miglustat, and for 4 weeks after discontinuing treatment. ***Pregnancy:*** Pombiliti in combination with miglustat therapy is not recommended during pregnancy. ***Breast feeding:*** It is not known if Pombiliti and miglustat are secreted in human breast milk. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Pombiliti in combination with miglustat therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman. ***Summary of the safety profile:*** The most commonly reported adverse reactions only attributable to Pombiliti were chills (4.0%), dizziness (2.6%), flushing (2.0%), somnolence (2.0%), chest discomfort (1.3%), cough, (1.3%), infusion site swelling (1.3%), and pain (1.3%). Reported serious adverse reactions only attributable to Pombiliti were urticaria (2.0%), anaphylaxis (1.3%), pyrexia (0.7%), presyncope (0.7%), dyspnoea (0.7%), pharyngeal oedema (0.7%), wheezing (0.7%), and hypotension (0.7%). Refer to SmPC for full list.

Opfolda (miglustat) 65 mg hard capsules Important Safety Information

Posology and Method of Administration: Opfolda must be used in combination with Pombiliti. The recommended dose is to be taken orally every other week and is based on body weight. Opfolda should be taken approximately 1 hour but no more than 3 hours before the start of the Pombiliti infusion. **Paediatric population:** The safety and efficacy of Opfolda in combination with Pombiliti therapy in paediatric patients less than 18 years old have not yet been established. No data are available. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. Contraindication to cipaglucosidase alfa. **Food Interaction:** Patients should fast for 2 hours before and 2 hours after taking Opfolda. **Contraception in females:** Reliable contraceptive measures must be used by women of childbearing potential during treatment with Opfolda in combination with Pombiliti, and for 4 weeks after discontinuing treatment. **Pregnancy:** Opfolda crosses the placenta. Opfolda in combination with Pombiliti therapy is not recommended during pregnancy. **Breast feeding:** It is not known if Opfolda and Pombiliti are secreted in human breast milk. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Opfolda in combination with Pombiliti therapy taking into account the benefit of breastfeeding for the child and the benefit of therapy for the woman. **Summary of the safety profile:** The most commonly reported adverse reaction only attributable to Opfolda 65 mg was constipation (1.3%). Refer to SmPC for full list.

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 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 expectations regarding the regulatory process in the UK and US. There can be no assurance that the MHRA or FDA will grant full approval for both components of AT-GAA or when any such approvals may occur. 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 full global regulatory approvals for, or successfully manufacture and commercialize AT-GAA once fully approved in each geography. 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, 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.

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