UNITED THERAPEUTICS Corp
Form 8-K
November 15, 2018

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 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 15, 2018**

United Therapeutics Corporation

(Exact name of registrant as specified in its charter)

Delaware	**000-26301**	**52-1984749**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

1040 Spring Street
Silver Spring, MD 20910
(Address of principal executive offices, including zip code)

(301) 608-9292
(Registrant s telephone number, including area code)

N/A

(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:

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))

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 o

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. o

Item 1.01. **Entry into a Material Definitive Agreement.**

On November 15, 2018, United Therapeutics Corporation (the ***Company***) entered into an Exclusive License Agreement (the ***License Agreement***) with Arena Pharmaceuticals, Inc. (***Arena***). Under the License Agreement, Arena will grant the Company the exclusive rights throughout the universe to develop, manufacture and commercialize the compound ralinepag (***Ralinepag***), an IP receptor agonist being developed for treatment of pulmonary arterial hypertension. All licenses granted to the Company are perpetual and irrevocable. Arena has granted and pending U.S. patents and applications relating to Ralinepag covering drug formulation, manufacturing and dosage, among others. Many of these patents and patent applications would be eligible for listing in the Orange Book. Based on potential patent term extensions and additional patent filings, the Company believes patent protection for Ralinepag through at least the mid-2030s is likely. Arena has no rights to re-acquire the Ralinepag program from the Company.

At the closing of the transaction, Arena will also transfer to the Company certain other assets relating to Ralinepag, including, among others, related domain names and trademarks, permits, certain contracts, inventory, regulatory documentation, IND No. 109021 (relating to Ralinepag) (the ***IND***) and non-clinical, pre-clinical and clinical trial data. The Company has agreed to assume certain limited liabilities, including, among others, all post-closing obligations under assumed contracts and the IND. No Arena employees are expected to be transferred in connection with the proposed transaction.

In exchange for the license, the Company agreed to pay Arena an upfront payment at closing of $800,000,000. Under the License Agreement, the Company will also to pay Arena (i) a one-time payment of $250,000,000 for the first, if any, marketing approval received by the Company in the United States for an inhaled version of Ralinepag to treat pulmonary arterial hypertension, (ii) a one-time payment of $150,000,000 for the first, if any, receipt by the Company of a marketing approval in any of Japan, France, Italy, the UK, Spain or Germany for oral Ralinepag to treat any indication and (iii) low double-digit, tiered royalties on net sales of Ralinepag, subject to certain adjustments for third party license payments. The closing payment of $800,000,000 may be adjusted upward to compensate Arena for certain ongoing development costs between signing and closing.

Closing of the transactions is subject to customary conditions, including the expiration or termination of the required waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (***HSR Act***). The License Agreement contains customary representations, warranties and covenants. The License Agreement also contains a covenant by Arena not to compete, during the period in which royalties are payable (or during the five-year period following the closing if Arena is subject to a change of control transaction), in the development of any prostacyclin-class therapy to treat pulmonary hypertension (***PH***). Arena has also agreed to grant the Company, for a period of six years following the closing, certain rights to negotiate for potential access to future compounds developed by Arena for the treatment, prevention or amelioration of PH. The Company has no diligence obligations with respect to further development or commercialization of Ralinepag. Subject to certain exceptions and other provisions, each party has agreed to indemnify the other for breaches of representations and warranties, breaches of covenants, certain liabilities and certain other matters.

The License Agreement may be terminated (i) by mutual written consent, (ii) by either party if the closing of the transaction has not taken place within 180 days of the execution of the License Agreement (subject to a 90 day extension if the HSR Act closing condition remains unsatisfied), (iii) by either party if a governmental or regulatory authority issues a non-appealable order prohibiting the transaction, (iv) by the Company if a governmental or regulatory authority enacts a non-appealable action or order that would prohibit the Company s ownership of any material portion of the transferred or licensed assets and (v) by either party in the event that the other party s material breach of any representation, warranty, covenant or agreement such that the applicable closing condition would not be satisfied (subject to a right to cure).

The foregoing summary is qualified in its entirety by reference to a copy of the Agreement, which will be filed as an exhibit to the Company s annual report on Form 10-K for the year ended December 31, 2018.

The representations, warranties and covenants contained in the License Agreement were made only for the

purposes of the License Agreement, were made as of specific dates, were made solely for the benefit of the parties to the License Agreement and may not have been intended to be statements of fact, but rather, as a method of allocating risk and governing the rights and relationships among the parties to the License Agreement. In addition, such representations, warranties and covenants may have been qualified by certain disclosures not reflected in the text of the License Agreement and may apply standards of materiality and other qualifications and limitations in a way that is different from what may be viewed as material by the Company s stockholders. In reviewing the representations, warranties and covenants contained in the License Agreement or any descriptions thereof in this summary, it is important to bear in mind that such representations, warranties and covenants or any descriptions were not intended by the parties to the License Agreement to be characterizations of the actual state of facts or conditions of the Company or Ralinepag. Moreover, information concerning the subject matter of the representations and warranties may change after the date of the License Agreement, which subsequent information may or may not be fully reflected in public disclosures. For the foregoing reasons, the representations, warranties and covenants in the License Agreement, or any descriptions of those provisions, should not be read alone and should instead be read in conjunction with the other information contained in the reports, statements and filings that the Company publicly files with the U.S. Securities and Exchange Commission.

Item 7.01. **Regulation FD.**

On November 15, 2018, the Company issued a press release announcing its entry into the License Agreement. A copy of the press release is being furnished as Exhibit 99.1 hereto and is incorporated herein by reference.

The information in this Item 7.01 and the related Item 9.01, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the ***Exchange Act***), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act as amended, regardless of any general incorporation language in such filing.

Item 9.01. **Financial Statements and Exhibits.**

(d) Exhibits

Exhibit No.	**Description of Document**
99.1	Press release dated November 15, 2018.

Forward-Looking Statements

Statements included in this Current Report on Form 8-K that are not historical in nature are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 including, but not limited to, statements related to the timing of the consummations of the transactions contemplated by the License Agreement. Forward-looking statements are based on the beliefs of the Company s management team, as well as assumptions made by, and information currently available to, them. Because such statements are based on expectations as to future events and results and are not statements of fact, actual events and results may differ materially from those projected depending on a number of factors affecting the transactions contemplated by the License Agreement. The risks and uncertainties to which the forward-looking statements are subject include, but are not limited to: the risk that the transaction may not be completed in a timely manner or at all; the failure to satisfy the conditions to the consummation of the transaction, including the expiration or termination of the required waiting period under the HSR Act; and the occurrence of any event, change or other circumstance that could give rise to the termination of the License Agreement. Such forward-looking statements are qualified by the cautionary statements, cautionary language and risk factors set forth in the Company s periodic reports and documents filed with the Securities and Exchange Commission, including the Company s most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. The Company claims the protection of the safe harbor contained in the Private Securities Litigation Reform Act of 1995 for forward-looking statements. The Company is providing this information as of November 15, 2018 and assumes no obligation to update or revise the information contained in this Current Report on Form 8-K whether as a result of new information, future events or any other reason.

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.

UNITED THERAPEUTICS CORPORATION

Date: November 15, 2018

By: /s/ Paul A. Mahon
Name: Paul A. Mahon
Title: General Counsel