

# UNITED THERAPEUTICS CORP

# FORM 10-K (Annual Report)

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Address 1040 SPRING ST

SILVER SPRING, MD 20910

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Sector Healthcare

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**Table of Contents** 

# 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, 2010

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:

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 🗆



| (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 🗆 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 区   |  |  |  |
| The aggregate market value of the Common Stock held by non-affiliates of the registrant, based on the closing price on June 30, 2010, as reported by the NASDAQ Global Select Market was approximately \$2,020,812,000.  |  |  |  |
| The number of shares outstanding of the issuer's common stock, par value \$0.01 per share, as of February 18, 2011, was 57,753,901.  |  |  |  |
| DOCUMENTS INCORPORATED BY REFERENCE  |  |  |  |
| Portions of the registrant's definitive proxy statement for the registrant's 2011 annual meeting of shareholders scheduled to be held on June 29, 2011, 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 are:

- 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) to be administered subcutaneously or intravenously for the treatment of pulmonary arterial hypertension (PAH). The United States Food and Drug Administration (FDA) initially approved Remodulin in 2002 for subcutaneous (under the skin) administration. Subsequently, the FDA broadened its approval of Remodulin for intravenous (in the vein) use and for the treatment of patients who require transition from Flolan®. In addition to the United States, Remodulin is approved in many other countries, primarily for subcutaneous use. In July 2009, the FDA approved Tyvaso® (treprostinil) Inhalation Solution (Tyvaso), an inhaled prostacyclin therapy for the treatment of PAH. We commenced commercial sales of Tyvaso in the third quarter of 2009. Our oral tablet of treprostinil diethanolamine is in the later stages of development. Our subsidiary, Lung Rx, LLC (Lung Rx), is separately developing modified release beraprost (beraprost-MR), another type of oral prostacyclin analogue, for the treatment of PAH;
- Phosphodiesterase Type 5 (PDE-5) Inhibitor. PDE-5 inhibitors act to inhibit the degradation of cyclic guanosine monophosphate (cGMP) in cells. cGMP is activated by nitric oxide (NO) to signal 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 certain exclusive commercialization rights to Adcirca from Eli Lilly and Company (Lilly) in 2008. In May 2009, the FDA approved Adcirca for the treatment of PAH. We commenced commercial sales of Adcirca in the third quarter of 2009;
- *Monoclonal Antibodies (MAb)*. MAb 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. We are also developing another antibody, 8H9 MAb, for the treatment of metastatic brain cancer, under an agreement with Memorial Sloan-Kettering Cancer Center; and
- *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.

We devote most of our research and development resources to developing these key products and product candidates.

We generate revenues primarily from the sale of Remodulin, Tyvaso and Adcirca (which we refer to as our commercial products). Our sales and marketing staff supports the availability of our commercial products in the countries in which they are approved. These efforts are supplemented by our specialty pharmaceutical distributors in the United States and our other distributors internationally.

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



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