UNITED THERAPEUTICS CORP

FORM 10-K (Annual Report)

Filed 2/27/2006 For Period Ending 12/31/2005

Address 1110 SPRING ST

SILVER SPRING, Maryland 20910

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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

(Mark One)

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

For the fiscal year ended December 31, 2005

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

> For the transition period from 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.)

20910

1110 Spring Street, Silver Spring, MD

(Address of Principal Executive Offices)

(Zip Code)

(301) 608-9292

Registrant's Telephone Number, Including Area Code

(Former Name, Former Address and Former Fiscal Year, If Changed Since Last Report)

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

None

Securities registered pursuant to Section 12(g) of the Act: Common Stock, par value \$.01 per share and associated preferred stock purchase rights

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 a v	vell-known seasoned issuer a	s defined in Rule 405 of the	Securities Act Yes 🗵	ΝοП

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange 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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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 Securities Exchange Act. (Check one) Large accelerated filer 🗵 Accelerated filer Non-accelerated filer □

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes \Box

The number of shares outstanding of the issuer's common stock, par value \$.01 per share, as of February 21, 2006 was 23,370,889.

The aggregate market value of the Common Stock held by non-affiliates of the registrant, based on the closing price on June 30, 2005 as reported by the NASDAQ National Market was approximately \$963.3 million.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for the registrant's 2006 annual shareholders meeting are incorporated by reference in Part III of this Form 10-K.



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PART I

ITEM 1. BUSINESS

United Therapeutics is 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 Food and Drug Administration (FDA) in the United States for the treatment of pulmonary arterial hypertension in patients with NYHA Class II-IV symptoms to diminish symptoms associated with exercise, and in other countries for similar use;
- Immunotherapeutic Monoclonal Antibodies, which are antibodies that activate patients' immune systems to treat cancer, including OvaRex [®], which is being developed for the treatment of ovarian cancer;
- Glycobiology Antiviral Agents, which are a novel class of small molecules which may be effective as an oral therapy for hepatitis C and other infections:

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.

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 product portfolio includes the following:

Product Remodulin ®	Mode of Delivery Continuous subcutaneous	Indication/Market Pulmonary arterial hypertension	Current Status Commercial in U.S., most of Europe**, Australia, Canada, Israel, Chile and Argentina	Our Territory Worldwide
Remodulin [®]	Continuous intravenous	Pulmonary arterial hypertension	Commercial in U.S., Canada and Israel. 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 *
Remodulin	Intermittent subcutaneous	Critical limb ischemia	Phase II	Worldwide
TRIUMPH	Inhaled	Pulmonary arterial hypertension	Phase II/III	Worldwide
UT-15C Sustained Release	Oral	Pulmonary arterial hypertension and peripheral vascular disease	Phase I/II	Worldwide
BrevaRex ®	Intravenous	Pancreatic cancer	Phase I	Worldwide *
Beraprost ® SR	Oral	Peripheral vascular disease and pulmonary arterial hypertension	Phase I	U.S./Canada
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 *

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

Remodulin

In January 1997 and December 1996, we obtained worldwide rights for all indications to Remodulin, a prostacyclin analog, from Glaxo Wellcome, Inc. and Pharmacia & Upjohn Company (see *Patent and Proprietary Rights* below). In October 1999, we acquired all the outstanding stock of SynQuest, Inc., the manufacturer of treprostinil, the bulk active ingredient in Remodulin. In May 2002, Remodulin, our main product, was approved by the FDA in the United States as a continuous subcutaneous (under the skin) infusion. In November 2004, the FDA approval was expanded to permit continuous intravenous (through a vein or artery) infusion in patients who cannot tolerate subcutaneous infusion. Remodulin is also approved as a continuous subcutaneous infusion in most of Europe, Canada, Israel, Australia, Argentina and Chile. It is also approved as a continuous infusion in Canada and Israel.

Pulmonary Arterial Hypertension

We have focused primarily on developing Remodulin as our lead product for treating pulmonary arterial hypertension. Pulmonary arterial hypertension, or PAH, is a life-threatening vascular disease that



^{**} We have obtained approval of 23 member countries of the European Union, but are awaiting formal approval letters and pricing approvals in most of them.

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.

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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.

