

# UNITED THERAPEUTICS CORP

## FORM 10-K (Annual Report)

Filed 2/25/2005 For Period Ending 12/31/2004

Address	1110 SPRING ST SILVER SPRING, Maryland 20910
Telephone	301-608-9292
CIK	0001082554
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Fiscal Year	12/31

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**Securities and Exchange Commission**  
**Washington, DC 20549**  
**Form 10-K**

☒ **ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2004  
OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OF 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)

1110 Spring Street  
Silver Spring, MD

(Address of principal executive offices)

52-1984749

(IRS Employer Identification No.)

20910

(zip code)

Registrant's telephone number, including area code: (301) 608-9292

Securities registered under Section 12(b) of the Exchange Act:  
None

Securities registered under Section 12(g) of the Exchange Act:  
Common Stock, par value \$.01 per share  
and associated preferred stock purchase rights  
(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 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 an accelerated filer (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 30, 2004 as reported by the NASDAQ National Market was approximately \$468.8 million. <sup>(1)</sup>

The number of shares outstanding of the registrant's Common Stock, par value \$.01 per share, as of February 9, 2005 was 22,492,980 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for the registrant's 2005 annual shareholders meeting are incorporated by reference in Part III of this Form 10-K.

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- (1) Excludes 3,153,074 shares of common stock held by directors and officers, and any stockholders whose ownership exceeds ten percent of the shares outstanding at June 30, 2004. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, directly or indirectly, to direct or cause the direction of the management or policies of the registrant, or that such person is controlled by or under common control with the registrant.
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## PART I

### ITEM 1. BUSINESS

United Therapeutics is a biotechnology company focused on the development and commercialization of unique products for patients with chronic and life-threatening diseases. United Therapeutics is active in three therapeutic areas — cardiovascular medicine, cancer and infectious disease — with five therapeutic platforms:

- *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. United Therapeutics' 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 metastatic 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;
- *Telemedicine* , which involves portable digital devices that enable physicians to remotely monitor patients' bodily measurements such as heart function, including the CardioPAL® family of cardiac event recorders and the Decipher™ Holter monitors; and
- *Arginine Formulations* , including the HeartBar® and other products, which deliver the amino acid arginine that is necessary for maintaining vascular function.

Most of United Therapeutics' resources are focused on its prostacyclin analogs for the treatment of cardiovascular disease and immunotherapeutic monoclonal antibodies for the treatment of cancer. United Therapeutics' other principal focus area is the development of glycobiology antiviral agents for the treatment of hepatitis and other diseases. United Therapeutics also devotes resources to the commercialization and further development of arginine supplementation therapy, especially in cardiovascular health, and of telecardiology, principally for the detection of cardiac arrhythmias.

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

United Therapeutics' product portfolio includes the following:

<u>Product</u>	<u>Mode of Delivery</u>	<u>Indication/Market</u>	<u>Current Status</u>	<u>UT Territory</u>
Remodulin	Continuous subcutaneous	Pulmonary arterial hypertension	Commercial in U.S., Australia, Canada, Israel, and Switzerland. European reviews are ongoing	Worldwide
Remodulin	Continuous intravenous	Pulmonary arterial hypertension	Commercial in U.S.	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
UT-231B	Oral	Hepatitis C	Phase II	Worldwide
TRIUMPH	Inhaled	Pulmonary arterial hypertension Pulmonary arterial	Phase II	Worldwide
UT-15C Sustained Release	Oral	hypertension and peripheral vascular disease	Phase I	Worldwide
BrevaRex®	Intravenous	Multiple myeloma/breast cancer	Phase I	Worldwide *
Beraprost® SR	Oral	Peripheral vascular disease	Phase I	U.S./Canada
Glycobiology Antiviral Agents	Oral	Hepatitis B, 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 December 1996 and January 1997, United Therapeutics obtained worldwide rights for all indications to Remodulin (also known as UT-15 and formerly known as Uniprost), a prostacyclin analog, from Glaxo Wellcome, Inc. and Pharmacia & Upjohn Company (see *Patent and Proprietary Rights* below). In October 1999, United Therapeutics acquired all the outstanding stock of SynQuest, Inc., the manufacturer of treprostinil, the bulk active ingredient in Remodulin. In May 2002, Remodulin, United Therapeutics' 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 infusion in patients who cannot tolerate subcutaneous infusion. Remodulin is also approved as a continuous subcutaneous infusion in Canada, Israel, Australia and Switzerland and is under review in other countries.

### ***Pulmonary Arterial Hypertension***

United Therapeutics has focused primarily on developing Remodulin as its lead product for treating pulmonary arterial hypertension. Pulmonary arterial hypertension is a life-threatening vascular disease that affects the blood vessels between the heart and lungs known as the pulmonary blood vessels. Pulmonary arterial hypertension is characterized by the degradation of the blood vessel wall lining, the aggregation of platelets and the disruption of smooth muscle cell function. These conditions cause blockages and affect the ability of the blood vessels to dilate and then constrict as blood flows to the lungs. The resulting elevated pulmonary blood pressure causes increasing strain on the right side of the heart as it tries to pump blood to the lungs. It is estimated that there are between 50,000 and 100,000 individuals with pulmonary arterial hypertension worldwide.

Pulmonary arterial hypertension is associated with reduced production of the natural hormone prostacyclin in the pulmonary blood vessels. Prostacyclin appears to dilate blood vessels where necessary, prevent platelet aggregation, and prevent proliferation of smooth muscle cells surrounding the vessels. The first FDA-approved prostacyclin for pulmonary arterial hypertension was Flolan®, a synthetic form of prostacyclin delivered continuously by an external pump through a surgically implanted intravenous catheter. Flolan was approved for use in certain subsets of late-stage pulmonary arterial hypertension.

In March 2000, United Therapeutics completed an international, randomized, placebo-controlled, double-blind study of subcutaneous Remodulin involving a total of 470 patients with pulmonary arterial hypertension. Half of the patients received Remodulin subcutaneously for 12 weeks, while the other half received a placebo. The study data show that patients who received Remodulin had significant improvement in exercise capacity, pulmonary blood pressure and in the signs and symptoms of the disease. Based on the favorable results of this study, United Therapeutics filed a New Drug Application (NDA) with the FDA in late 2000. On May 21, 2002, the FDA approved Remodulin (treprostinil sodium) Injection as a continuous subcutaneous infusion for the treatment of pulmonary arterial hypertension in patients with NYHA class II-IV symptoms to diminish symptoms associated with exercise. Remodulin may be prescribed for all forms of pulmonary arterial hypertension and is the only pulmonary arterial hypertension treatment approved for patients with NYHA class II (early-stage) symptoms.

United Therapeutics believes Remodulin provides patients with convenient and less invasive alternatives to Flolan. In contrast to Flolan, Remodulin is stable at room temperature and is significantly longer lived in the human body. These attributes allow for safer and more convenient delivery of Remodulin to patients. Unlike Flolan, Remodulin can be delivered by subcutaneous infusion with a pager-sized microinfusion device made by Medtronic MiniMed (see *The Medtronic MiniMed Strategic Alliance* below). Subcutaneous delivery of Remodulin also eliminates the risk of sepsis infection and related hospitalization associated with the intravenous catheter. Remodulin's extended life in the body also greatly reduces the risk of an abrupt recurrence of pulmonary hypertension and death if treatment is interrupted. The stability of Remodulin also allows it to be prepackaged, thus eliminating the need to reconstitute the drug one or more times daily under completely sterile conditions, as is required with Flolan. Lastly, Remodulin does not require the use of cooling packs or refrigeration as is required with Flolan to keep it stable. When infused subcutaneously, Remodulin causes infusion site pain and infusion site reaction in most patients in varying degrees. Patients who cannot tolerate subcutaneous Remodulin may use it intravenously. Intravenous Remodulin is delivered continuously by an external pump through a surgically implanted intravenous catheter, similar to Flolan. When delivered intravenously, Remodulin bears a risk of infection, similar to that of Flolan, but it does not require cooling packs or refrigeration and can be continuously infused for up to 48 hours before refilling the infusion pump.

Upon FDA approval of Remodulin in 2002, United Therapeutics was required to perform a post-marketing Phase IV clinical study to further assess the clinical benefits of Remodulin. Continued FDA approval of Remodulin is subject to the diligent and timely completion of that Phase IV trial, as well as its outcome. The study was originally to have been completed by May 2004 and involve 100 patients. In mid-2003, the FDA agreed to amend the due date of the final study report and



make other changes to the trial design including reducing the number of patients to 39.

As amended, the Phase IV clinical trial was required to be one-half enrolled by June 2004 and must be fully enrolled by June 2005; however, the FDA has permitted an interim assessment and opportunity to terminate the Phase IV study after only 21 patients have completed the study. The final study report is required to be submitted in December 2005. To date, only 15 patients have been enrolled in this 39-patient Phase IV trial. Enrolling patients in this study is difficult, in part because it involves randomizing some of the patients to placebo despite the fact that approved drugs are available for these patients.

United Therapeutics is not currently enrolling the Phase IV trial within the time frame specified by the FDA, and therefore is at risk of the FDA at any time instituting a public hearing to withdraw marketing approval for Remodulin. United Therapeutics is in discussions with the FDA about its due diligence in enrolling the Phase IV trial and has made a proposal which United Therapeutics believes will ensure that it is able to provide interpretable results of this trial by the December 2005 final study report delivery deadline. Specifically, United Therapeutics has proposed that the FDA evaluate the results of the Phase IV trial based on the number of patients enrolled through September 15, 2005. The FDA is reviewing this proposal. The FDA could, among other things, accept this proposal, grant an extension of time to continue to enroll the trial, or institute a public hearing to withdraw marketing approval for Remodulin. If a withdrawal hearing were instituted by the FDA, United Therapeutics would pursue the opportunity to participate as it believes that it has exercised good faith due diligence in pursuing enrollment of this trial.

Subcutaneous infusion of Remodulin has also been approved in the following countries:

<u>Country</u>	<u>Date</u>	<u>Approved Indication</u>
Canada	October 7, 2002	Long term subcutaneous treatment of pulmonary arterial hypertension in NYHA class III and IV patients who do not respond adequately to conventional therapy
Israel	October 31, 2002	Primary pulmonary arterial hypertension, pulmonary arterial hypertension associated with connective tissue disorders and pulmonary arterial hypertension associated with congenital systemic to pulmonary shunts
Australia	May 21, 2004	Pulmonary arterial hypertension in NYHA class III and IV to diminish symptoms associated with exercise
Switzerland	November 26, 2004	Long-term treatment of primary pulmonary hypertension and pulmonary hypertension with connective tissue disease for NYHA class III and IV patients

Marketing authorization applications are currently under review in France and other countries for subcutaneous Remodulin.

#### *Intravenous Remodulin*

In July 2003, the FDA accepted United Therapeutics' Investigational New Drug Application (IND) for the development of Remodulin by intravenous delivery for the treatment of pulmonary arterial hypertension. A bioequivalence study in human volunteers was performed in late 2003, which established that intravenous and subcutaneous Remodulin are bioequivalent (meaning that both routes of infusion result in comparable levels of Remodulin in the blood). In addition, animal toxicology studies were completed and indicated comparable safety of chronic intravenous infusion as compared to chronic subcutaneous infusion.

