UNITED THERAPEUTICS CORP

FORM 10-K
(Annual Report)

Filed 02/25/16 for the Period Ending 12/31/15

Address	1040 SPRING ST
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Telephone	3016089292
CIK	0001082554
Symbol	UTHR
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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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, 2015

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	**52-1984749**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
1040 Spring Street, Silver Spring, MD	**20910**
(Address of Principal Executive Offices)	(Zip Code)

(301) 608-9292
Registrant's Telephone Number, Including Area Code

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

Title of each class	**Name of each exchange on which registered**
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 not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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

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, 2015, as reported by the NASDAQ Global Select Market was approximately $6,657,883,891.

The number of shares outstanding of the issuer's common stock, par value $0.01 per share, as of February 12, 2016, was 45,352,746.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for the registrant's 2016 annual meeting of shareholders scheduled to be held on June 21, 2016, are incorporated by reference in Part III of this Form 10-K.

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PART I

ITEM 1. BUSINESS

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 diseases.

Our key therapeutic products and product candidates include:

- *Prostacyclin Analogues.* Prostacyclin analogues are stable synthetic forms of prostacyclin, an important molecule produced by the body that has powerful effects on blood vessel health and function. Our lead product is Remodulin® (treprostinil) Injection (Remodulin), which is administered subcutaneously (under the skin) or intravenously (in the vein) for the treatment of pulmonary arterial hypertension (PAH) to diminish symptoms associated with exercise. The United States Food and Drug Administration (FDA) approved Remodulin for subcutaneous and intravenous administration in 2002 and 2004, respectively. Outside the United States, Remodulin is approved in 39 countries, most of which have approved both routes of administration. We are developing new technologies to make Remodulin delivery more convenient, such as implantable pump systems for intravenous Remodulin and pre-filled, semi-disposable pumps for subcutaneous Remodulin. In 2009, the FDA approved Tyvaso® (treprostinil) Inhalation Solution (Tyvaso), an inhaled prostacyclin therapy for the treatment of PAH. In December 2013, the FDA approved Orenitram® (treprostinil) Extended-Release Tablets (Orenitram), an oral prostacyclin analogue for the treatment of PAH, which commenced sales during the second quarter of 2014. Our wholly-owned subsidiary, Lung Biotechnology PBC, is developing another oral prostacyclin analogue for the treatment of PAH called esuberaprost.

- *Phosphodiesterase Type 5 (PDE-5) Inhibitor.* PDE-5 inhibitors act to inhibit the degradation of cyclic guanosine monophosphate (cyclic GMP) in cells. Cyclic GMP is activated by nitric oxide (NO), a naturally occurring substance in the body that mediates the relaxation of vascular smooth muscle. Our PDE-5 inhibitor is Adcirca® (tadalafil) tablets (Adcirca), a once-daily oral therapy for the treatment of PAH. We acquired exclusive U.S. commercialization rights to Adcirca from Eli Lilly and Company (Lilly) in 2008. In 2009, the FDA approved Adcirca for the treatment of PAH.

- *Monoclonal Antibody (MAb).* MAbs are antibodies that bind to cancerous tumors and destroy the cancer cells through a mechanism called antibody-dependent cell mediated cytotoxicity. In March 2015, the FDA approved Unituxin® (dinutuximab) Injection (Unituxin), in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), interleukin-2 (IL-2), and 13-cis-retinoic acid (RA), for the treatment of pediatric patients with high-risk neuroblastoma who achieve at least a partial response to prior first-line multiagent, multimodality therapy. We commenced U.S. sales of Unituxin in the third quarter of 2015. We received European Commission approval during the third quarter of 2015, and plan to commence commercial sales in individual European countries following pricing and reimbursement approvals on a country-by-country basis.

During the fourth quarter of 2015, we sold the rights to our glycobiology antiviral platform under terms that entitle us to milestone and royalty payments from the buyer in the event the program is successful. Additionally, during the fourth quarter of 2015, we terminated our license agreement with Pluristem Ltd. (Pluristem) relating to the development of a cell-based product for the treatment of PAH using Pluristem's PLacental eXpanded (PLX) cells.

We generate revenues from sales of Remodulin, Tyvaso, Adcirca, Orenitram and Unituxin (which we refer to as our commercial products). We commenced sales of Orenitram and Unituxin during the second quarter of 2014 and third quarter of 2015, respectively. We expect that sales of our existing

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