# 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 1, 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):

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o 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

ndicate by check mark v	whether the registrant is an e	emerging growth comp	any as defined in Rule 405	of the Securities	Act of 1933 (17 CFF	R §230.405) or
Rule 12b-2 of the Securit	ties Exchange Act of 1934 (	17 CFR 8240 12b-2) 1	Emerging growth company	v 🗆		

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.  $\Box$ 

### **Item 8.01 Other Events**

On July 1, 2019, Amicus Therapeutics, Inc. (the "Company") issued a press release announcing a strategic gene therapy development and manufacturing collaboration with Brammer Bio, a part of Thermo Fisher Scientific, to support clinical and commercial supply needs for multiple Batten disease programs and to develop platform manufacturing capabilities to support the Company's broader portfolio of AAV gene therapy programs. 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	
99.1	Press Release dated July 1, 2019		

# 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 1, 2019

AMICUS THERAPEUTICS, INC.

By: /s/ Ellen S. Rosenberg

Name: Ellen S. Rosenberg

Title: Chief Legal Officer and Corporate Secretary



# Amicus Therapeutics and Brammer Bio, a part of Thermo Fisher Scientific, Enter Strategic Gene Therapy Development and Manufacturing Collaboration

# Supports Clinical and Commercial Supply Needs for Multiple Batten Disease Programs

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

**CRANBURY, NJ, July 1, 2019** – Amicus Therapeutics, Inc. (NASDAQ:FOLD) has entered into a strategic manufacturing collaboration with Thermo Fisher Scientific. Thermo Fisher, a best-in-class contract development and manufacturing organization (CDMO) with late-stage clinical and commercial-scale capabilities provides Amicus with immediate clinical and commercial manufacturing capabilities and capacity for the Amicus intrathecal AAV Batten disease gene therapy programs. Amicus has also established a plasmid supply network together with multiple long-term supply agreements from industry leading plasmid suppliers to support advancement of all current gene therapy pipeline programs in the Amicus portfolio.

### Key Highlights of Amicus-Thermo Fisher Scientific Partnership:

- Batten disease programs: current research and development production technologies and capabilities related to the Amicus preclinical and clinical-stage gene therapy programs for CLN6, CLN3, and other potential Batten disease programs are being transferred to and developed at Thermo Fisher's viral vector services business.
- **CLN6 Batten disease gene therapy**: the existing process for the CLN6 Batten disease gene therapy is being transferred to Thermo Fisher and undergoing a similar GMP process for clinical and commercial-scale manufacturing and supply.
- **Broader portfolio**: Thermo Fisher and Amicus to collaborate to develop platform manufacturing capabilities to support the broader portfolio of AAV gene therapy programs.

John F. Crowley, Chairman and Chief Executive Officer of Amicus stated, "As we advance one of the industry's leading gene therapy pipelines, our partnership with Brammer Bio, now part of Thermo Fisher, is a significant next step in fulfilling our manufacturing strategy so that we can deliver novel gene therapies to more people living with rare genetic diseases as quickly as possible, especially in devastating diseases like Batten's, where time is of the essence. With our decade of experience in biologics manufacturing, we understand the importance and complexities of technology transfer during the drug development process. We look forward to embedding our Amicus team and other strategic partners in the tech transfer process to Thermo Fisher, and to further augmenting our manufacturing capabilities and partnerships across our entire gene therapy portfolio."

"We are thrilled to begin working with Amicus and to contribute to the successful development of their gene therapy pipeline," said Chris Murphy, vice president and general manager, viral vector services at Thermo Fisher Scientific. "We see this as a strong strategic relationship to enable manufacturing of a deep gene therapy pipeline across various stages of development for people with devastating genetic diseases. These therapies have the potential to transform patients' lives and, as an organization, we are delighted to support partners such as Amicus as they advance tomorrow's potential medicines."

## **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 <a href="https://www.amicusrx.com">www.amicusrx.com</a>, and follow on <a href="https://www.amicusrx.com">Twitter</a> and <a href="https://www.amicusrx.com">LinkedIn</a>.

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