On January 30, 2004, a supplemental New Drug Application (sNDA) was filed with the FDA to request approval for intravenous use of Remodulin for pulmonary arterial hypertension. On November 24, 2004, based on data establishing intravenous Remodulin's bioequivalence with the previously approved subcutaneous administration of Remodulin, the FDA approved the intravenous use of Remodulin for those not able to tolerate subcutaneous infusion. This approval was also conditioned upon the diligent and timely completion of the Phase IV trial described above, as well as its outcome. A marketing authorization application for intravenous Remodulin is under review in Canada and other filings are being planned.

Although intravenous Remodulin does not possess all the safety and convenience benefits as subcutaneously delivered Remodulin, it eliminates the infusion site pain and reaction currently experienced by most patients using Remodulin subcutaneously. In addition, it serves as an alternative to intravenous Flolan, which must be continuously refrigerated, including during infusion, while Remodulin does not require any refrigeration. Furthermore, the active ingredient in Flolan is highly unstable and only remains active in the body for a few minutes, whereas the active ingredient in Remodulin remains active for a few hours. This may reduce the risk of rebound hypertension, which is a severe recurrence of the disease in the case of inadvertent therapy interruption. In addition, Remodulin can be infused continuously for up to 48 hours as opposed to only 24 hours for Flolan, allowing patients to prepare medication solutions every other day as opposed to daily.

#### *Peripheral Vascular Disease/Critical Limb Ischemia*

United Therapeutics is also developing Remodulin for late-stage peripheral vascular disease known as critical limb ischemia. Peripheral vascular disease is a disease that affects the blood vessels in the legs. While the precise cause of peripheral vascular disease is unknown, diabetes, obesity, smoking and lack of exercise are associated with the disease. Peripheral vascular disease appears to be similar to pulmonary hypertension in that there is a reduction in natural prostacyclin in the affected blood vessels.

In the United States, it is estimated that 750,000 people suffer from critical limb ischemia. The disease is characterized by extreme pain, non-healing ulcers in the legs, reduced exercise capacity and severely reduced blood flow in the limbs. There are currently no drugs approved to treat critical limb ischemia. Physicians, therefore, perform surgical interventions (such as balloon angioplasty, stents and by-passes) to restore or improve blood flow in the limbs. These procedures can provide relief to patients, but do not address the underlying causes of peripheral vascular disease. Due to the lack of adequate treatments, approximately 200,000 amputations of limbs are performed each year on patients with critical limb ischemia.

In September 1998, United Therapeutics completed a Phase II study which assessed the safety and blood flow effects of Remodulin administered intravenously to patients with critical limb ischemia. The study demonstrated that Remodulin can be administered safely to patients with critical limb ischemia and that Remodulin substantially increased blood flow in the affected areas of the legs. United Therapeutics commenced a 30 patient placebo-controlled pre-pivotal clinical study of Remodulin for critical limb ischemia in 2002. Approximately 19 patients were enrolled. The study was ended before becoming fully enrolled due to difficulties in recruiting patients for the study. United Therapeutics believes that more convenient formulations of Remodulin, such as an oral form, may be more appropriate for patients with peripheral vascular disease.

#### *UT-15C Sustained Release*

United Therapeutics is currently in Phase I studies of a longer-acting prostacyclin analog, known as UT-15C Sustained Release. UT-15C Sustained Release will be developed as an oral therapy for vascular diseases, including pulmonary arterial hypertension and peripheral vascular disease. A longer-acting prostacyclin formulation could enable patients to take fewer doses per day. A Phase I study in healthy human volunteers was conducted in 2004 and confirmed bioavailability (meaning that the drug reaches the blood stream after being swallowed orally) using a liquid solution of treprostinil. Additional Phase I studies were conducted in 2004 with sustained release dosage forms (tablets and capsules) in healthy volunteers to assess which formulation provided sustained blood plasma exposure. The Investigational New Drug Application for UT-15C Sustained Release was filed with the FDA on January 28, 2005.

#### *TRIUMPH*

During 2004, independent clinical investigators performed small uncontrolled trials of inhaled treprostinil. United Therapeutics is now planning a controlled trial in patients with pulmonary arterial hypertension using treprostinil, in an inhaled formulation known as TRIUMPH ( TReprostinil Inhalation Used in the Management of Pulmonary Hypertension). Such a trial, if allowed by the FDA and European authorities, is expected to commence in 2005.

#### *Sales and Marketing*

United Therapeutics' marketing strategy for Remodulin relies upon United Therapeutics staff to educate the prescribing community. During 2002, United Therapeutics formed an internal marketing team to handle these educational efforts. The team consisted of ten people as of December 2004 with further employee growth expected in 2005. Additionally, United Therapeutics relies on chronic care specialty pharmacy distributors to handle doctor and patient requests for

Remodulin on a non-exclusive basis in the United States. See *Domestic Distribution Agreements* below. These specialty distributors are experienced in the sale, distribution and reimbursement from insurance companies and other payers of chronic therapies. Outside of the United States, United Therapeutics has entered into six exclusive distributor agreements covering Canada, most of Europe, Australia, South America and Israel. United Therapeutics sells Remodulin to its distributors in the United States at a discount from an average wholesale price suggested by United Therapeutics, and to its international distributors at a transfer price set by United Therapeutics. Approximately \$66.1 million, \$45.1 million and \$21.2 million of revenues were earned from the sales of Remodulin in 2004, 2003 and 2002, respectively.

### ***Immunotherapeutic Monoclonal Antibodies***

In April 2002, Unither Pharmaceuticals, Inc., a wholly owned subsidiary of United Therapeutics, entered into an agreement with AltaRex Corp. (which later became known as AltaRex Medical Corp.) to exclusively license certain rights to a platform of five immunotherapeutic monoclonal antibodies. These products were being developed by AltaRex to treat various forms of cancer, including ovarian, prostate, lung, breast, multiple myeloma and gastrointestinal. The lead product, OvaRex, had completed Phase II studies in metastatic ovarian cancer.

Ovarian cancer is the deadliest of women's reproductive cancers and is the fifth leading cause of cancer death among women in the United States. Over 25,000 cases of ovarian cancer are diagnosed in the United States every year, with over 16,000 women dying of the disease annually.

In January 2003, United Therapeutics initiated two identical Phase III pivotal clinical trials of OvaRex in patients with stage III/IV advanced ovarian cancer, called IMPACT I and II. These studies are being conducted throughout the United States and are expected to be fully enrolled in the next 12 to 18 months. These studies could take up to two years to complete, following full enrollment, depending on trial patients' relapse rates. A total of 354 patients are being recruited. As of December 31, 2004, approximately 210 patients were enrolled in the Phase III trials at approximately 60 centers. Patients enrolled in these studies have successfully completed front-line therapy, consisting of surgery and chemotherapy. The primary endpoint for these trials is to assess the time to disease relapse. Patients will also be followed for survival.

### ***Telemedicine Services***

United Therapeutics provides telemedicine services to detect cardiac arrhythmias and ischemic heart disease through its wholly owned subsidiary Medicomp, Inc. which was acquired in December 2000. Cardiac arrhythmias and ischemic heart disease afflict an estimated 20 million Americans, and possibly ten times that number worldwide. If left undetected and untreated, these conditions can result in heart attacks and death. Medicomp provides cardiac Holter, event monitoring and analysis and pacemaker monitoring remotely via telephone lines and the Internet for hospitals, clinicians and other providers. Medicomp's services are delivered through its proprietary, miniaturized, digital Decipher Holter recorder/analyzer and CardioPAL family of event monitors.

Holter, event and pacemaker services and systems are marketed to physicians, hospitals, and managed care providers directly by Medicomp's internal sales force. Revenues of approximately \$5.3 million, \$4.2 million and \$3.9 million from the sales of telemedicine products and services were earned in 2004, 2003 and 2002, respectively.

### ***Glycobiology Antiviral Agents***

In March 2000, Unither Pharmaceuticals, Inc. (UPI), a wholly owned subsidiary of United Therapeutics, entered into a license agreement with Synergy Pharmaceuticals, Inc. to obtain from Synergy the exclusive worldwide rights to certain patents relating to novel antiviral compounds. These glycobiology antiviral agents are small molecules which may be effective as an oral therapy for the treatment of hepatitis C and B infections, as well as dengue fever, Japanese encephalitis virus and other infectious diseases. Currently, many of these agents are undergoing laboratory testing and new agents are being synthesized.

The most advanced agent identified to date is UT-231B. An Investigational New Drug Application (IND) was submitted for UT-231B in 2002 and accepted by the FDA. UT-231B completed acute and chronic Phase I dosing studies in early 2003. Phase II clinical studies in patients infected by hepatitis C were initiated in July 2003 and were completed in October 2004. In that trial, UT-231B did not demonstrate efficacy against hepatitis C in a population of patients that previously failed conventional treatments. United Therapeutics is now planning a trial in patients who responded positively to conventional treatments in order to determine if UT-231B can prevent disease relapse in such patients.

## *Arginine*

In December 2000, United Therapeutics expanded its cardiovascular focus when it acquired the assets and certain liabilities of Cooke Pharma, Inc., the exclusive maker of the HeartBar line of arginine-enriched products that is now operating as Unither Pharma, Inc., a wholly owned subsidiary of United Therapeutics. Arginine is required by the body to produce nitric oxide, and Unither Pharma is the exclusive licensee of patents entitling it to claim that arginine is critical for maintaining vascular function and certain other arginine-based claims.

Presently, the HeartBar and a related line of products are marketed directly to consumers by Unither Pharma and by independent distributors and the Internet. Unither Pharma is currently suing other parties believed to have violated Unither Pharma's patents related to the arginine line. It has entered into a patent license with one infringer and is in negotiations with others. Unither Pharma believes that there are a substantial number of additional infringers and intends to vigorously enforce its patents requiring these infringers to pay royalties to United Therapeutics. Approximately \$531,000, \$2.3 million and \$1.4 million of revenues were earned from the sales of HeartBar and related products in 2004, 2003 and 2002, respectively.

## *Beraprost SR*

In June 2000, United Therapeutics obtained from Toray Industries, Inc. the exclusive right to develop and market oral prostacyclin beraprost in a sustained release formulation in the United States and Canada for the treatment of all vascular and cardiovascular indications.

Beraprost is an oral form of prostacyclin that is chemically stable. Like natural prostacyclin and Remodulin, beraprost is believed to dilate blood vessels, prevent platelet aggregation and prevent proliferation of smooth muscle cells surrounding blood vessels. Intermittent oral doses of immediate release beraprost did not prove effective in Phase III studies conducted by United Therapeutics during 2000 and 2001. However, United Therapeutics believes that sustained release oral doses of beraprost may be an important treatment for early-stage peripheral vascular disease and for early-stage pulmonary hypertension. Beraprost is presently in Phase I clinical testing being conducted by Toray Industries in Japan.

Toray is required to complete testing of sustained release beraprost through Phase I to adequately document its performance in humans. If Toray is able to do so, United Therapeutics would be obligated to grant Toray an option to purchase 500,000 shares of United Therapeutics' common stock at the then current fair value of that stock. The development of sustained release beraprost, however, has been significantly delayed by Toray and United Therapeutics may cancel this agreement prior to granting any options.

## *Northern Therapeutics, Inc.*

In December 2000, Lung Rx, Inc., a wholly owned subsidiary of United Therapeutics, formed a new company in Canada, Northern Therapeutics, Inc., with the inventor of a new form of autologous (meaning it is derived from the patient's own body and not from foreign material such as viruses) gene therapy for the treatment of pulmonary arterial hypertension and other diseases. Northern Therapeutics is currently planning its first human trial with the gene therapy in Canada and also is distributing certain United Therapeutics' products there, including Remodulin. United Therapeutics received approximately 59 percent of the initial outstanding common stock of Northern Therapeutics in exchange for \$5.0 million, and currently owns approximately 68 percent of Northern Therapeutics. Although United Therapeutics owns approximately 68 percent of Northern Therapeutics, minority shareholders possess substantive participating rights that preclude United Therapeutics from controlling Northern Therapeutics and consolidating Northern Therapeutics' financial statements.

