UNITED THERAPEUTICS Corp
Form 8-K
March 24, 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): **March 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 7.01. Regulation FD Disclosure.

Remodulin® Implantable System

On March 15, 2016, United Therapeutics Corporation (the ***Company***) was informed by Medtronic Inc. (***Medtronic***) that the U.S. Food and Drug Administration (***FDA***) had issued a response letter to Medtronic s premarket approval application (***PMA***) for the Remodulin Implantable System, indicating that the PMA is not approvable. In its response letter, the FDA noted various measures that Medtronic should take to make the PMA approvable. Medtronic and the Company are currently assessing the response letter and measures to address the agency s concerns.

In parallel, the Company continues to expect FDA action in October 2016 regarding its new drug application (***NDA***) seeking FDA approval of new labeling for Remodulin to allow administration with the Remodulin Implantable System. Both the NDA and PMA must be approved in order to launch the Remodulin Implantable System in the United States.

For additional information regarding the Remodulin Implantable System development program, please refer to the Company s Annual Report on Form 10-K, filed with the Securities and Exchange Commission on February 25, 2016.

The information contained in Item 7.01 to this Current Report on Form 8-K, and Exhibits 99.1 attached hereto, 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 of 1933, as amended, 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 future regulatory actions relating to the Medtronic Implantable System. These forward-looking statements are subject to certain risks and uncertainties, such as those described in our periodic and other reports filed with the Securities and Exchange Commission that could cause actual results to differ materially from anticipated results. These risks and uncertainties include, among others, our ability to successfully execute repurchases on favorable terms, and such 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. We claim the protection of the safe harbor contained in the Private Securities Litigation Reform Act of 1995 for forward-looking statements. We are providing this information as of March 24, 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: March 24, 2016

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