

UNITED THERAPEUTICS CORP

FORM 10-K (Annual Report)

Filed 02/22/17 for the Period Ending 12/31/16

Address	1040 SPRING ST SILVER SPRING, MD 20910
Telephone	3016089292
CIK	0001082554
Symbol	UTHR
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the fiscal year ended December 31, 2016

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the transition period from _____ to _____

Commission file number 0-26301

United Therapeutics Corporation

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

52-1984749
(I.R.S. Employer
Identification No.)

1040 Spring Street, Silver Spring, MD
(Address of Principal Executive Offices)

20910
(Zip Code)

(301) 608-9292

Registrant's Telephone Number, Including Area Code

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$.01 per share and associated preferred stock purchase rights	NASDAQ Global Select Market

Securities registered pursuant to Section 12(g) of the Act:

None
(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a
smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes No

The aggregate market value of the Common Stock held by non-affiliates of the registrant, based on the closing price on June 30, 2016, as reported by the NASDAQ Global Select Market was approximately \$4,094,026,937.

The number of shares outstanding of the issuer's common stock, par value \$0.01 per share, as of February 10, 2017, was 44,961,616.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for the registrant's 2017 annual meeting of shareholders scheduled to be held on June 28, 2017, are incorporated by reference in Part III of this Form 10-K.

TABLE OF CONTENTS

PART I		
Item 1.	Business	3
Item 1A.	Risk Factors	33
Item 1B.	Unresolved Staff Comments	48
Item 2.	Properties	48
Item 3.	Legal Proceedings	48
Item 4.	Mine Safety Disclosures	48
PART II		
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	49
Item 6.	Selected Financial Data	51
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	51
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	66
Item 8.	Financial Statements and Supplementary Data	F-1
Item 9.	Changes In and Disagreements With Accountants on Accounting and Financial Disclosure	67
Item 9A.	Controls and Procedures	67
PART III		
Item 10.	Directors, Executive Officers and Corporate Governance	68
Item 11.	Executive Compensation	69
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	69
Item 13.	Certain Relationships and Related Transactions, and Director Independence	69
Item 14.	Principal Accounting Fees and Services	70
PART IV		
Item 15.	Exhibits, Financial Statement Schedules	71
SIGNATURES		72

PART I

ITEM 1. BUSINESS

Overview

United Therapeutics Corporation is a biotechnology company focused on the development and commercialization of innovative products to address the unmet medical needs of patients with chronic and life-threatening conditions. We market and sell four commercial therapies in the United States to treat pulmonary arterial hypertension (PAH): Remodulin[®] (treprostinil) Injection; Tyvaso[®] (treprostinil) Inhalation Solution (Tyvaso); Orenitram[®] (treprostinil) Extended-Release Tablets (Orenitram); and Adcirca[®] (tadalafil) Tablets (Adcirca). We also market and sell an oncology product in the United States, Unituxin[®] (dinutuximab) Injection (Unituxin), which is approved for treatment of high-risk neuroblastoma. Outside the United States, our only significant revenues are derived from the sale of Remodulin, which is approved in Europe and various other countries. We are also engaged in research and development of new indications and delivery devices for our existing products, as well as new products to treat PAH and other conditions. Finally, we are engaged in early-stage research and development of a number of organ transplantation-related technologies.

We generate revenues from sales of our five commercially approved products noted above. Remodulin was approved by the U.S. Food and Drug Administration (FDA) for subcutaneous and intravenous administration in 2002 and 2004, respectively, and has been sold commercially in the United States since 2002. Tyvaso and Adcirca were both approved by the FDA and launched commercially in the United States in 2009. Orenitram was approved by the FDA in 2013 and Unituxin was approved by the FDA in 2015. We commenced sales of Orenitram and Unituxin during the second quarter of 2014 and third quarter of 2015, respectively. We expect sales of our current commercial products will continue to be our primary sources of revenues for the next several years. Our sales and marketing staff supports the availability of our commercial products in the United States, and these efforts are supplemented by our contract distributors. Outside the United States, our contract distributors are primarily responsible for sales and marketing efforts.

United Therapeutics was incorporated in Delaware in June 1996. Our principal executive offices are located at 1040 Spring Street, Silver Spring, Maryland 20910 and at 55 T.W. Alexander Drive, Research Triangle Park, North Carolina 27709.

Unless the context requires otherwise or unless otherwise noted, all references in this Annual Report on Form 10-K (this Report) to "United Therapeutics" and to the "company", "we", "us" or "our" are to United Therapeutics Corporation and its subsidiaries.

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.