## **The Medtronic MiniMed Strategic Alliance**

Medtronic MiniMed partnered with United Therapeutics for the use of Medtronic MiniMed's pager-sized continuous microinfusion pump for delivery of Remodulin subcutaneously. United Therapeutics entered into an agreement with MiniMed, Inc. (now Medtronic MiniMed) in September 1997, which was implemented in a detailed set of guidelines to collaborate in the design, development and implementation of therapies to treat pulmonary hypertension utilizing MiniMed products and Remodulin. The guidelines require United Therapeutics to purchase its Remodulin infusion pumps exclusively from Medtronic MiniMed at a discount to MiniMed list prices unless MiniMed's infusion pumps fail to receive certain government approvals or cannot be appropriately used. The term of the agreement commenced on September 3, 1997 and continues for seven years after the May 2002 FDA approval of Remodulin. The agreement will be automatically extended for additional 12-month periods unless otherwise terminated. The agreement is subject to early termination in the event of a material breach or bankruptcy of either party. In the event that there are any discoveries or improvements arising out of work performed under the agreement, the parties will have joint ownership of those discoveries or improvements. United

Therapeutics acquires Medtronic MiniMed products and resells these products to its distributors. United Therapeutics is working toward having its distributors purchase all Medtronic MiniMed products directly from Medtronic MiniMed. In 2004, several distributors commenced purchasing supplies directly from Medtronic MiniMed. Approximately \$1.7 million, \$1.7 million and \$3.7 million of revenues were earned from the resale of MiniMed pumps and supplies in 2004, 2003 and 2002, respectively.

### **Domestic Distribution Agreements**

To provide the marketing, promotion and distribution of Remodulin in the United States, United Therapeutics entered into non-exclusive distribution agreements with Priority Healthcare Corporation, Accredo Therapeutics, Inc. (formerly Gentiva Health Services, Inc.) and Caremark, Inc. in February 2000, March 2000 and May 2003, respectively. Under these distribution agreements, United Therapeutics sells Remodulin at a discount from an average wholesale price recommended by United Therapeutics and sells Medtronic MiniMed infusion pumps at a list price. The distributors are responsible for assisting patients with obtaining reimbursement for the cost of the therapy and providing other support services. The terms of the agreements commenced on signing and continue for two years following the May 2002 FDA approval of Remodulin for Priority (which has been extended through September 30, 2005) and three years following the May 2002 launch of Remodulin for Accredo. The terms of the Caremark agreement commenced on signing and continue for two years from signing. These agreements will be automatically renewed thereafter for additional two-year periods, in the case of Priority and one-year periods in the case of Accredo and Caremark, unless any party provides notice of termination. If these distributor agreements expire or terminate, under certain conditions, United Therapeutics may be required to repurchase unsold Remodulin inventory held by the distributors.

### **Patents And Proprietary Rights**

United Therapeutics' success will depend in part on its ability to obtain and maintain patent protection for its products, preserve trade secrets, prevent third parties from infringing upon its proprietary rights and operate without infringing upon the proprietary rights of others in the United States and worldwide. (See *Notes to Consolidated Financial Statements* and *Management's Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources* for information regarding royalties and milestone payments under these agreements.)

#### ***Glaxo Wellcome Assignment***

In January 1997, Glaxo Wellcome, Inc. (now GlaxoSmithKline PLC) assigned to United Therapeutics all rights to the use of the stable prostacyclin analog now known as Remodulin. For pulmonary hypertension, the patent does not expire in the United States until October 2014 (as extended — see *Patent Term Extensions* below) and until various dates from September 2009 to August 2013 in nine other countries.

#### ***Pharmacia License***

In December 1996, Pharmacia & Upjohn Company (now Pfizer, Inc.) exclusively licensed to United Therapeutics certain patents, a patent application and know-how for the composition and production of the stable prostacyclin analog now known as Remodulin. United Therapeutics filed its own United States patent application for a new synthesis and production method for Remodulin in October 1997, and the patent was granted in August 2002. Two additional patents covering this synthesis and production method were granted in March 2003 and August 2004. United Therapeutics believes that its method is a substantial improvement over the Pharmacia method. United Therapeutics is using its unique synthesis method rather than the licensed Pharmacia method for the production of Remodulin. United Therapeutics also has two registered patents and one pending patent application with respect to additional Remodulin synthesis improvements.

#### ***AltaRex Medical Corp. Agreement***

In April 2002 and August 2003, UPI entered into license agreements with AltaRex Medical Corp. (formally known as AltaRex Corp.) for the exclusive worldwide rights (other than certain European and Middle Eastern countries) to certain patents relating to a platform of immunotherapeutic monoclonal antibodies. These antibodies are currently in various stages of clinical and preclinical testing. The lead compound, OvaRex, is in Phase III clinical trials. The compounds and the method of using the compounds are the subject of a combination of issued patents and pending applications in the United States and around the world. The issued patents have expiration dates ranging from 2017 to 2020 (subject to extension — see *Patent Term Extensions* below). Additional inventions relating to the compounds may be owned jointly by AltaRex and UPI or individually by AltaRex, depending on the source of the invention.

On December 10, 2004, AltaRex Medical Corp. was acquired by ViRexx Medical Corporation in an all stock for stock transaction. AltaRex Medical now operates as a wholly owned subsidiary of ViRexx.

#### ***Synergy Pharmaceuticals, Inc.***

In March 2000, UPI entered into a license agreement with Synergy Pharmaceuticals, Inc. (Synergy) to obtain from Synergy the exclusive worldwide rights to certain patents relating to novel antiviral compounds known as iminosugars. The compounds are currently in late stages of preclinical testing or early clinical testing, and are the subject of a combination of issued patents and pending applications in the United States and around the world.

In November 2000, UPI and Synergy amended the exclusive license agreement to include the development of new analogs of the licensed compounds. As part of this amendment, UPI agreed to directly assume Synergy's role in funding ongoing research being conducted by the University of Oxford into analogs of the antiviral compounds being developed by UPI and Synergy. UPI received an exclusive license from the University of Oxford to all inventions arising from such research and entered into the first such license in November 2002 for the lead compound, UT-231B. A second exclusive license for different rights is pending.

In March 2003, UPI and Synergy entered into an Assignment and Assumption Agreement and a Redemption and Termination Agreement (together referred to as the Agreements). Under the Agreements, Synergy assigned to UPI all of its intellectual property rights in the glycobiology antiviral agents and exclusively sublicensed to UPI all of the intellectual property rights that had been licensed to it by third parties, the prosecution and maintenance of which are now the responsibility of UPI. Synergy also released United Therapeutics from all milestone and royalty obligations that would have become due should a product be successfully developed.

#### ***Stanford University and New York Medical College Licenses***

In 2000, Unither Pharma, Inc. acquired the exclusive license to patents related to arginine-based dietary supplements to enhance the level of naturally occurring nitric oxide in the vascular system from Stanford University and New York Medical College. The licenses cover worldwide territories and are valid for the life of the patents (ranging from 2010 to 2018). Unither Pharma will own all rights to all new products that may be or are derived from these licenses, including Unither Pharma's HeartBar product line.

#### ***Patent Term Extensions***

United Therapeutics believes that some of the patents to which it has rights may be eligible for extensions of up to five years based upon patent term restoration procedures in Europe and in the United States under the Waxman-Hatch Act. In February 2005, United Therapeutics was granted a five-year patent term extension by the United States Patent and Trademark Office for its patent covering the method of treating pulmonary hypertension using Remodulin. U.S. Patent Number 5,153,222 titled "Method of Treating Pulmonary Hypertension with Benzidine Prostaglandins," was originally scheduled to expire on October 6, 2009. It will now expire on October 6, 2014. The five-year Hatch-Waxman Act extension is the maximum extension allowed under 35 U.S.C. §156.

#### **Research & Development Expenditures**

United Therapeutics is engaged in research and development and has incurred substantial expenses for these activities. These activities generally include the cost of acquiring or inventing new technologies and products as well as their development. Research and development expenses during 2004, 2003 and 2002 totaled approximately \$30.6 million, \$35.4 million and \$26.8 million, respectively. (See *Management's Discussion and Analysis of Financial Condition and Results of Operations — Major Research and Development Projects* for additional information regarding expenditures related to major research and development projects.)

#### **Manufacturing and Supply**

United Therapeutics produces treprostinil, the active ingredient in Remodulin, in Chicago and is planning to move its laboratories to Silver Spring, Maryland. Baxter Healthcare Corporation (formerly Cook Imaging Corporation) formulates Remodulin for United Therapeutics. The agreement with Baxter had an initial term which ended in October 2004 and was renewed for an additional eighteen months. The contract is renewable for successive eighteen month terms. We rely on Cardinal Health Inc., for stability studies on Remodulin and to analyze other products we are developing. Medtronic

MiniMed provides the delivery device used to administer subcutaneous Remodulin to patients.

Products manufactured by contract manufacturers include UT-231B, OvaRex, arginine and telemedicine products. Prior to mid-2003, telemedicine products were manufactured by Medicomp at its facility in Florida.

Although management believes that other manufacturers and suppliers could provide similar products, services and materials, there are a limited number of companies which could replace these manufacturers and suppliers. A change in supplier or manufacturer could cause a delay in the manufacture, distribution and research efforts associated with the respective product or result in increased costs. (For further discussion on this risk, see — *Risk Factors — Risks Related to Our Business — We have limited experience with manufacturing and depend on third parties, who may not perform, to synthesize and manufacture many of our products.*)

## **Competition**

Many drug companies engage in research and development to commercialize products to treat cardiovascular, infectious and oncological diseases. United Therapeutics is aware of three existing treatments already approved in the United States for pulmonary arterial hypertension with which Remodulin competes. They are: Flolan®, an intravenously delivered prostacyclin marketed by GlaxoSmithKline, PLC; Tracleer®, an oral endothelin antagonist marketed by Actelion, Ltd.; and Ventavis®, an inhaled prostacyclin marketed by CoTherix, Inc. in the United States and by Schering A.G. in Europe. Two additional oral endothelin antagonists are being developed. One is sitaxsentan, being developed by Encysive Pharmaceuticals, Inc., and the other is ambrisentan, being developed by Myogen, Inc. Additionally, in December 2004, Pfizer, Inc. submitted an application seeking FDA permission to market sildenafil for the treatment of pulmonary arterial hypertension. (Pfizer, Inc. currently markets sildenafil as Viagra® for erectile dysfunction.) In addition, competitors may develop and commercialize other products that compete with United Therapeutics' products and may do so more rapidly than United Therapeutics.

Tracleer is the first drug in a class of drugs known as endothelin antagonists. Sildenafil is a phosphodiesterase type 5 (PDE5) inhibitor. Pharmacologic blockade of endothelin and PDE5 enzyme dilates pulmonary blood vessels in patients with pulmonary arterial hypertension. Endothelin antagonists and PDE5 inhibitors may be used in combination with prostacyclins since these drugs provide symptomatic relief in different ways and might complement each other to treat these seriously ill patients.

