UNITED THERAPEUTICS Corp
Form 8-K
August 09, 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): **August 8, 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)	(I.R.S. Employer Identification Number)

1040 Spring Street Silver Spring, MD	**20910**
(Address of Principal Executive Offices)	(Zip Code)

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

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 8.01. Other Events.

On August 8, 2018, United Therapeutics Corporation (the ***Company***) and Watson Laboratories, Inc. (***Watson***) entered into a Settlement Agreement (the ***Settlement Agreement***) to settle their ongoing litigation concerning certain patents relating to Tyvaso® (treprostinil) Inhalation Solution (***Tyvaso***) and Watson s Abbreviated New Drug Application (***ANDA***) seeking approval by the U.S. Food and Drug Administration (***FDA***) to market a generic version of Tyvaso.

The litigation with Watson consists of (a) one civil case pending in the United States District Court for the District of New Jersey (Case Nos. 3:15-cv-5723), which was filed July 22, 2015; and (b) two *inter partes* reviews (IPRs) at the Patent Trial and Appeal Board (***PTAB***) of the Unites States Patent and Trademark Office (***PTO***) initiated by Watson seeking a ruling that two of the Company s patents are invalid (Case IPR Nos. IPR2017-01622 and IPR2017-01621, both filed on June 21, 2017). In the District Court litigation, United Therapeutics asserts the following patents against Watson: United States Patent Nos. 6,521,212, 6,756,033, 8,497,393, 9,339,507 (***the 507 patent***) and 9,358,240 (***the 240 patent***). In the IPRs, Watson seeks to invalidate all claims of the 507 and 240 patents. On January 11, 2018, the PTAB issued decisions to institute IPR proceedings with respect to both patents.

Under the Settlement Agreement, the Company grants Watson a license under its patents to manufacture and commercialize the generic version of Tyvaso described in Watson s ANDA filing in the United States beginning on January 1, 2026, although Watson may be permitted to enter the market earlier under certain circumstances. The Settlement Agreement does not grant Watson a license to manufacture a generic version of any other Company product, such as Remodulin® (treprostinil) Injection or Orenitram® (treprostinil) Extended-Release Tablets. The Settlement Agreement does not grant Watson any rights other than those required to launch Watson s generic version of Tyvaso. The terms of the Settlement Agreement are generally consistent with those of the Settlement Agreement, dated September 29, 2015, between the Company and Sandoz Inc. relating to Sandoz s ANDA to market a generic version of Remodulin, which is filed as Exhibit 10.2 to the Company s Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2015.

In accordance with the terms of the Settlement Agreement, the parties will submit the Settlement Agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review. They will also take certain procedural steps to dismiss without prejudice their respective claims in the pending District Court litigation, as well as a withdrawal of the pending IPR proceedings.

On August 8, 2018, the Company also issued the press release attached hereto as Exhibit 99.1, which is incorporated herein by reference.

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. Forward-looking statements include, among others, statements regarding the potential launch of generic competition for Tyvaso. These forward-looking statements are subject to certain risks and uncertainties, such as those described in the Company s periodic and other reports filed with the Securities and Exchange Commission that could cause actual results to differ materially from anticipated results. 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 August 8, 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.

Item 9.01 Exhibits.

(d) Exhibits

Exhibit No.	Description of Exhibit
99.1	Press release dated August 8, 2018

SIGNATURE

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

Dated: August 8, 2018

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