UNITED THERAPEUTICS Corp
Form 8-K
September 30, 2015

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): **September 29, 2015**

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 1.01. Entry into a Material Definitive Agreement.

On September 29, 2015, United Therapeutics Corporation (the ***Company***) and Sandoz Inc. (***Sandoz***) entered into a Settlement Agreement (the ***Settlement Agreement***) to settle their ongoing litigation concerning certain patents relating to Remodulin® (treprostinil) Injection (***Remodulin***) and Sandoz 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 three lawsuits filed by the Company against Sandoz alleging infringement of certain patents. The trial for the first two lawsuits (the ***Sandoz I Litigation***), involved U.S. Patent No. 6,765,117, which expires in October 2017 and U.S. Patent No. 7,999,007, which expires in March 2029. That trial occurred in May and June 2014, and the Court issued its decision in August 2014. In that decision, with respect to U.S. Patent No. 6,765,117, the Court ruled that the patent is valid and infringed upon by Sandoz, and enjoined Sandoz from marketing its generic product until the expiration of that patent in October 2017. With respect to U.S. Patent No. 7,999,007, the Court ruled that the patent is valid, but that it would not be infringed upon by Sandoz s generic product. Sandoz has appealed the ruling that U.S. Patent No. 6,765,117 is valid and would be infringed upon, and that U.S. Patent No. 7,999,007 is valid. The Company filed a cross-appeal challenging the Court s ruling that U.S. Patent No. 7,999,007 would not be infringed upon by Sandoz s generic version of Remodulin. Both appeals are pending before the United States Court of Appeals for the Federal Circuit.

The Settlement Agreement also relates to a separate, pending lawsuit (the ***Sandoz II Litigation***) filed by the Company against Sandoz in the U.S. District Court for the District of New Jersey for patent infringement with respect to U.S. Patent No. 8,497,393, which expires in December 2028. These actions are described in further detail in Part II, Item 1 of the Company s Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, filed with the U.S. Securities and Exchange Commission (***SEC***) on July 28, 2015.

Under the Settlement Agreement, the Company grants Sandoz a non-exclusive license to manufacture and commercialize in the United States the generic version of Remodulin described in Sandoz ANDA filing beginning on June 26, 2018, although Sandoz may be permitted to enter the market earlier under certain circumstances. The Settlement Agreement does not grant Sandoz 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 Sandoz any rights other than those required to launch Sandoz 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 appeal in the Sandoz I Litigation and dismiss with prejudice their respective claims in the Sandoz II Litigation.

The foregoing description of the Settlement Agreement does not purport to be complete and is qualified in its entirety by reference to the complete text of the Settlement Agreement, which will be filed, with certain confidential terms redacted, with the SEC as an exhibit to the Company s Quarterly Report on Form 10-Q for the quarter ending September 30, 2015.

Item 9.01. Exhibits

(d) Exhibits

Exhibit No.	Description of Exhibit
99.1	Press Release dated September 30, 2015

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: September 30, 2015

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