Many companies market or are developing products that will compete with the HeartBar product line in the nutritional supplement market. However, United Therapeutics is the only company that owns the patent rights to use HeartBar's key ingredient, arginine, for maintaining vascular function. One competitor agreed to pay a royalty to United Therapeutics on its arginine products. United Therapeutics is pursuing other potential infringers and is currently prosecuting three patent enforcement lawsuits.

Holter and event monitoring analysis services and systems are provided by many local and regional competitors and a few national competitors.

United Therapeutics competes with all of these companies for customers, funding, access to licenses, personnel, third-party collaborators, product development and commercialization. Almost all of these companies have substantially greater financial, marketing, sales, distribution and technical resources, and more experience in research and development, product development and marketing, clinical trials and regulatory matters, than United Therapeutics, such as GlaxoSmithKline, Pfizer PLC, Inc., Actelion, Ltd. and other competitors.

## **Governmental Regulation**

The research, development, testing, manufacture, promotion, marketing and distribution of drug products are extensively regulated by government authorities in the United States and in other countries. Drugs are subject to rigorous regulation by the FDA in the United States and similar regulatory bodies in other countries. The steps ordinarily required before a new drug may be marketed in the United States, which are similar to steps required in most other countries, include:

- Preclinical laboratory tests, preclinical studies in animals and formulation studies and the submission to the FDA of an investigational new drug application for a new drug;
- Adequate and well-controlled clinical trials to establish the safety and efficacy of the drug for each indication;
- The submission of a new drug application to the FDA; and
- FDA review and approval of the new drug application prior to any commercial sale or shipment of the drug.

Preclinical tests include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal





studies. The results of preclinical testing are submitted to the FDA as part of an investigational new drug application. A 30-day waiting period after the filing of each investigational new drug application is required prior to the commencement of clinical testing in humans. At any time during this 30-day period or at any time thereafter, the FDA may halt proposed or ongoing clinical trials until the FDA authorizes trials under specified terms. The investigational new drug application process may be extremely costly and substantially delay development of United Therapeutics' products. Moreover, positive results of preclinical tests will not necessarily indicate positive results in clinical trials.

Clinical trials to support new drug applications are typically conducted in three sequential phases, but the phases may overlap. During Phase I, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess its effects on bodily functions and safety, including side effects associated with increasing doses. Phase II usually involves studies in a limited patient population to:

- Assess the efficacy of the drug in specific, targeted indications;
- Assess dosage tolerance and optimal dosage; and
- Identify possible adverse effects and safety risks.

If a compound is found to be potentially effective and to have an acceptable safety profile in Phase II evaluations, Phase III trials, also called pivotal studies, major studies or advanced clinical trials, are undertaken to further demonstrate clinical efficacy and to further test for safety within an expanded patient population at geographically dispersed clinical study sites.

After successful completion of the required clinical testing, generally a new drug application is submitted. The FDA may request additional information before accepting a new drug application for filing, in which case the application must be resubmitted with the additional information. Once the submission has been accepted for filing, the FDA generally takes ten months to review the application and respond to the applicant. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the new drug application to an appropriate advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee. The FDA may also inspect the manufacturing facility before approving a new drug application.

If FDA evaluations of the new drug application and the manufacturing facilities are favorable, the FDA may issue either an approval letter or an approvable letter. An approvable letter will usually contain a number of conditions that must be met in order to secure final approval of the new drug application and authorization of commercial marketing of the drug for certain indications. The FDA may refuse to approve the new drug application and issue a not approvable letter, outlining the deficiencies in the submission and often requiring additional testing or information.

At the request of an applicant, the FDA may designate a product as an "orphan drug" if the drug is intended to treat a rare disease or condition. A disease or condition is considered rare if it affects fewer than 200,000 people in the United States. If an applicant obtains the first FDA marketing approval for a certain orphan drug, the applicant will have a seven-year exclusive right to market the drug for the orphan indication. The FDA has approved the orphan designation for Remodulin for the treatment of pulmonary arterial hypertension, a designation that includes both primary pulmonary hypertension and secondary pulmonary hypertension. OvaRex MAb (oregovomab) has received both orphan drug and fast track designations by the FDA for the treatment of patients with Stage III or IV epithelial adenocarcinoma of ovarian, tubal or peritoneal origin. Under the Food and Drug Administration Modernization Act (FDAMA), fast track designations are designed to help accelerate the regulatory approval process for key investigational drugs that meet an unmet medical need. The designations provide the potential for expedited FDA review and accelerated approval.

Subcutaneous Remodulin was approved by the FDA for the treatment of pulmonary arterial hypertension in patients with NYHA Class II-IV symptoms to diminish symptoms associated with exercise, and intravenous Remodulin was approved for those patients not able to tolerate subcutaneous infusion. If regulatory approval of United Therapeutics' other products is granted, it will similarly be limited to certain disease states or conditions. The manufacturers of approved products and their manufacturing facilities will be subject to continual review and periodic inspections. In addition, identification of certain side effects or the occurrence of manufacturing problems after a drug is on the market could cause subsequent withdrawal of approval, reformulation of the drug, additional preclinical testing or clinical trials, and changes in labeling of the product.

The Waxman-Hatch Act provides that patent terms may be extended to compensate for some of the patent life that is lost during the FDA regulatory review period for the product. This extension period would generally be one-half the time between the effective date of an investigational new drug application and the submission date of a new drug application, plus all of the time between the submission date of a new drug application and the approval of that application, subject to a maximum extension of five years. Similar patent term extensions are available under European laws. United Therapeutics

filed with the United States Patent and Trademark Office a patent term extension application for its patent covering the method of treating pulmonary arterial hypertension using Remodulin following its FDA approval. The application was approved in February 2005 and the patent now expires on October 6, 2014.

Outside the United States, United Therapeutics' ability to market its products will also be contingent upon receiving marketing authorizations from the appropriate regulatory authorities. The foreign regulatory approval process may include some or all of the risks associated with FDA approval set forth above. The requirements governing the conduct of clinical trials and marketing authorization vary widely from country to country. At present, foreign marketing authorizations are applied for at a national level, although within Europe, procedures are available to companies wishing to market a product in more than one European Union (EU) member state.

In the EU, marketing authorizations may be submitted to a centralized, a decentralized or a national level process. The centralized procedure is mandatory for the approval of biotechnology products and high technology products and is available at the applicant's option for other products. The centralized procedure provides for the grant of a single marketing authorization that is valid in all EU member states. The decentralized procedure is available for all medicinal products that are not subject to the centralized procedure. The decentralized procedure provides for mutual recognition of national approval decisions, changes existing procedures for national approvals and establishes procedures for coordinated EU actions on products, suspensions and withdrawals. Under this procedure, the holder of a national marketing authorization for which mutual recognition is sought may submit an application to one or more EU member states, certify that the dossier is identical to that on which the first approval was based or explain any differences and certify that identical dossiers are being submitted to all member states for which recognition is sought. Within 90 days of receiving the application and assessment report, each EU member state must decide whether to recognize approval. The procedure encourages member states to work with applicants and other regulatory authorities to resolve disputes concerning mutual recognition. Lack of objection of a given country within 90 days automatically results in approval of the EU country. Following receipt of marketing authorization in a member state, United Therapeutics would then be required to engage in pricing discussions and negotiations with a separate prescription pricing authority in that country.

United Therapeutics intends to secure European regulatory approvals for the use of Remodulin for pulmonary arterial hypertension under the decentralized procedure and filed its first Marketing Authorization Application (MAA) in France in February 2001. That review is currently ongoing. If approval from France is received under the decentralized procedures, United Therapeutics would make submissions to other EU countries to request mutual recognition of the French approval in their respective countries. Regulatory applications for the use of Remodulin for pulmonary arterial hypertension in Canada and Israel were approved in October 2002. Regulatory applications in Switzerland and Australia were approved in 2004.

Arginine and telemedicine products are manufactured at contract facilities that are regulated by the FDA under different regulations that apply to dietary supplements in the case of arginine and medical devices in the case of telemedicine products. The telemedicine devices designed and sold by Medicomp have received marketing clearance from the FDA under Section 510(k) of the Food, Drug and Cosmetic Act. Medical devices are required to be manufactured in conformance with FDA's Quality System Regulations.

## **Employees**

United Therapeutics had approximately 170 employees as of February 15, 2005. The company also maintains active independent contractor relationships with various individuals, most of whom are on month-to-month or annual consulting contracts. The company believes its employee relations are excellent.

## **Revenues and Industry Segments**

The information required by Regulation S-K Items 101(b) and 101(d) related to financial information about segments and financial information about sales is contained in Note 15 of the audited consolidated financial statements, which are included in this Annual Report on Form 10-K.

## **Corporate Website**

United Therapeutics' Internet website address is [www.unither.com](http://www.unither.com). United Therapeutics' filings on Form 10-K, Form 10-Q, Form 3, Form 4, Form 5, and Form 8-K, and amendments thereto, are available free of charge through this internet website as soon as reasonably practicable after they are filed or furnished to the SEC.

## **Risk Factors**

This Annual Report on Form 10-K contains forward-looking statements made pursuant to the safe harbor provisions of Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995 which are based on United Therapeutics' beliefs and expectations as to future outcomes. These statements include, among others, statements relating to the following:

- expectations of revenues and profitability;
- the timing and outcome of clinical studies and regulatory filings;
- the achievement and maintenance of regulatory approvals;
- the ability to find alternate sources of supply and manufacturing for our products;
- the existence and activities of competitors;
- the expectation not to pay dividends on common stock in the foreseeable future;
- the pricing of Remodulin;
- the dosing and rate of patient consumption of Remodulin;
- the impacts of price changes and changes in patient consumption of Remodulin on future revenues;
- the expectation of reimbursement by third-party payers for intravenous Remodulin;
- the timing, impact, materiality and outcome of under-reimbursement by third party payers, such as Medicare;
- the timing and outcome of the Phase IV clinical trial;
- any actions that may or may not be taken by the FDA as a result of the timing and outcome of the Phase IV clinical trial;
- the rate of physician and patient acceptance of our products as safe and effective;
- the development and sale of products covered by licenses and assignments;
- the adequacy of our intellectual property protections;
- the outcome of any litigation in which we are or become involved;
- the ability of third parties to develop, market, distribute and sell our products;
- the composition of our management team;
- the adequacy of our insurance coverage;
- the ability to obtain financing in the future;
- the value of our common stock;
- the funding of operations from future revenues;
- the expectation of continued profits or losses;
- expectations concerning milestone and royalty payments in 2005;
- expectations concerning payments of contractual obligations in all future years and their amounts;
- the use of net operating loss carryforwards and business tax credit carryforwards;
- the completion of in-process research and development projects and their impact on United Therapeutics;
- the pace and timing of enrollment in clinical trials;
- the expectation, outcome and timing of new and continued regulatory approvals;
- the expected levels and timing of Remodulin sales;

- the adequacy of our resources to fund operations through 2007;
- the potential amount of the minimum residual value guarantee to Wachovia;
- events that could occur upon termination of the Wachovia agreements;
- the timing and level of spending to construct a laboratory facility;
- the potential impacts of new accounting standards;
- the sale of common stock at favorable terms under the primary registration statement filed with the SEC in February 2005;
- any statements preceded by, followed by or that include the words “believes,” “expects,” “predicts,” “anticipates,” “intends,” “estimates,” “should,” “may” or similar expressions; and
- other statements contained or incorporated by reference in this prospectus that are not historical facts.

The statements identified as forward-looking statements may exist in “Item 7 — Management’s Discussion and Analysis of Financial Condition and Results of Operations” or elsewhere in this Annual Report on Form 10-K. These statements are subject to risks and uncertainties and United Therapeutics’ actual results may differ materially from anticipated results. Factors that may cause such a difference include, but are not limited to, those discussed below. United Therapeutics undertakes no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise.

