

AMICUS THERAPEUTICS INC

Form 8-K

October 12, 2018

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): **October 8, 2018**

AMICUS THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware

(State or Other Jurisdiction of
Incorporation)

001-33497
(Commission File Number)

71-0869350
(IRS Employer Identification No.)

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1 Cedar Brook Drive, Cranbury, NJ
(Address of Principal Executive Offices)

08512
(Zip Code)

Registrant's telephone number, including area code: **(609) 662-2000**

(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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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 1.01. Entry into a Material Definitive Agreement

On October 8, 2018, Amicus Therapeutics, Inc. (Amicus or the Company) entered into a Research, Collaboration and License Agreement (the Agreement) with The Trustees of the University of Pennsylvania (Penn) pursuant to which Amicus will collaborate with the Wilson Laboratory at Penn with respect to the pre-clinical research and development of adeno-associated virus (AAV) gene therapy products for the treatment of Pompe disease, Fabry disease, CDKL5 deficiency and one additional rare metabolic disorder to be selected within 18 months after the effective date of the Agreement (collectively, the Indications).

Under the Agreement, Penn granted the Company exclusive, worldwide licenses (with the right to sublicense) under certain patent rights arising out of the research program or covering an Amicus-selected AAV developed at Penn and non-exclusive, worldwide licenses (with the right to sublicense) under certain patent rights pertaining to manufacturing, background patent rights and know-how, in each case, to make, have made, use, sell, offer for sale and import licensed products for the Indications.

The pre-clinical research and development activities of Penn under the Agreement will be overseen by James M. Wilson, M.D., Ph.D. and will be conducted by the Wilson Laboratory at Penn in accordance with a mutually-agreed research plan for a specified period of time. The Company will fund the research program in accordance with a mutually-agreed budget and will be responsible for clinical development and commercialization of the licensed products.

Following the effective date of the Agreement, the Company paid to Penn a license issue fee in the mid to high single-digit millions. Following the selection of the fourth Indication, the Company will be obligated to pay Penn an option fee in the low single-digit millions. Amicus will pay Penn an annual alliance management fee during the term of the research program, and, following the completion of the research program, an annual license maintenance fee. The alliance management fee and license maintenance fees are each in the low single-digit hundreds of thousands.

The Company is also obligated to make certain milestone and royalty payments, as further described below, with respect to licensed products for each Indication. Licensed products include any AAV gene therapy for an Indication that utilizes the licensed Penn know-how (but not any clinical stage AAV gene therapy independently developed by a third party that acquires the Company or is acquired by the Company) and any AAV gene therapy for an Indication conceived during or tested in the research program.

The milestone payments are payable by Amicus to Penn under the Agreement following the achievement of certain development and commercial milestone events by a licensed product in each Indication up to an aggregate of \$86.5 million per Indication.

Amicus is also obligated to pay Penn mid to high single-digit percentage royalties on net sales of licensed products. These royalties are payable, on a country-by-country and licensed product-by-licensed product basis, until the latest of (i) the expiration of certain patent rights covering the relevant licensed product, (ii) the expiration of all regulatory exclusivity for such licensed product, or (iii) an agreed period of time after the first commercial sale of such licensed product in the applicable country, but not longer than an additional agreed period of time after the first commercial sale of such licensed product in the applicable country if there are no issued patent claims covering such licensed product after the expiration of regulatory exclusivity and the initial agreed period of time after the first commercial sale of such licensed product in the applicable country. Additionally, the Company is obligated to pay Penn a certain percentage of income from sublicensees, ranging from a mid-single-digit percentage to a low double-digit percentage, based on the stage of development of the relevant licensed product at the time of the sublicense grant.

Unless earlier terminated, the Agreement will continue on a country-by-country basis and licensed product-by-licensed product basis, until there are no more royalty payments owed to Penn with respect to such licensed product in such country. Amicus may terminate the Agreement, or their rights with respect to any Indication, without cause upon prior written notice to Penn. Penn may terminate the Agreement for Amicus uncured breach of specified covenants or may terminate an Indication for Amicus uncured failure to achieve an agreed diligence obligation for such Indication. Either party may terminate the Agreement for an uncured material breach of the agreement by the other party in the event of the bankruptcy of the other party. If Amicus terminates the Agreement during the term of the research program, other than for Penn's uncured breach or bankruptcy, the Company will be obligated to pay Penn any portion of the initial budget for the research program that has not yet been paid.

The foregoing description of the Agreement does not purport to be complete and is subject to, and qualified in its entirety by, the full text of such agreement. The Company intends to seek confidential treatment for certain portions of the Agreement and expects to file a copy of the Agreement as an exhibit to the Company's Annual Report on Form 10-K for the year ending December 31, 2018.

SIGNATURES

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: October 12, 2018

AMICUS THERAPEUTICS, INC.

By: /s/ Ellen S. Rosenberg

Name: Ellen S. Rosenberg

Title: General Counsel and Corporate Secretary