

UNITED THERAPEUTICS Corp
Form 8-K
July 28, 2017

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 27, 2017**

United Therapeutics Corporation

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other
Jurisdiction of
Incorporation)

000-26301
(Commission
File Number)

52-1984749
(I.R.S. Employer
Identification Number)

1040 Spring Street
Silver Spring, MD
(Address of Principal Executive Offices)

20910
(Zip Code)

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

Edgar Filing: UNITED THERAPEUTICS Corp - Form 8-K

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 7.01. Regulation FD Disclosure

As disclosed previously in the Quarterly Report on Form 10-Q (the "**10-Q**") filed by United Therapeutics Corporation (the "**Company**") on July 27, 2017, the Company is engaged in litigation with Watson Laboratories, Inc. ("**Watson**") based on Watson's Abbreviated New Drug Application seeking approval by the U.S. Food and Drug Administration to market a generic version of Tyvaso® (treprostinil) Inhalation Solution before the expiration of certain of the Company's U.S. patents at various dates from November 2018 through December 2028. This litigation is pending in the U.S. District Court for the District of New Jersey (the "**District Court**"), and the Company previously disclosed that trial is scheduled for September 2017.

Separately, Watson has filed petitions for *inter partes* review ("**IPR**") with the Patent Trial and Appeal Board ("**PTAB**") of the U.S. Patent and Trademark Office, seeking to invalidate the claims of two of the Company's patents that expire in 2028, relate to Tyvaso and are asserted in the District Court case.

On July 27, 2017, the Company filed with the District Court an agreement with Watson to stay the District Court case until the PTAB resolves Watson's petitions for IPR either through declining to institute the IPRs or by issuing a final written decision on the merits of the IPR. The agreement is subject to the District Court's approval. If the District Court approves the agreement, trial may occur in early 2018 if the IPRs are not instituted, and the Company does not expect trial to take place before early 2019 if the IPRs are instituted. The Company does not expect Watson will launch a generic version of Tyvaso during the period that the stay of the District Court case is in effect.

The Company intends to vigorously enforce our intellectual property rights relating to Tyvaso.

For additional information regarding the Company's litigation with Watson, please refer to Note 12 *Legal Proceedings* to the financial statements contained in the 10-Q.

The information contained in this Current Report on Form 8-K shall not be deemed to be filed for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to liability under that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act except as shall be expressly set forth by specific reference in such filing.

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 Company's ongoing litigation with Watson relating to patents relating to 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, and 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 claim 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 July 28, 2017, and assumes no obligation to update or revise the information contained in this Current Report on

Edgar Filing: UNITED THERAPEUTICS Corp - Form 8-K

Form 8-K whether as a result of new information, future events or any other reason.

TYVASO is a registered trademark of United Therapeutics Corporation.

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: July 28, 2017

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