

**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): **July 2, 2019**



AMICUS THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-33497
(Commission
File Number)

71-0869350
(I.R.S. Employer
Identification No.)

1 Cedar Brook Drive, Cranbury, NJ 08512
(Address of Principal Executive Offices, and Zip Code)

609-662-2000
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 (*see* General Instruction A.2. below):

- 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 July 2, 2019, Amicus Therapeutics, Inc. issued a press release announcing a strategic partnership for gene therapy development and manufacturing with Catalent Biologics. 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
<u>99.1</u>	<u>Press Release dated July 2, 2019</u>

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: July 2, 2019

AMICUS THERAPEUTICS, INC.

By: /s/ Ellen S. Rosenberg

Name: Ellen S. Rosenberg

Title: Chief Legal Officer and Corporate Secretary



Amicus Therapeutics and Catalent Biologics Enter Strategic Partnership for Gene Therapy Development and Manufacturing

Supports Clinical and Commercial Supply Needs for Pompe and Other Lysosomal Disease Gene Therapy Programs

Advances Amicus' Mission to Deliver Novel Gene Therapies to Rare Disease Patients

CRANBURY, NJ, June 27, 2019 – Amicus Therapeutics, Inc. (NASDAQ:FOLD) has entered into a strategic manufacturing agreement with Paragon Gene Therapy, a unit of Catalent Biologics, for clinical manufacturing capabilities and capacity for multiple active preclinical lysosomal disorder programs that are currently in development in collaboration with the University of Pennsylvania (Penn). Penn has transferred technology to Paragon in the past and will collaborate with Amicus throughout the process. Amicus has also established a plasmid supply network and long-term supply agreements with industry-leading plasmid suppliers to support advancement of all current gene therapy pipeline programs.

Key Highlights of Amicus-Paragon Collaboration:

- **Collaboration includes multiple active preclinical lysosomal disorder programs:** the current research and development production technologies and capabilities related to multiple active preclinical lysosomal disorder programs are being transferred to and developed at Paragon.
- **Adeno-Associated Virus (AAV) manufacturing platform:** establishing an AAV manufacturing platform will further advance and establish manufacturing for multiple Amicus preclinical gene therapy programs while leveraging Paragon's established manufacturing capabilities for initial clinical supply and commercial product.
- **Pompe preclinical gene therapy program:** Initial technology transfer and process development to focus on Amicus Pompe AAV gene therapy program.

John F. Crowley, Chairman and Chief Executive Officer of Amicus stated, "As we continue to articulate our near- and long-term Amicus gene therapy manufacturing strategy, our collaboration with Paragon Bioservices is a significant next step in securing clinical scale-up and supply for our Pompe gene therapy, as well as our other active preclinical programs. Advancing a robust manufacturing process and supply is critical to our success. Leveraging our internal expertise and process development in combination with Paragon's expertise and platform capabilities we hope to expedite the process of moving our preclinical gene therapy programs into the clinic as quickly as possible."

"Amicus has a strong gene therapy pipeline focused on addressing many life-threatening conditions where there are urgent needs for treatments and cures," said Pete Buzy, President of Paragon Gene Therapy. "Paragon has a proven track record to develop and successfully manufacture complex biotherapeutics using commercially-scalable processes. This agreement with Amicus highlights our world-class manufacturing team and our track record as a center of excellence for gene therapy, trusted by top biopharmaceutical companies."

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 on [Twitter](#) and [LinkedIn](#).

About Catalent Biologics

Catalent Biologics has 20+ years' experience in development, manufacturing, and analytical services for new biological entities, biosimilars, gene therapies and antibody-drug conjugates. Catalent has worked with 600+ mAbs and 80+ proteins, and more than 115 clinical trials and 11 marketed products have used GPEX[®] cell line engineering technology. A further 20 commercially-approved products have employed Catalent Biologics' capabilities through to aseptic fill/finish. Using advanced protein improvement technology and tailored solutions from DNA through to clinical and commercial supply, Catalent Biologics brings better biologic treatments to patients, faster. For more information, visit biologics.catalent.com.

Paragon Gene Therapy, a unit of Catalent Biologics, is an industry leader focusing on transformative technologies, including gene therapies (AAV), next-generation vaccines, and oncology immunotherapies. Paragon Gene Therapy has two facilities in Baltimore, Maryland dedicated to process development through commercial manufacturing of most scalable AAV platforms across multiple serotypes. Since 2016, Paragon Gene Therapy has completed over 100 clinical GMP AAV batches across 40 programs.

CONTACTS:

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