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): **November 18, 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 November 18, 2021, Amicus Therapeutics, Inc. issued a press release announcing that the data from the Phase 3 PROPEL pivotal trial, assessing the efficacy, safety and tolerability of AT-GAA in adults with late-onset Pompe disease compared to the standard of care, alglucosidase alfa, were published online in The Lancet Neurology. 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 November 18, 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: November 18, 2021

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

Exhibit 99.1

The Lancet Neurology Publishes Pivotal Phase 3 PROPEL Study Results of AT-GAA in Late-Onset Pompe Disease

Peer Reviewed Results from PROPEL Show Treatment with AT-GAA Provided Clinically Meaningful Improvements Over Standard of Care, including ERT Experienced Patients with High Unmet Need

AT-GAA Deemed to Provide a Differentiated Mechanism of Action and Potential Alternative Treatment Option for People Living with Late-onset Pompe Disease

PHILADELPHIA, PA, November 18, 2021 – Amicus Therapeutics (Nasdaq: FOLD), a patient-dedicated global biotechnology company focused on developing and commercializing novel medicines for rare diseases, announced today that the data from the Phase 3 PROPEL pivotal trial, assessing the efficacy, safety and tolerability of AT-GAA in adults with late-onset Pompe disease compared to the standard of care, alglucosidase alfa, were published online in The Lancet Neurology. The manuscript includes data on the primary and key secondary endpoints, which were previously reported, as well as additional secondary endpoints. Based on the outcomes observed in the key domains of Pompe disease (muscle strength, pulmonary and motor function, patient-reported outcomes and biomarkers), the peer reviewed results determined the PROPEL data showed clinically meaningful improvements over standard of care, even among those who had been receiving approved therapy for at least 2 years, a subgroup that has been shown to plateau or decline after several years on treatment. AT-GAA is a two-component therapy consisting of cipaglucosidase alfa, an enhanced phosphorylated enzyme and miglustat, an enzyme stabilizer, thereby providing a different mechanism of action compared with alglucosidase alfa.

“Pompe disease is a rare genetic disease that causes premature death and has a debilitating effect on people’s lives. There is significant unmet medical need that persists within Pompe disease and patients are in need of new, effective and safe therapies. The outcomes of the PROPEL study demonstrate meaningful improvements in motor and respiratory functions in patients who are living with Pompe disease,” stated Prof. Benedikt Schoser, Professor of Neurology at Ludwig-Maximillians-University of Munich LMU Department of Neurology. “Results are particularly encouraging for the population switching from standard of care ERT to AT-GAA, who saw positive improvements in key manifestations of the disease.”

John F. Crowley, Chairman and Chief Executive Officer of Amicus Therapeutics, stated, “We are pleased that The Lancet Neurology has published our PROPEL pivotal data in adults living with late-onset Pompe disease. Based on the clinical data we have seen from the Phase 3 trial, in addition to the body of data that we have accumulated over nearly a decade of preclinical and clinical studies, we have generated a compelling data set that supports the potential of AT-GAA becoming the next standard of care in the treatment of Pompe disease. We are honored by this publication and would like to thank all of the investigators, patients and families who participated in the study.”

The U.S. Food and Drug Administration (FDA) previously granted Breakthrough Therapy designation for AT-GAA and accepted for review the Biologics License Application (BLA) and the New Drug Application (NDA). The FDA has set a Prescription Drug User Fee Act action date of May 29, 2022 for the NDA and July 29, 2022 for the BLA. In the EU, the Marketing Authorization Applications for AT-GAA have been submitted in the fourth quarter of 2021.

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. 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.

In addition, Amicus is enrolling an open-label, uncontrolled, multicenter study to evaluate the PK, safety, efficacy, and PD of AT-GAA in pediatric patients aged 0 to 18 years with LOPD (ATB200-04). More information, including a list of participating sites, is available at www.clinicaltrials.gov: NCT03911505

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 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 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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