Unless the context requires otherwise or unless otherwise noted, all references in this section to “United Therapeutics” and to the “company”, “we”, “us” or “our” are to United Therapeutics Corporation and its subsidiaries.

## RISKS RELATED TO OUR BUSINESS

**Actual revenue run rates, consolidated revenues and net income or losses may differ from our projections. In addition, we have a history of losses and may not continue to be profitable.**

We have made public projections of our estimated Remodulin annual revenue run rate, a range of potential 2004 consolidated revenues and achieving profitability in 2004. These projections were based on numerous factors and assumptions taken into consideration at the time the estimates were made. Those factors and assumptions are inherently subject to a degree of uncertainty. As a result, the actual revenues and net income or losses may be greater or less than projected. Even small differences in the factors and assumptions can lead to significant changes in our stock price. We achieved net income of approximately \$15.5 million for the year ended December 31, 2004. Prior to 2004, we incurred net losses aggregating to \$195.8 million.

In addition, although we were profitable for the three-month periods ended June 30, 2004, September 30, 2004, and December 31, 2004, we lost money from the date of our inception in 1996 through March 31, 2004. At December 31, 2004, our accumulated deficit was approximately \$180.3 million. We may incur additional losses and may not stay a profitable company.

Factors that could affect the accuracy of our expectations of revenue run rates, consolidated revenues, and profitability and cause our quarterly and annual operating results to fluctuate include the following:

- Extent and timing of sales of Remodulin to distributors;
- Level of patient demand for Remodulin and other products;
- Levels of research and development, selling, general and administrative expenses;
- Timing of payments to licensors and corporate partners;
- Retention and growth of patients treated with Remodulin;
- Remodulin side effects, including impact of infusion site pain and reaction from subcutaneous use of Remodulin;
- Changes in the current pricing and dosing of Remodulin;
- Willingness of private insurance companies, Medicare and Medicaid to reimburse Remodulin at current pricing levels;
- Impacts of new legislation and regulations and changes to the Medicare and Medicaid programs;
- Diligent and timely completion, as well as the outcome, of the Phase IV post-marketing study of Remodulin;
- Our ability to maintain regulatory approval of Remodulin in the United States and other countries;
- Additional regulatory approvals in other countries for Remodulin;
- Status and impact of other approved and investigational competitive products;
- Continued performance by current Remodulin distributors under existing agreements;
- Size, scope and outcome of development efforts for existing and additional products;
- Future milestone and royalty payments;
- Cost, timing and outcomes of regulatory reviews;
- Rate of technological advances;
- Establishing, defending and enforcing intellectual property rights;
- Development of manufacturing resources or the establishment, continuation or termination of third-party manufacturing arrangements;
- Establishment, continuation or termination of third-party clinical trial arrangements;
- Development of sales and marketing resources or the establishment, continuation or termination of third-party sales and marketing arrangements;

- Recovery of goodwill, intangible assets and investments in affiliates;
- Collection of accounts receivable and realization of inventories;
- Unforeseen expenses;
- Actual growth in sales of telemedicine and arginine products;
- Actual expenses incurred in future periods; and
- Establishment of additional acquisitions or licensing agreements.

Most of our pharmaceutical products are in clinical studies. We might not maintain or obtain regulatory approvals for our pharmaceutical products and may not be able to sell our pharmaceutical products commercially. Even if we sell our products, we may not be profitable and may not be able to sustain any profitability we achieve.

**If third-party payers will not reimburse patients for our drug products or if third-party payers limit the amount of reimbursement, our sales will suffer.**

Our commercial success depends heavily on third-party payers, such as Medicare, Medicaid and private insurance companies, agreeing to reimburse patients for the costs of our pharmaceutical products. Third-party payers frequently challenge the pricing of new and expensive drugs. Remodulin and the associated infusion pump and supplies are very expensive. Intravenous infusion of Remodulin was just approved in November 2004 and payers may or may not agree to reimburse it. We believe our investigational products, if approved, will also be very expensive. Presently, most third-party payers, including Medicare and Medicaid, reimburse patients for the cost of Remodulin therapy. In the past, Medicare has not reimbursed the full cost of the therapy for some patients. Third-party payers may not approve our new products for reimbursement or continue to approve Remodulin for reimbursement. If third-party payers do not approve a product of ours for reimbursement or limit the amount of reimbursement, sales will suffer, as patients will opt for a competing product that is approved for reimbursement.

**We rely on third parties to develop, market, distribute and sell most of our products and those third parties may not perform.**

We are currently marketing products in three of our five therapeutic platforms: Remodulin in the prostacyclin analog platform, the HeartBar and other product lines in the arginine formulations platform, and CardioPAL cardiac event monitors and Holter monitors in the telemedicine platform. We do not have the ability to independently conduct clinical studies, obtain regulatory approvals, market, distribute or sell most of our products and intend to rely substantially on experienced third parties to perform all of those functions. We may not locate acceptable contractors or enter into favorable agreements with them. If third parties do not successfully carry out their contractual duties or meet expected deadlines, we might not be able to obtain marketing approvals and sell our products. Medtronic MiniMed is our exclusive partner for the subcutaneous delivery of Remodulin using the MiniMed microinfusion device for pulmonary arterial hypertension. We are relying on Medtronic MiniMed's experience, expertise and performance. Similarly, we are relying on Accredo Therapeutics, Inc., Priority Healthcare Corporation and Caremark, Inc. to market, distribute, and sell Remodulin in the United States. If our partners and contractors do not achieve acceptable profit margins, they may not continue to distribute our products. If our partners in the United States and internationally are unsuccessful in their efforts, our revenues will suffer.

**If we cannot maintain regulatory approvals for our products, we cannot sell those products and our revenues will suffer.**

The process of obtaining and maintaining regulatory approvals for new drugs is lengthy, expensive and uncertain. The manufacturing, distribution, advertising and marketing of these products are subject to extensive regulation. Any new product approvals we receive in the future could include significant restrictions on the use or marketing of the product. Product approvals, if granted, can be withdrawn for failure to comply with regulatory requirements or upon the occurrence of adverse events following commercial introduction of the products.

The FDA has approved Remodulin for the treatment of pulmonary arterial hypertension in patients with NYHA Class II-IV symptoms to diminish symptoms associated with exercise. This approval is subject to the requirement that we perform a post-marketing Phase IV clinical study to further assess the clinical benefits of Remodulin. Continued FDA approval of Remodulin is subject to the diligent and timely completion of that trial, as well as its outcome. The Phase IV clinical trial was required to be one-half enrolled by June 2004 and must be fully enrolled by June 2005; however, the FDA has permitted an interim assessment and opportunity to terminate the Phase IV study after only 21 patients have completed the study. The final study report is required to be submitted in December 2005. To date, we have only enrolled 15 patients in this 39-patient Phase IV trial. Enrolling patients in this study is difficult, in part because it involves randomizing some of the patients to placebo despite the fact that approved drugs are available for these patients.

We are not currently enrolling the Phase IV trial within the time frame specified by the FDA, and therefore are at risk of the FDA at any time instituting a public hearing to withdraw marketing approval for Remodulin. We are in discussions with the FDA about our due diligence in enrolling the Phase IV trial and have made a proposal which we believe will ensure that we are able to provide interpretable results of this trial by the December 2005 final study report delivery deadline. Specifically, we have proposed that the FDA evaluate the results of the Phase IV trial based on the number of patients enrolled through September 15, 2005. The FDA is reviewing our proposal. The FDA could, among other things, accept this proposal, grant us an extension of time to continue to enroll the trial, or institute a public hearing to withdraw marketing approval for Remodulin. If a withdrawal hearing were instituted by the FDA, we would pursue the opportunity to participate as we believe that we have exercised good faith due diligence in pursuing enrollment of this trial.

We rely heavily on sales of Remodulin. During the year ended December 31, 2004, our Remodulin sales accounted for 90% of our total revenues. If approvals are withdrawn for a product, we cannot sell that product and our revenues will suffer. In addition, if product approvals are withdrawn, governmental authorities could seize our products or force us to recall our products.

**Our products may not be commercially successful because physicians and patients may not accept them.**

Even if regulatory authorities approve our products, these products may not be commercially successful. We expect that most of our products, including Remodulin, which is already approved by the FDA, will be very expensive. Patient acceptance of and demand for our products will depend largely on the following factors:

- Acceptance by physicians and patients of our products as safe and effective therapies;
- Willingness of payers to reimburse and the level of reimbursement of drug and treatment costs by third-party payers such as Medicare, Medicaid and private insurance companies;
- Pricing of alternative products;
- Convenience and ease of administration of our products; and
- Prevalence and severity of side effects associated with our products, including the infusion site pain and reaction associated with the use of subcutaneous Remodulin and the potential for infections associated with intravenous Remodulin.

**We may not successfully compete with established drug companies.**

We compete with established drug companies during product development for, among other things, funding, access to licenses, expertise, personnel and third-party collaborators. We will also compete with these companies following approval of our products. Almost all of these competitors have substantially greater financial, marketing, sales, distribution and technical resources, and more experience in research and development, clinical trials and regulatory matters, than we do.

We are aware of existing treatments that compete with our products. For the treatment of pulmonary arterial hypertension, approved products that compete with Remodulin include the intravenous prostacyclin, Flolan, marketed by GlaxoSmithKline PLC, the inhaled prostacyclin, Ventavis, marketed by CoTherix, Inc., and Tracleer, an oral endothelin antagonist marketed by Actelion, Ltd. Products that are being developed that may also compete with Remodulin include sitaxsentan being developed by Encysive Pharmaceuticals, Inc., and ambrisentan, being developed by Myogen, Inc. In December 2004, Pfizer, Inc. submitted an application seeking FDA permission to market sildenafil for the treatment of pulmonary arterial hypertension. (Currently, Pfizer markets sildenafil as Viagra for erectile dysfunction.) Many companies are marketing and developing products containing arginine which will compete with the HeartBar product line. Cardiac Holter and event monitoring services and systems are provided by many local and regional competitors and a few national competitors. A number of drug companies are pursuing treatments for ovarian and other cancers and hepatitis that will compete with products in our immunotherapeutic monoclonal antibody platform and glycobiology antiviral agent's platform.

