UNITED THERAPEUTICS CORP

FORM 10-K (Annual Report)

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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, 2009

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 \square No \square			
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 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 Non-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 \square No \boxtimes			
The aggregate market value of the Common Stock held by non-affiliates of the registrant, based on the closing price on June 30, 2009, as reported by the NASDAQ Global Select Market was approximately \$1,923,449,000.			
The number of shares outstanding of the issuer's common stock, par value \$0.01 per share, as of February 19, 2010, was 54,608,343.			
DOCUMENTS INCORPORATED BY REFERENCE			
Portions of the registrant's definitive proxy statement for the registrant's 2010 annual meeting of shareholders scheduled to be held on June 28, 2010, are incorporated by reference in Part III of this Form 10-K.			



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EXHIBITS		
EX-10.46**	Form of Amendment to Employment Agreement between the Registrant and each of Roger Jeffs, Paul Mahon and John Ferrari, each dated as of February 22, 2010.	
EX-10.47	Distribution Agreement, dated August 17, 2009, between the Registrant and Accredo Health Group, Inc.	
EX-10.48**	Forms of terms and conditions for awards granted to Employees by Registrant on or after January 1, 2010, under the United Therapeutics Corporation Share Tracking Awards Plan.	
EX-12.1	Computation of Earnings to Fixed Charges	
EX-21	Subsidiaries of the Registrant	
EX-23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm	
EX-31.1	Rule 13a-14(a) Certification of CEO	
EX-31.2	Rule 13a-14(a) Certification of CFO	
EX-32.1	Section 1350 Certification of CEO	
EX-32.2	Section 1350 Certification of CFO	



^{**} Designates management contracts and compensation plans.

PART I

ITEM 1. BUSINESS

We are 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 platforms are:

- Prostacyclin Analogues, which 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®, the first drug approved by the FDA for the treatment of PAH. 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. We are also developing modified release beraprost (beraprost-MR), another oral prostacyclin analogue, for the treatment of PAH:
- Phosphodiesterase Type 5 (PDE-5) Inhibitors, which 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*, which act by targeting tumor-associated antigens on cancer cells. We are developing the antibodies 3F8 MAb and 8H9 MAb for the treatment of neuroblastoma and metastatic brain cancer, respectively. We began a Phase II clinical trial in the second quarter of 2009 with 3F8 in primary refractory neuroblastoma; and
- Glycobiology Antiviral Agents, which are a novel class of small, sugar-like molecules that have shown pre-clinical indications of efficacy against a broad range of viruses, such as hepatitis C, dengue fever and certain influenza viruses. We are currently conducting preclinical tests on potential compounds for further development.

We devote most of our resources to developing products within our key therapeutic platforms. We also devote our resources to developing products in other therapeutic platforms and to the commercialization and further development of telemedicine products and services, principally for the detection of cardiac arrhythmias (abnormal heart rhythms).

We generate revenues from the sale of Remodulin, Tyvaso and Adcirca (which we refer to as our Commercial Products) and telemedicine products and services. Our sales and marketing staff for our Commercial Products, which is supplemented by our specialty pharmaceutical distributors, supports the commercial availability of our Commercial Products in the countries in which they are approved.

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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