

UNITED THERAPEUTICS Corp
Form 8-K
March 30, 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): **March 30, 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 March 30, 2018, United Therapeutics Corporation (the *Company*) received notification from the U.S. Food and Drug Administration (*FDA*) that its New Drug Application (*NDA*) for the Implantable System for Remodulin® (*ISR*) has been accepted for a 6-month review as a Class 2 Resubmission. The NDA was submitted on January 30, 2018, and the Company therefore anticipates FDA action on the NDA by July 30, 2018. For additional information regarding the Company's efforts to develop the ISR, please refer to the Company's Annual Report on Form 10-K for the year ended December 31, 2017.

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 regulatory approval process for the ISR. 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 providing this information as of March 30, 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.

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 30, 2018

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