**We have limited experience with manufacturing and depend on third parties, who may not perform, to synthesize and manufacture many of our products.**

Prior to the 1999 acquisition of SynQuest, Inc., a company that manufactured treprostinil, the bulk active ingredient in Remodulin, we had no experience with manufacturing. Presently, treprostinil is being manufactured only by us. We rely on third parties for the manufacture of all our products other than treprostinil. We rely on Baxter Healthcare Corporation for the formulation of Remodulin from treprostinil. We rely on Cardinal Health Inc. for stability studies on Remodulin and to analyze other products that we are developing. We rely on Mnemonics Inc. to manufacture our telemedicine devices and Nellson Nutraceutical and Garden State Nutritionals to manufacture our arginine products. We rely on other manufacturers to make our investigational drugs for use in trials. Although there are a limited number of companies that could replace each of these suppliers, management believes that other suppliers could provide similar services and materials. A change in suppliers, however, could cause a delay in distribution of Remodulin and other products, and in the conduct of clinical trials and commercial launch, which would adversely affect our research and development efforts and future sales efforts. Our manufacturing strategy presents the following risks:

- The manufacturing processes for some of our products have not been tested in quantities needed for commercial sales;
- Delays in scale-up to commercial quantities could delay clinical studies, regulatory submissions and commercialization of our products;
- A long lead time is needed to manufacture Remodulin, and the manufacturing process is complex;
- We and manufacturers of our products are subject to the FDA's good manufacturing practices regulations and similar foreign standards, and although we control compliance issues with respect to synthesis and manufacturing conducted internally, we do not have control over compliance with these regulations by our third-party manufacturers;





- If we have to change to another manufacturing contractor or abandon our captive manufacturing operations, FDA and comparable foreign regulators would require new testing and compliance inspections and the new manufacturer would have to be educated in the processes necessary for the production of the affected product;
- We may not be able to develop or commercialize our products, other than Remodulin, as planned or at all and will have to rely solely on internal manufacturing capacity;
- In the future, we intend to transfer all of our drug laboratory operations to the Silver Spring, Maryland facility currently being built, and such transfer could result in manufacturing inefficiencies or delays;
- Without substantial experience in operating a manufacturing facility, we may not be able to successfully manufacture Remodulin without a third party manufacturer; and
- We may not have intellectual property rights, or may have to share intellectual property rights, to many improvements in the manufacturing processes or new manufacturing processes for our products.

Any of these factors could delay clinical studies or commercialization of our products, entail higher costs and result in our being unable to effectively sell our products.

**If our products fail in clinical studies, we will not be able to obtain or maintain FDA and foreign approvals and will not be able to sell those products.**

In order to sell our pharmaceutical products, we must receive regulatory approvals. To obtain those approvals, we must conduct clinical studies demonstrating that the drug product, including its delivery mechanism, is safe and effective. If we cannot obtain approval from the FDA for a product, that product cannot be sold, and our revenues will suffer.

We are currently conducting a Phase IV clinical study for Remodulin. For a description of the status of this Phase IV study, see our discussion above under “Risk Factors” — *If we cannot maintain regulatory approvals for our products, we cannot sell those products and our revenues will suffer*. We have initiated a Phase II clinical study of an inhaled formulation of treprostinil and Phase I studies of an oral formulation of Remodulin. Our lead glycobiology antiviral agent, UT-231B, recently completed a Phase II, proof-of-concept study. In that trial, UT-231B did not demonstrate efficacy against hepatitis C in a population of patients that previously failed conventional treatments. We are now planning a trial in patients who responded positively to conventional treatments to determine if UT-231B can prevent disease relapse in such patients. We are also currently conducting two Phase III pivotal studies of OvaRex for the treatment of metastatic ovarian cancer. We are still completing or planning pre-clinical studies for our other products. Our ongoing and planned clinical studies might be delayed or halted for various reasons, including:

- The drug is not effective, or physicians think that the drug is not effective;
- Patients do not enroll in the studies at the rate we expect;
- Patients experience severe side effects during treatment, including site pain;
- Other investigational or approved therapies are viewed as more effective or convenient by physicians or patients;
- Patients die during the clinical study because their disease is too advanced or because they experience medical problems that are not related to the drug being studied;
- Drug supplies are not available or suitable for use in the studies; and
- The results of preclinical testing cause delays in clinical trials.

In addition, the FDA and foreign regulatory authorities have substantial discretion in the approval process. The FDA and foreign regulatory authorities may not agree that we have demonstrated that our products are safe and effective.

**Discoveries or developments of new technologies by others may make our products obsolete or less useful.**

Other companies may conduct research, make discoveries or introduce new products that render all or some of our technologies and products obsolete or not commercially viable. Researchers are continually making new discoveries that may lead to new technologies to treat the diseases for which our products are intended. In addition, alternative approaches to treating chronic diseases, such as gene therapy, may make our products obsolete or noncompetitive. One therapy recently approved in the United States in 2001 is Tracleer, an oral endothelin antagonist developed by Actelion, Ltd. which competes with Remodulin. More recently, in December 2004, Ventavis, an inhaled prostacyclin developed by CoTherix, Inc., was approved in the United States. Ventavis will also compete with Remodulin. We are aware that other endothelin antagonists are being developed, such as sitaxsentan by Encysive Pharmaceuticals, Inc. and ambrisentan by Myogen, Inc. In

December 2004, Pfizer, Inc. submitted an application seeking FDA permission to market sildenafil for the treatment of pulmonary arterial hypertension. (Currently, Pfizer markets sildenafil as Viagra for erectile dysfunction.)

Other approved or investigational therapies for pulmonary hypertension could be used in combination with Remodulin. If this happens, doctors may reduce the dose of Remodulin given to their patients. This could result in less

Remodulin being used by such patients and, hence, reduced sales of Remodulin.

**If the licenses, assignments and alliance agreements we depend on are breached or terminated, we would lose our right to develop and sell the products covered by the licenses, assignments and alliance agreements.**

Our business depends upon the acquisition, assignment and license of drugs and other products which have been discovered and initially developed by others, including Remodulin, all of the products in the immunotherapeutic monoclonal antibody platform, all of the products in the glycobiology antiviral agents platform, and the HeartBar line of products. Under our product license agreements, we retain ownership of the intellectual property subject to the terms of each license agreement, whereas assignment agreements transfer all right, title and ownership of the intellectual property to us, subject to the terms of each assignment agreement. In addition, we have obtained licenses to other third-party technology to conduct our business, including licenses for our products and an alliance agreement for the use of the Medtronic MiniMed microinfusion device for the administration of Remodulin. In addition, we may be required to obtain licenses to other third-party technology to commercialize our early-stage products. This dependence has the following risks:

- We may not be able to obtain future licenses, assignments and agreements at a reasonable cost or at all;
- If any of our licenses or assignments are terminated, we will lose our rights to develop and market some or all of our products;
- The licenses and assignments that we hold generally provide for termination by the licensor or assignor in the event we breach the license or assignment agreement, including failing to pay royalties and other fees on a timely basis;
- In the event that GlaxoSmithKline (formerly Glaxo Wellcome) terminates its assignment agreement or Pfizer (formerly Pharmacia) terminates its license agreement, we will have no further rights to utilize the assigned patents or trade secrets to develop and commercialize Remodulin. For the year ended December 31, 2004, sales of Remodulin accounted for approximately 90% of our revenues. GlaxoSmithKline or Pfizer could seek to terminate the assignment in the event that we fail to pay royalties based on sales of Remodulin; and
- If licensors fail to maintain the intellectual property licensed or assigned to us as required by most of our license and assignment agreements, we may lose our rights to develop and market some or all of our products and may be forced to incur substantial additional costs to maintain the intellectual property ourselves or force the licensor or assignor to do so.

**If our patent and other intellectual property protection is inadequate, our sales and profits could suffer or competitors could force our products completely out of the market.**

The United States patent for the method of treating pulmonary hypertension with Remodulin was originally set to expire in 2009. The patent for OvaRex and its method of use are the subject of a combination of issued patents and pending applications in the United States and around the world. The issued patents have expiration dates ranging from 2017 to 2020. We believe that some of the patents to which we have rights may be eligible for extensions of up to five years based upon patent term restoration procedures in Europe and in the United States under the Waxman-Hatch Act. For instance, in February 2005 under Waxman-Hatch, the United States patent relating to the method of treating pulmonary hypertension using Remodulin was extended by five years, giving the product patent protection until October 6, 2014. In addition, patent extensions are available under similar laws in Europe. We may not be able to extend these or any other patents. Competitors may develop products based on the same active ingredients as our products, including Remodulin, and market those products after the patents expire, or may design around our existing patents. If this happens, our sales would suffer and our profits could be severely impacted.

Patents may be issued to others which prevent the manufacture or sale of our products. We may have to license those patents and pay significant fees or royalties to the owners of the patents in order to keep marketing our products. This would cause profits on sales to suffer.

We have been granted patents in the United States for the synthesis of Remodulin, but patent applications that have been, or may in the future be, filed by us may not result in the issuance of additional patents. The scope of any patent issued may not be sufficient to protect our technology. The laws of foreign jurisdictions in which we intend to sell our products may not protect our rights to the same extent as the laws of the United States.

In addition to patent protection, we also rely on trade secrets, proprietary know-how and technology advances. We enter into confidentiality agreements with our employees and others, but these agreements may not be effective in protecting our proprietary information. Others may independently develop substantially equivalent proprietary information or obtain access to our know-how.

Litigation, which is very expensive, may be necessary to enforce or defend our patents or proprietary rights and may not end favorably for us. We are currently a party to pending litigation initiated by us against other parties believed to have

violated our patents related to our arginine products line. We may also choose to initiate litigation against other parties who we come to believe are infringing these patents. If such litigation is unsuccessful or if the patents are invalidated or canceled, we may have to write off the related intangible assets and such an event could significantly reduce our earnings. Any of our licenses, patents or other intellectual property may be challenged, invalidated, canceled, infringed or circumvented and may not provide any competitive advantage to us.

**If our highly qualified management and technical personnel leave us, our business may suffer.**

We are dependent on our current management, particularly our founder and Chief Executive Officer, Martine Rothblatt, Ph.D., our President and Chief Operating Officer, Roger Jeffs, Ph.D., our Executive Vice President for Business Development and Chief Financial Officer, Fred Hadeed, and our Executive Vice President for Strategic Planning, General Counsel and Corporate Secretary, Paul Mahon, all of whom are employed pursuant to multi-year employment agreements. We do not maintain key person life insurance on these officers. Our success will depend in part on retaining the services of our existing management and key personnel and attracting and retaining new highly qualified personnel. Expertise in the field of cardiovascular medicine, infectious disease and oncology is not generally available in the market, and competition for qualified management and personnel is intense.

**We may not have adequate insurance and may have substantial exposure to payment of product liability claims.**

The testing, manufacture, marketing, and sale of human drugs involve product liability risks. Although we currently have product liability insurance covering claims up to \$20 million per occurrence, we may not be able to maintain this product liability insurance at an acceptable cost, if at all, and this insurance may not provide adequate coverage against potential losses. If claims or losses exceed our liability insurance coverage, we may go out of business.

**We may not have, or may have to share rights to, future inventions arising from our license, assignment and alliance agreements and may lose potential profits or savings.**

Pursuant to our agreements with certain business partners, any new inventions or intellectual property that arise from our activities will be owned jointly by us and these partners. If we do not have rights to new developments or inventions that arise during the terms of these agreements, or we have to share the rights with others, we will lose the benefit of the new rights which may mean a loss of future profits or savings generated from improved technology.

**If we need additional financing and cannot obtain it, product development and sales may be limited.**

We may need to spend more money than currently expected because we may need to change our product development plans or product offerings to address difficulties with clinical studies, to prepare for commercial sales or to continue sales of Remodulin. We may not be able to obtain additional funds on commercially reasonable terms or at all. If additional funds are not available, we may be compelled to delay clinical studies, curtail operations or obtain funds through collaborative arrangements that may require us to relinquish rights to certain products or potential markets.

**RISKS RELATED TO OWNING OUR COMMON STOCK**

**Our stock price could be volatile and could decline.**

The market prices for securities of drug and biotechnology companies are highly volatile, and there are significant price and volume fluctuations in the market that may be unrelated to particular companies’ operating performances. The table below sets forth the high and low closing prices for our common stock for the periods indicated:

	High	Low
January 1, 2002 - December 31, 2002	\$ 17.61	\$ 9.10
January 1, 2003 - December 31, 2003	\$ 24.65	\$ 14.70
January 1, 2004 - December 31, 2004	\$ 46.73	\$ 20.51

Our stock price could decline suddenly due to the following factors, among others:

- Quarterly and annual financial and operating results;
- Failure to meet estimates or expectations of securities analysts or our projections;
- Public concern as to the safety of products developed by us or by others;
- Changes in or new legislation and regulations affecting reimbursement of Remodulin by Medicare or Medicaid;



- Announcements by us or others of technological innovations or new products or announcements regarding our existing products;
- Developments in patent or other proprietary rights;
- Future sales of substantial amounts of common stock by our existing stockholders;
- Results of clinical trials;
- Future sales of common stock by our directors and officers;
- Failure to maintain approvals to sell Remodulin;
- Timing and outcome of additional regulatory approvals; and
- General market conditions.

