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 15, 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 August 15, 2023, Amicus Therapeutics, Inc. issued a press release announcing that the Medicines and Healthcare products Regulatory Agency of the United Kingdom has granted marketing authorizations for Pombiliti® (cipaglucosidase alfa) + Opfolda® (miglustat) for adults living with late-onset Pompe disease. In addition, it announced that the National Institute for Health and Care Excellence issued final guidance recommending reimbursement of Pombiliti + Opfolda for use within the National Health Service in England and Wales. 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 Securities Exchange Act of 1934, as amended (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 August 15, 2023
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: August 15, 2023

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 United Kingdom

Pombiliti® (cipaglucosidase alfa) + Opfolda® (miglustat) Approved for Adults Living with Late-Onset Pompe Disease in Great Britain

National Institute for Health and Care Excellence (NICE) Issues Final Positive Recommendation

PHILADELPHIA, PA and MARLOW, United Kingdom, August 15, 2023 (GLOBE NEWSWIRE) – Amicus Therapeutics (Nasdaq: FOLD), a patient-dedicated global biotechnology company focused on developing and commercializing novel medicines for rare diseases, today announced that the Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom (U.K.) has granted marketing authorizations for Pombiliti® (cipaglucosidase alfa) + Opfolda® (miglustat) for adults living with late-onset Pompe disease (acid α-glucosidase [GAA] deficiency). The indication for Pombiliti is a long-term enzyme replacement therapy (ERT) used in combination with miglustat for adults with late-onset Pompe disease (LOPD). The indication for Opfolda is an enzyme stabilizer of cipaglucosidase alfa long-term enzyme replacement therapy for adults with LOPD.

In addition, the National Institute for Health and Care Excellence (NICE) issued final guidance recommending reimbursement of Pombiliti + Opfolda for use within the National Health Service (NHS) in England and Wales. As stated in the guidance, NICE concluded that the cost-effectiveness estimates for Pombiliti + Opfolda showed a positive net health benefit and recommended Pombiliti + Opfolda for adults with LOPD as first line and later lines of therapy.

Prior to Great Britain (GB) approval, Pombiliti + Opfolda was granted an Innovation Passport under the Innovative Licensing and Access Pathway (ILAP), a Priority Innovative Medicines designation, as well as a positive scientific opinion under the Early Access to Medicines Scheme (EAMS). This accelerated the time to market and enabled healthcare professionals to prescribe the treatment prior to marketing authorization based on clinical factors for patients with a clear unmet need.

“The MHRA approvals for Pombiliti and Opfolda are a major step forward for adults in the U.K. living with late-onset Pompe who are seeking new treatments. We are grateful to the global Pompe community who have helped advance this therapy, especially the patients, families, and physicians who participated in our clinical studies,” stated Bradley Campbell, President and Chief Executive Officer of Amicus Therapeutics, Inc. “The speed in which NICE recommended reimbursement of Pombiliti and Opfolda is reflective of the U.K.’s Innovative Licensing and Access Pathway, the data behind Pombiliti and Opfolda, the strong collaboration with the reimbursement authorities, and the Amicus commitment to bring this therapy to those living with Pompe disease as quickly as possible. I am proud of Amicus’ relentless commitment toward ensuring patient access to our innovative therapies, and we are working as quickly as possible to make Pombiliti and Opfolda commercially available.”

Late-onset Pompe disease (LOPD) is a rare, debilitating, and life-threatening lysosomal disorder caused by a deficiency of the enzyme acid alpha-glucosidase (GAA). Reduced levels of GAA lead to the accumulation of the substrate glycogen in the lysosomes of muscles and other tissues. Disease severity ranges on a spectrum, but predominant manifestations are skeletal muscle weakness and progressive respiratory involvement.

Prof. Mark Roberts, Consultant Neurologist at the Greater Manchester Neurosciences Unit at Salford Royal NHS Foundation Trust stated, “From the positive uptake of the Early Access to Medicines Scheme, we have already seen the impact that this treatment is having for patients. Having widespread access to this treatment is an exciting development for the Pompe community, giving HCPs and patients a new option that exhibits a novel mode of action.”

The MHRA and NICE decisions were based on clinical data from the Phase 3 pivotal study (PROPEL), the only trial in LOPD to study both ERT-naïve and ERT-experienced participants in a controlled setting.

Allan Muir, Chair of the Board of Trustees of Pompe Support Network, stated, “Pompe disease is a rare disease, one that extensively affects all aspects of life for an individual and their family, friends, and colleagues. We are very grateful to companies such as Amicus Therapeutics that seek to make meaningful differences for our small community and we welcome new treatments that bring further choice to patients.”

Val Buxton, Chief Executive, Association for Glycogen Storage Diseases, stated, “Being able to gain rapid access to effective new therapies via the Early Access to Medicines Scheme has had a meaningful impact on many people affected by Pompe. This approval has provided a much-needed new therapy option for the Pompe community.”

Pombiliti + Opfolda has demonstrated fulfilment of the Great Britain orphan designation criteria and will be added to the Orphan Register held by the MHRA. Both will benefit from 10 years of market exclusivity in respect of similar medicinal products in the approved orphan indication.

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.

Important Safety Information

Pombiliti (cipaglucosidase alfa) Important Safety Information

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.***Contraindications*****:** Life-threatening hypersensitivity to the active substance, or to any of the excipients. Contraindication to miglustat. ***Special warnings and precautions for use:*** Pombiliti must be used in combination with Opfolda 65 mg hard capsules. ***Anaphylaxis and infusion-associated reactions (IARs):*** Serious anaphylaxis and IARs have occurred in some patients during infusion and following infusion with Pombiliti. 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.

Opfolda (miglustat) 65 mg hard capsules Important Safety Information

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. ***Contraindications:*** Hypersensitivity to the active substance or to any of the excipients. Contraindication to cipaglucosidase alfa. ***Special warnings and precautions for use:*** Opfolda 65 mg hard capsules must be used in combination with Pombiliti. ***Food Interaction:*** Patients should fast for 2 hours before and 2 hours after taking Opfolda.

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 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 the anticipated commercial launch of Pombiliti and Opfolda in the UK. There can be no assurance the launch will be commercially successful and that pricing and reimbursement negotiations will be successful outside of England and Wales. 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 Pombiliti and Opfolda. .. 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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NP-AT-ALL-00020823 August 2023