

UNITED THERAPEUTICS Corp
Form 8-K
February 16, 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): **February 15, 2018**

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**

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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 8.01. Other Events.

On February 15, 2018, United Therapeutics Corporation (the **Company**) and Actavis Laboratories FL, Inc. (**Actavis**) entered into a Settlement Agreement (the **Settlement Agreement**) to settle their ongoing litigation concerning certain patents relating to Orenitram® (treprostinil) Extended-Release Tablets (**Orenitram**) and Actavis Abbreviated New Drug Application (**ANDA**) seeking approval by the U.S. Food and Drug Administration (**FDA**) to market a generic version of Orenitram.

The litigation with Actavis consists of two cases pending in the United States District Court for the District of New Jersey: (i) Case Nos. 3:16-cv-01816-PGS-LHG, which was filed March 31, 2016; and (ii) 3:16-cv-03642-PGS-LHG filed June 17, 2016, which was consolidated with the earlier filed case. In these cases, United Therapeutics asserts the following patents against Actavis: United States Patent Nos. 7,417,070, 7,544,713, 8,252,839, 8,349,892, 8,410,169, 8,497,393, 9,050,311, 9,278,901, 9,422,223, 8,747,897 (**the 897 patent**), and 9,393,203 (**the 203 patent**). Supernus Pharmaceuticals, Inc. is also a party to the litigation and the Settlement Agreement because the 897 patent and the 203 patent are exclusively licensed to United Therapeutics by Supernus.

Under the Settlement Agreement, the Company grants Actavis a license to manufacture and commercialize the generic version of Orenitram described in Actavis ANDA filing in the United States beginning on June 15, 2027, although Actavis may be permitted to enter the market earlier under certain circumstances. The Settlement Agreement does not grant Actavis a license to manufacture a generic version of any other Company product, such as Tyvaso® (treprostinil) Inhalation Solution or Remodulin® (treprostinil) Injection. The Settlement Agreement does not grant Actavis any rights other than those required to launch Actavis' generic version of Orenitram. 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 litigation.

On February 15, 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 Orenitram. 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

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providing this information as of February 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.

Item 9.01 Exhibits.

(d) Exhibits

Exhibit No.	Description of Exhibit
99.1	<u>Press release dated February 15, 2018</u>

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: February 15, 2018

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