**Future sales of shares of our common stock may depress our stock price.**

If our stockholders transfer their ownership of our common stock or sell a substantial number of shares of common stock in the public market, or investors become concerned that substantial sales might occur, the market price of our common stock could decrease. Each of our four executive officers has announced their adoption of 10b5-1 trading plans. In accordance with these plans, twice each month the executives sell a specified number of our common stock either owned by them or acquired through the exercise of stock options. In addition, Toray Industries Inc. has an option to acquire 500,000 shares of our common stock and piggyback registration rights with respect to such shares that arise if and when this option becomes exercisable. A decrease in our common stock price could make it difficult for us to raise capital by selling stock or to pay for acquisitions using stock. To the extent outstanding options are exercised or additional shares of capital stock are issued, existing stockholders may incur additional dilution.

**Provisions of Delaware law and our certificate of incorporation, by-laws and rights plan could prevent or delay a change of control or change in management that could be beneficial to us and our public stockholders.**

Certain provisions of Delaware law and our certificate of incorporation, by-laws and shareholder rights plan may prevent, delay or discourage:

- A merger, tender offer or proxy contest;
- The assumption of control by a holder of a large block of our securities; and
- The replacement or removal of current management by our stockholders.

For example, our certificate of incorporation divides the board of directors into three classes, with members of each class to be elected for staggered three-year terms. This provision may make it more difficult for stockholders to change the majority of directors and may frustrate accumulations of large blocks of common stock by limiting the voting power of such blocks. This may further result in discouraging a change of control or change in current management.

**Our existing directors and executive officers own a substantial block of our stock and might be able to influence the outcome of matters requiring stockholder approval.**

Our directors and named executive officers beneficially owned approximately 9.8% percent of our outstanding common stock as of February 1, 2005 including stock options that could be exercised by those directors and executive officers within 60 days of that date. Accordingly, these stockholders as a group might be able to influence the outcome of matters requiring approval by our stockholders, including the election of our directors. Such stockholder influence could delay or prevent a change of control with respect to us.

**If stockholders do not receive dividends, stockholders must rely on stock appreciation for any return on their investment in us.**

We have never declared or paid cash dividends on any of our capital stock. We currently intend to retain our earnings for future growth and therefore do not anticipate paying cash dividends in the future.

## EXECUTIVE OFFICERS OF THE REGISTRANT

The following is a list, as of February 15, 2005, setting forth certain information regarding the executive officers of United Therapeutics. Each executive officer holds office until the first meeting of the Board of Directors after the annual meeting of stockholders, and until his or her successor is elected and qualified or until his or her earlier resignation or removal. Each executive officer's employment will end pursuant to the terms of his or her employment contract. Each of the employment contracts generally provide for an initial term of service of five years which may be renewed after each year for additional one-year periods.

<u>Name</u>	<u>Age</u>	<u>Position</u>
Martine A. Rothblatt, Ph.D., J.D., M.B.A.	50	Chairman, Chief Executive Officer and Director
Roger Jeffs, Ph.D.	43	President, Chief Operating Officer and Director
Paul A. Mahon, J.D.	41	Executive Vice President for Strategic Planning, General Counsel and Corporate Secretary
Fred T. Hadeed	40	Executive Vice President for Business Development and Chief Financial Officer

*Martine A. Rothblatt, Ph.D., J.D., M.B.A.* , started United Therapeutics in 1996 and has served as Chairman and Chief Executive Officer since its inception. Prior to founding United Therapeutics, she founded and served as Chief Executive Officer of Sirius Satellite Radio, co-founded and served as Chief Operating Officer of satellite sound broadcasting pioneer WorldSpace Corp., and was principally responsible for several other unique applications of satellite communications technology. She also represented the radio astronomy interests of the National Academy of Sciences' Committee on Radio Frequencies before the FCC and led the International Bar Association's efforts to present the United Nations with a draft Human Genome Treaty. Dr. Rothblatt is President of the William Harvey Medical Research Foundation and past-Chairman of the Law and Medicine Committee of the International Bar Association. Her book, *Your Life or Mine: HOW GEOETHICS CAN RESOLVE THE CONFLICT BETWEEN PUBLIC AND PRIVATE INTERESTS IN XENOTRANSPLANTATION* was published by Ashgate in 2004.

*Roger Jeffs, Ph.D.* , joined United Therapeutics in September of 1998 as Director of Research, Development and Medical. Dr. Jeffs was promoted to Vice President of Research, Development and Medical in July 2000 and to President and Chief Operating Officer in January 2001. Prior to 1998, Dr. Jeffs worked at Amgen, Inc. as Manager of Clinical Affairs and Associate Director of Clinical Research from 1995 to 1998, where he served as the worldwide clinical leader of the Infectious Disease Program.

*Paul A. Mahon, J.D.*, has served as General Counsel and Assistant Corporate Secretary of United Therapeutics since its inception in 1996. In June 2001, Mr. Mahon joined United Therapeutics as a full-time employee as Senior Vice President, General Counsel, and Corporate Secretary. In November 2003, Mr. Mahon was promoted to Executive Vice President for Strategic Planning, General Counsel and Corporate Secretary. Prior to June 2001, he served United Therapeutics from its formation in 1996 in his capacity as principal and managing partner of the law firm, Mahon Patusky Rothblatt & Fisher, Chartered.

*Fred T. Hadeed*, has served as Chief Financial Officer of United Therapeutics since January 2000. In November 2003, Mr. Hadeed was promoted to Executive Vice President for Business Development and Chief Financial Officer. Prior to joining United Therapeutics, Mr. Hadeed practiced as a certified public accountant from 1989 to 2000 at KPMG LLP, where he served as a senior manager in KPMG's life sciences practice.



## **ITEM 2. PROPERTIES**

United Therapeutics currently maintains several leased and owned facilities. The company owns its corporate office in Silver Spring, Maryland and an office in Satellite Beach, Florida. United Therapeutics also owns three buildings and land adjacent to its corporate headquarters in Silver Spring, Maryland and has commenced building a laboratory facility on the vacant land adjacent to its corporate headquarters. It is anticipated that this building will be completed in early 2006. The company leases its legal and governmental affairs office in Washington, D.C. The company leases its clinical development office in Research Triangle Park, North Carolina. The company leases laboratory and office space in Chicago, Illinois where the bulk active ingredient in Remodulin is synthesized. The Chicago facility contains approximately 19,000 square feet of total space. The company's subsidiaries, Unither Pharma, Inc. and Lung Rx, Inc. occupy the office in Satellite Beach, Florida. The company's subsidiary, Unither Pharmaceuticals, Inc., leases office space in Wellesley, Massachusetts. The company's subsidiary, Medicomp, Inc., leases office space in Melbourne, Florida. United Therapeutics' subsidiary, Unither Nutraceuticals, Inc., leases office space in Burlington, Vermont. United Therapeutics' subsidiary, United Therapeutics Europe Ltd., leases office space near London, England. United Therapeutics believes these facilities are adequate for its current and planned operations.

The office space in Melbourne, Florida is used in United Therapeutics' telemedicine segment. All other properties and leased facilities are used in United Therapeutics' pharmaceutical segment.

## **ITEM 3. LEGAL PROCEEDINGS**

None.

## **ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

No matters were submitted to a vote of security holders during the fourth quarter of the fiscal year covered by this report.

## PART II

### ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

#### Market for Common Equity

United Therapeutics' common stock (and associated preferred stock purchase rights) trades on the NASDAQ Stock Market's NASDAQ National Market under the symbol "UTHR". The table below sets forth the high and low closing prices for the common stock for the periods indicated:

	2004		2003	
	High	Low	High	Low
January 1 - March 31	\$ 24.25	\$ 20.51	\$ 17.24	\$ 14.70
April 1 - June 30	\$ 25.93	\$ 22.27	\$ 23.24	\$ 16.57
July 1 - September 30	\$ 34.93	\$ 23.15	\$ 24.65	\$ 18.14
October 1 - December 31	\$ 46.73	\$ 29.00	\$ 23.49	\$ 18.29

As of February 9, 2005, there were 98 holders of record of common stock. United Therapeutics estimates that included within the holders of record are approximately 3,900 beneficial owners of common stock. As of February 9, 2005, the closing price for the common stock was \$44.57.

#### Dividend Policy

United Therapeutics has never paid and has no present intention to pay dividends on its common stock in the foreseeable future and intends to retain any earnings for use in its business operations.

#### Recent Sales of Unregistered Securities

At various times throughout 2004, United Therapeutics issued options to consultants in exchange for services, which issuance was exempt from registration pursuant to Section 4(2) of the Securities Act of 1933. The aggregate number of these options was 14,334. Upon exercise, each option may be converted into one share of United Therapeutics' common stock in exchange for cash equal to the exercise price. All exercise prices were set at the closing price of United Therapeutics' common stock on the day of the grant of each of these options. The weighted average exercise price was \$29.77 and these options generally vest over a period of up to one year.

In December 2000, a subsidiary of United Therapeutics acquired the assets of Medicomp, Inc. and Telemedical Procedures, LLC (together referred to as Medicomp). Under terms of the acquisition agreement, United Therapeutics was required to issue additional shares to the sellers because the average closing price of United Therapeutics' common stock over the 30 calendar days prior to the third anniversary of the acquisition was less than \$70.00 per share. In August 2004, 591,832 shares of United Therapeutics' common stock were issued to the sellers in satisfaction of this obligation. This issuance was exempt from registration pursuant to Section 4(2) of the Securities Act of 1933. The resale of these shares was registered in January 2005.

## ITEM 6. SELECTED FINANCIAL DATA

The following selected consolidated financial data should be read in conjunction with United Therapeutics' consolidated financial statements and related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this Annual Report on Form 10-K. The historical results are not necessarily indicative of results to be expected for future periods. The following information is presented in thousands, except per share data.

