UNITED THERAPEUTICS CORP

FORM 10-K (Annual Report)

Filed 2/28/2007 For Period Ending 12/31/2006

Address 1110 SPRING ST

SILVER SPRING, Maryland 20910

Telephone 301-608-9292 CIK 0001082554

Industry Biotechnology & Drugs

Sector Healthcare

Fiscal Year 12/31



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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2006

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□ 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.)

1110 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 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, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer $\ \square$ Accelerated filer $\ \square$ Non-accelerated filer $\ \square$

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, 2006, as reported by the NASDAQ National Market was approximately \$1,201,000.

The number of shares outstanding of the issuer's common stock, par value \$0.01 per share, as of February 20, 2007, was 21,314,670

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for the registrant's 2007 annual shareholders meeting are incorporated by reference in Part III of this Form 10-K.



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PART I

ITEM 1. BUSINESS

We are a biotechnology company focused on the development and commercialization of innovative therapeutic products for patients with chronic and life-threatening diseases. We are active in three therapeutic areas—cardiovascular, cancer and infectious diseases. Our key therapeutic platforms include:

- *Prostacyclin Analogs*, 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 drug Remodulin [®] has been approved by the U.S. Food and Drug Administration, or FDA, for the treatment of pulmonary arterial hypertension, or PAH, in patients with New York Heart Association (NYHA) Class II-IV (moderate to severe) symptoms to diminish symptoms associated with exercise, and in other countries for similar use, and in most of Europe for the treatment of NYHA Class III patients with PAH;
- Immunotherapeutic Monoclonal Antibodies, which are antibodies that activate patients' immune systems to treat cancer. This platform includes OvaRex [®], which is being developed for the treatment of metastatic ovarian cancer; and
- Glycobiology Antiviral Agents, which are a class of small molecules that have shown pre-clinical indications of efficacy against a broad range of viruses.

Most of our resources are focused on our prostacyclin analogs for the treatment of cardiovascular disease and immunotherapeutic monoclonal antibodies for the treatment of cancer. Our other principal focus area is the development of glycobiology antiviral agents for the treatment of hepatitis and other diseases. We also devote resources to the commercialization and further development of telemedicine products and services, principally for the detection of cardiac arrhythmias, as well as to arginine supplementation therapy for cardiovascular health.

Revenues from the sales of Remodulin for PAH commenced following its May 2002 FDA approval, and we have also generated revenues from sales of arginine products and telemedicine products and services. We field a sales and marketing organization that supports the commercial availability of Remodulin in the United States, Canada, Europe and other countries, aided by chronic-care specialty pharmaceutical distributors.

United Therapeutics was incorporated in Delaware in June 1996. United Therapeutics' principal executive offices are located at 1110 Spring Street, Silver Spring, Maryland 20910.



United Therapeutics' Products

Our Products

Our product portfolio includes the following:

Product	Mode of Delivery	Indication/Market	Current Status	Our Territory
Remodulin	Continuous subcutaneous	Pulmonary arterial hypertension	Commercial in U.S., and 32 countries including most of the European Union, Canada, Israel, and Australia*	Worldwide
Remodulin	Continuous intravenous	Pulmonary arterial hypertension	Commercial in U.S., Canada, Israel, Mexico, Argentina and Peru. European reviews are ongoing	Worldwide
Arginine Formulations	Oral dietary supplement	Vascular function	Commercial	Worldwide
CardioPAL [®] and Decipher [®] Recorders	Telemedicine	Arrhythmias and ischemic heart disease	Commercial	Worldwide
OvaRex	Intravenous	Ovarian cancer	Phase III	Worldwide**
Viveta TM (Treprostinil for Inhalation)	Inhaled	Pulmonary arterial hypertension	Phase III	Worldwide
UT-15C Sustained Release	Oral	Pulmonary arterial hypertension	Phase II/III	Worldwide
UT-15C Sustained Release	Oral	Peripheral vascular disease/critical limb ischemia	Phase II	Worldwide
Remodulin	Intravenous	Improved transplant outcome	Phase II	Worldwide
Beraprost ® SR	Oral	Pulmonary arterial hypertension	Phase I	U.S./Canada
BrevaRex ®	Intravenous	Pancreatic cancer	Preclinical	Worldwide**
Glycobiology Antiviral Agents	Oral	Hepatitis B/C, dengue fever and Japanese encephalitis	Preclinical	Worldwide
OncoRex ®	Intravenous	Various cancers	Preclinical	Worldwide**
ProstaRex ®	Intravenous	Prostate cancer	Preclinical	Worldwide**
GivaRex ®	Intravenous	Gastrointestinal cancer	Preclinical	Worldwide**

^{*} We have obtained approval in 23 member countries of the European Union (Austria, Belgium, Czech Republic, Denmark, Estonia, France, Germany, Greece, Iceland, Italy, Luxembourg, Netherlands, Portugal, Cyprus, Finland, Hungary, Latvia, Lithuania, Norway, Poland, Slovakia, Slovenia, and Serbia), and have received formal approval letters and pricing approvals in most of them.

Remodulin

We obtained worldwide rights for all indications to Remodulin, a prostacyclin analog, from Glaxo Wellcome, Inc. (now GlaxoSmithKline PLC) in January 1997 and Pharmacia & Upjohn Company (now Pfizer, Inc.) in December 1996. In May 2002, Remodulin was approved by the FDA as a continuous subcutaneous (under the skin) infusion. In November 2004, our FDA approval was expanded to permit continuous intravenous (through a vein or artery) infusion in patients who cannot tolerate subcutaneous infusion. In March 2006, our FDA approval was expanded to allow transition from Flolan [®] (epoprostinil), the first FDA-approved prostacyclin for PAH. Remodulin is also approved as a continuous subcutaneous infusion in 32 countries throughout the world and as a continuous intravenous infusion in Canada, Israel,

^{**} Including Germany, but excluding most of the rest of Europe and the Middle East.

DOCKET

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.

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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.

