

MANNKIND CORP
Form 8-K
September 06, 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): September 3, 2018

MannKind Corporation

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation or organization)

000-50865
(Commission
File Number)

13-3607736
(IRS Employer
Identification No.)

30930 Russell Ranch Road, Suite 301

Westlake Village, California
(Address of principal executive offices)

91362
(Zip Code)

Registrant's telephone number, including area code: (818) 661-5000

N/A

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. of Form 8-K):

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 September 3, 2018, MannKind Corporation (MannKind) and United Therapeutics Corporation (United Therapeutics) entered into an exclusive global license and collaboration agreement (the License Agreement) for the rights to MannKind s dry powder formulation of tadalafil (the API) and inhalation delivery devices associated with the API (the Devices), both in combination with one another and separately (the API and the Devices, together and separately, the Product). Under the License Agreement, United Therapeutics will be responsible for global development, regulatory and commercial activities with respect to the Product. MannKind will manufacture clinical supplies and initial commercial supplies of the Product, and long-term commercial supplies will be manufactured by United Therapeutics.

Under the terms of the License Agreement, MannKind will receive an upfront payment of \$45 million within 10 business days following the effectiveness of the License Agreement and potential milestone payments of up to \$50 million upon the achievement of specified development targets. MannKind will also be entitled to receive low double-digit royalties on net sales of the Product. At United Therapeutics option, United Therapeutics may expand the scope of the Products covered by the License Agreement to include products with certain other active ingredients for the treatment of pulmonary hypertension. Each such optioned product would be subject to United Therapeutics payment to MannKind of up to \$40 million in additional option exercise and development milestone payments, as well as a low double-digit royalty on net sales of any such product.

United Therapeutics and MannKind may each terminate the License Agreement for material breach by the other party that is not cured within a specific time frame or in the event of liquidation, bankruptcy or insolvency of the other party. In addition, United Therapeutics may terminate the License Agreement, in its entirety or with respect to a particular Product, upon 90 days prior written notice to MannKind. MannKind may terminate the License Agreement upon a change of control of United Therapeutics if such change of control is reasonably anticipated to result in a material reduction in net sales of Products or access to manufacturing information by a party with very competitive products or pipelines to MannKind s products.

The effectiveness of the License Agreement is conditioned upon expiration or termination of the required waiting period under the Hart-Scott-Rodino Antitrust Improvements Act.

On September 3, 2018, MannKind and United Therapeutics also entered into a research agreement (the Research Agreement) for the conduct of research by MannKind in connection with multiple potential products, including evaluating the feasibility of preparing a dry powder formulation of a compound within additional classes of active ingredients (outside the scope of the License Agreement) for the treatment of pulmonary hypertension. MannKind received an upfront payment of \$10 million in consideration for its performance under the Research Agreement. In addition, United Therapeutics, at its option, may obtain a license to develop, manufacture and commercialize products based on specified compounds within the drug classes covered by the Research Agreement (the Option). Each specified compound advanced into development and commercialization under such a license would be subject to the payment to MannKind of additional milestone payments of up to \$30 million and a low double-digit royalty on net sales of such products. The Research Agreement will terminate in the event that United Therapeutics does not exercise the Option within five years following the date of the Research Agreement, or in the event United Therapeutics exercises the Option and the parties enter into a separate license agreement as contemplated by the Option. United Therapeutics may terminate the Research Agreement without cause upon 30 days prior written notice to MannKind, and either party may terminate the Research Agreement in the event of liquidation, bankruptcy or insolvency of the other party.

The foregoing description of the License Agreement and Research Agreement is only a summary and is qualified in its entirety by reference to the License Agreement and the Research Agreement, copies of which will be filed as exhibits to MannKind s quarterly report on Form 10-Q for the quarter ended September 30, 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.

MANNKIND CORPORATION

Date: September 6, 2018

By: /s/ David Thomson
David Thomson, Ph.D., J.D.
Corporate Vice President, General Counsel and
Secretary