UNITED THERAPEUTICS Corp
Form 8-K
January 19, 2016

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): **January 15, 2016**

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))

Item 8.01. Other Events.

On January 15, 2016, United Therapeutics Corporation (the ***Company***) and Teva Pharmaceuticals USA, Inc. (***Teva***) entered into a Settlement Agreement (the ***Settlement Agreement***) to settle their ongoing litigation concerning certain patents relating to Remodulin® (treprostinil) Injection (***Remodulin***) and Teva s Abbreviated New Drug Application (***ANDA***) seeking approval by the U.S. Food and Drug Administration (***FDA***) to market a generic version of Remodulin.

The Settlement Agreement relates to a lawsuit filed by the Company against Teva alleging infringement of U.S. Patent Nos. 6,765,117, 7,999,007, 8,497,393, 8,653,137 and 8,658,694. This action is described in further detail in Part II, Item 1 of the Company s Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, filed with the U.S. Securities and Exchange Commission (***SEC***) on October 27, 2015.

Under the Settlement Agreement, the Company grants Teva a non-exclusive license beginning on December 23, 2018 to manufacture and commercialize in the United States the generic version of Remodulin described in Teva s ANDA filing, although Teva may be permitted to enter the market earlier under certain circumstances. The Settlement Agreement does not grant Teva a license to manufacture a generic version of any other Company product, such as Tyvaso® (treprostinil) Inhalation Solution or Orenitram® (treprostinil) Extended-Release Tablets, nor does it grant any rights with respect to any technology associated with the Remodulin Implantable System being developed by the Company and Medtronic Inc., or the pre-filled semi-disposable pump system being developed by the Company and DEKA Research & Development Corp. The Settlement Agreement does not grant Teva any rights other than those required to launch Teva s generic version of Remodulin.

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 terminate the outstanding lawsuit.

The Company previously disclosed it had entered into a separate settlement agreement with Sandoz Inc. (***Sandoz***) relating to Sandoz ANDA seeking to market a generic version of Remodulin. Under that settlement agreement, Sandoz is permitted to launch its generic version of Remodulin on June 26, 2018.

ORENITRAM, REMODULIN and TYVASO are registered trademarks of United Therapeutics Corporation.

Forward-Looking Statements

Statements included in this current report on Form 8-K concerning the Settlement Agreement are forward-looking statements within the meaning of the safe harbor contained in the Private Securities Litigation Reform Act of 1995. These forward-looking statements are qualified by the cautionary statements, cautionary language and risk factors set forth in our periodic reports and documents filed with the Securities and Exchange Commission, including our most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and current reports on Form 8-K, which could cause actual results to differ materially from anticipated results. We are providing this information as of January 19, 2016, and assume 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

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: January 19, 2016

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