UNITED THERAPEUTICS CORP

FORM 10-K
(Annual Report)

Filed 02/25/14 for the Period Ending 12/31/13

Address	1040 SPRING ST SILVER SPRING, MD 20910
Telephone	3016089292
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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, 2013

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 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 filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☒	Accelerated filer ☐	Non-accelerated filer ☐ (Do not check if a smaller reporting company)	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 28, 2013, as reported by the NASDAQ Global Select Market was approximately $2,458,927,716.

The number of shares outstanding of the issuer's common stock, par value $0.01 per share, as of February 18, 2014, was 50,477,071.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for the registrant's 2014 annual meeting of shareholders scheduled to be held on June 26, 2014, 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 unique products to address the unmet medical needs of patients with chronic and life-threatening conditions.

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). The United States Food and Drug Administration (FDA) approved Remodulin in 2002 for subcutaneous administration. Subsequently, the FDA broadened its approval of Remodulin for intravenous use and for the treatment of patients who require transition from Flolan® (epoprostenol), the first FDA-approved prostacyclin therapy for PAH. Outside the United States, Remodulin is approved in 37 countries, most of which have approved both routes of administration. 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), which we expect to make commercially available in mid-2014. We are also conducting pre-clinical studies of a self-injectable form of treprostinil, which we refer to as TransCon treprostinil. Our wholly-owned subsidiary Lung Biotechnology Inc., formerly known as Lung LLC, is developing another prostacyclin analogue we licensed from Toray Industries, Inc. (Toray) called beraprost, for treatment of PAH both as an oral tablet known as 314d and as an extended release injection we refer to as TransCon beraprost.

- *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 product 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 act by targeting tumor-associated antigens on cancer cells to activate a patient's immune system against the cancer cells. We are developing the antibody Ch14.18 MAb for the treatment of neuroblastoma, under an agreement with the National Cancer Institute (NCI) of the United States National Institutes of Health (NIH). In December 2013, our marketing authorization application (MAA) for this antibody was accepted for review by the European Medicines Agency (EMA) and we plan to file a biologics license application (BLA) with the FDA during the first half of 2014.

- *Glycobiology Antiviral Agents.* Glycobiology antiviral agents are a novel class of small, sugar-like molecules that have shown pre-clinical indications of efficacy against a broad range of viruses. In September 2011, we were awarded a contract from the National Institute of Allergy and Infectious Diseases (NIAID) of the NIH for studies directed at the development of a broad spectrum antiviral drug based on our glycobiology antiviral platform. During the first half of 2014, we plan to begin enrolling a phase I clinical trial of our lead antiviral candidate, an alpha-glucosidase inhibitor called UV-4B, for the treatment of dengue.

- *Cell-Based Therapy.* In June 2011, we entered into a license agreement with Pluristem Ltd. (Pluristem) to develop and commercialize its cell-based product known as PLacental eXpanded

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