	Years Ended December 31,				
	2004	2003	2002	2001	2000
<b>Consolidated Statements of Operations Data:</b>					
Revenues	\$ 73,590	\$ 53,341	\$ 30,120	\$ 5,731	\$ 2,049
Operating expenses:					
Research and development	30,602	35,417	26,778	32,590	70,188
Selling, general and administrative	21,529	22,667	15,889	16,943	11,736
Cost of sales	8,250	6,783	5,456	3,137	1,626
Total operating expenses	60,381	64,867	48,123	52,670	83,550
Income (loss) from operations	13,209	(11,526)	(18,003)	(46,939)	(81,501)
Other income (expense):					
Interest income	2,986	2,435	4,954	10,021	10,693
Interest expense	(4)	(112)	(117)	(173)	(120)
Equity loss in affiliate	(785)	(953)	(209)	(257)	—
Write-down of investment	—	—	(2,893)	—	(4,790)
Loss on marketable investments	—	—	(7,428)	—	—
Other, net	43	187	45	60	109
Total other income (expense), net	2,240	1,557	(5,648)	9,651	5,892
Net income (loss) before income tax	15,449	(9,969)	(23,651)	(37,288)	(75,609)
Income tax expense	—	—	—	—	—
Net income (loss)	<u>\$ 15,449</u>	<u>\$ (9,969)</u>	<u>\$ (23,651)</u>	<u>\$ (37,288)</u>	<u>\$ (75,609)</u>
Net income (loss) per common share — basic (1)	<u>\$ 0.71</u>	<u>\$ (0.47)</u>	<u>\$ (1.15)</u>	<u>\$ (1.84)</u>	<u>\$ (3.93)</u>
Net income (loss) per common share — diluted (1)	<u>\$ 0.66</u>	<u>\$ (0.47)</u>	<u>\$ (1.15)</u>	<u>\$ (1.84)</u>	<u>\$ (3.93)</u>
Weighted average number of common shares outstanding — basic	<u>21,726</u>	<u>21,135</u>	<u>20,644</u>	<u>20,286</u>	<u>19,237</u>
Weighted average number of common shares outstanding — diluted	<u>23,351</u>	<u>21,135</u>	<u>20,644</u>	<u>20,286</u>	<u>19,237</u>

	Years Ended December 31,				
	2004	2003	2002	2001	2000
<b>Consolidated Balance Sheet Data:</b>					
Cash, cash equivalents and marketable investments (3)	\$ 139,140	\$ 117,337	\$ 132,655	\$ 172,299	\$ 215,419
Total assets	207,158	179,502	184,566	212,121	250,645
Notes and leases payable (2)	26	798	1,878	1,938	1,907
Accumulated deficit	(180,341)	(195,790)	(185,821)	(162,170)	(124,882)
Total stockholders' equity	191,636	167,765	171,658	196,399	234,738

(1) See Note 2 of Notes to Consolidated Financial Statements for a description of the computation of basic and diluted net income (loss) per share.

(2) Includes current portion of notes and leases payable.

(3) Includes restricted marketable investments and cash.

## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion should be read in conjunction with the consolidated financial statements and related notes appearing elsewhere in this Annual Report. The following discussion contains forward-looking statements made pursuant to the safe harbor provisions of Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995 concerning, among other things,

the pricing of Remodulin, the dosing and rate of patient consumption of Remodulin, the impacts of price changes and changes in patient consumption of Remodulin on future revenues, the timing,

impact, materiality and outcome of under-reimbursement by Medicare, the timing and outcome of the Phase IV clinical trial, any actions that may or may not be taken by the FDA as a result of the timing and outcome of the Phase IV clinical trial, the funding of operations from future revenues, the expectation of continued profits or losses, expectations concerning milestone and royalty payments in 2005, the use of net operating loss carryforwards and business tax credit carryforwards, the completion of in-process research and development products and their impact on United Therapeutics, the pace and timing of enrollment in clinical trials, the expectation, outcome and timing of new and continuing regulatory approvals, the expected levels and timing of Remodulin sales, the adequacy of United Therapeutics' resources to fund operations through 2007, the timing and level of spending to construct a laboratory production facility, the potential amount of the minimum residual value guarantee to Wachovia, events that could occur upon termination of the Wachovia agreements, expectations concerning payments of contractual obligations in all future years and their amounts, the potential impacts of new accounting standards, the sale of common stock at favorable terms under the primary registration statement filed with the SEC in February 2005, as well as statements preceded by, followed by or that include the words "believes", "expects", "anticipates", "intends", "estimates", "may" or similar expressions. These statements are based on the beliefs and expectations of United Therapeutics as to future outcomes and are subject to risks and uncertainties that could cause United Therapeutics' results to differ materially from anticipated results. Factors that could cause or contribute to such differences include those discussed below and elsewhere in this Annual Report, particularly in "Risk Factors." United Therapeutics undertakes no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise.

## Overview

United Therapeutics is a biotechnology company focused on the development and commercialization of unique products for patients with chronic and life-threatening cardiovascular, cancer and infectious diseases. United Therapeutics commenced operations in June 1996 and, since its inception, has devoted substantially all of its resources to acquisitions and research and development programs.

### *United Therapeutics Products and Services*

United Therapeutics' lead product is Remodulin. On May 21, 2002, the United States Food and Drug Administration (FDA) approved subcutaneous use of Remodulin (treprostinil sodium) Injection for the treatment of pulmonary arterial hypertension in patients with NYHA class II-IV symptoms to diminish symptoms associated with exercise. Pulmonary arterial hypertension is a life-threatening condition characterized by elevated blood pressures between the heart and lungs. United Therapeutics was required to perform a post-marketing Phase IV clinical study to further assess the clinical benefits of Remodulin. Continued FDA approval of Remodulin is subject to the diligent and timely completion of that Phase IV trial, as well as its outcome. The study was originally to have been completed by May 2004 and involve 100 patients. In mid-2003, the FDA agreed to amend the due date of the final study report and make other changes to the trial design including reducing the number of patients to 39.

The amended Phase IV clinical trial was required to be one-half enrolled by June 2004 and must be fully enrolled by June 2005; however, the FDA has permitted an interim assessment and opportunity to terminate the Phase IV study after only 21 patients have completed the study. The final study report is required to be submitted in December 2005. To date, only 15 patients have been enrolled in this 39-patient Phase IV trial. Enrolling patients in this study is difficult, in part because it involves randomizing some of the patients to placebo despite the fact that approved drugs are available for these patients.

United Therapeutics is not currently enrolling the Phase IV trial within the time frame specified by the FDA, and therefore is at risk of the FDA at any time instituting a public hearing to withdraw marketing approval for Remodulin. United Therapeutics is in discussions with the FDA about its due diligence in enrolling the Phase IV trial and has made a proposal which United Therapeutics believes will ensure that it is able to provide interpretable results of this trial by the December 2005 final study report delivery deadline. Specifically, United Therapeutics has proposed that the FDA evaluate the results of the Phase IV trial based on the number of patients enrolled through September 15, 2005. The FDA is reviewing this proposal. The FDA could, among other things, accept this proposal, grant an extension of time to continue to enroll the trial, or institute a public hearing to withdraw marketing approval for Remodulin. If a withdrawal hearing were instituted by the FDA, United Therapeutics would pursue the opportunity to participate as it believes that it has exercised good faith due diligence in pursuing enrollment of this trial.

On November 24, 2004, the FDA approved intravenous infusion of Remodulin, based on data establishing its bioequivalence with the previously approved subcutaneous administration of Remodulin, for patients who are not able to tolerate a subcutaneous infusion. This approval was also conditioned upon the diligent and timely completion of the Phase IV trial, as well as its outcome. Remodulin is also approved for subcutaneous use in Canada, Israel, Australia and Switzerland. Marketing authorization applications are currently under review in France, and other countries.

United Therapeutics has generated revenues from sales of Remodulin and arginine products in the United States and other countries. In addition, United Therapeutics has generated revenues from telemedicine products and services, primarily designed for patients with cardiac arrhythmias and ischemic heart disease, in the United States. United Therapeutics has funded its operations from the proceeds of sales of its common stock and from revenues from the sales of its products and services.

### ***Remodulin Marketing and Sales***

Remodulin is sold and marketed to patients in the United States by Accredo Therapeutics, Inc., Priority Healthcare Corporation and Caremark, Inc. and outside of the United States by international distributors. United Therapeutics sells Remodulin in bulk shipments to these distributors. The timing and extent of United Therapeutics' sales of Remodulin are impacted by the timing and extent of these bulk orders from distributors. Bulk orders placed by distributors are determined by them, based on their estimates of the amount of drug required for current and newly starting patients, as well as an inventory equivalent to approximately thirty to sixty days demand as a contingent supply since discontinuation of therapy can be life-threatening to patients. Therefore, sales of Remodulin to distributors in any given quarter may not be indicative of patient demand in that quarter. Sales of Remodulin and Remodulin delivery pumps and supplies are recognized as revenue when delivered to the distributors.

### ***Future Prospects***

While United Therapeutics was profitable during most of 2004, it incurred net losses for all periods from inception through March 31, 2004. At December 31, 2004, United Therapeutics had an accumulated deficit of approximately \$180.3 million. United Therapeutics may continue to incur net losses and cannot provide assurances that, in the future, it will be profitable. Future profitability will depend on many factors, including timely and successful completion of the Remodulin Phase IV study discussed above under *United Therapeutics Products and Services*, the price, level of sales, level of reimbursement by public and private insurance payers, and the number of patients using Remodulin and other currently commercialized products and services, as well as the results and costs of research and development projects.

### **Major Research and Development Projects**

The major research and development projects of United Therapeutics are the use of Remodulin to treat cardiovascular diseases, immunotherapeutic monoclonal antibodies (antibodies that activate a patient's immune response) to treat a variety of cancers and glycobiology antiviral agents (a novel class of small molecules that may be effective as oral therapies) to treat infectious diseases.

#### ***Cardiovascular Disease Projects***

Subcutaneous use of Remodulin was approved by the FDA in May 2002 for the treatment of pulmonary arterial hypertension in NYHA Class II-IV patients to diminish symptoms associated with exercise. A condition of continued FDA approval is that a Phase IV clinical study must be completed in a timely and diligent manner as discussed above under *United Therapeutics Products and Services*. Remodulin was also approved in Canada, Israel, Australia and Switzerland for similar uses. Regulatory applications and reviews of Remodulin for pulmonary arterial hypertension are ongoing in other countries. Material net cash inflows from the sales of Remodulin for pulmonary arterial hypertension commenced in May 2002 after FDA approval was received.

In 2003, United Therapeutics filed an investigational new drug application and performed animal toxicology and human bioequivalence studies to support intravenous use of Remodulin. Based on positive results of these studies, in January 2004, United Therapeutics filed a supplemental New Drug Application (sNDA) with the FDA for intravenous use of Remodulin in pulmonary arterial hypertension. On November 24, 2004, the FDA approved the intravenous use of Remodulin, based on data establishing its bioequivalence with the previously approved subcutaneous administration of Remodulin, for patients who are not able to tolerate a subcutaneous infusion. This approval was also conditioned on the diligent and timely completion of the Phase IV trial described above, as well as its outcome. Remodulin was also being evaluated for the treatment of critical limb ischemia (the advanced stage of vascular disease affecting blood vessels in the legs). United Therapeutics commenced a 30 patient placebo-controlled pre-pivotal clinical study of Remodulin for critical limb ischemia in 2002. Approximately 19 patients were enrolled. The study was ended before becoming fully enrolled due to difficulties in recruiting patients for the study. United Therapeutics believes that more convenient formulations of Remodulin, such as an oral form, may be more appropriate for patients with peripheral vascular disease.

United Therapeutics is in the early stages of developing oral and inhaled formulations of treprostinil. During 2004, United Therapeutics completed dosage studies of oral formulations of Remodulin in healthy volunteers and filed an Investigational New Drug Application on January 28, 2005 to perform an additional study. During 2004, independent clinical investigators performed small uncontrolled trials of inhaled formulations of treprostinil in patients with pulmonary arterial hypertension. United Therapeutics is currently planning a controlled trial of another formulation of inhaled Remodulin in patients with pulmonary arterial hypertension. United Therapeutics incurred expenses of approximately \$16.2 million, \$13.5 million, and \$8.8 million during the years ended December 31, 2004, 2003 and 2002, respectively, on Remodulin development. Approximately \$140.8 million from inception to date has been incurred on Remodulin development.

### ***Cancer Disease Projects***

United Therapeutics' monoclonal antibody immunotherapies were licensed in April 2002 from AltaRex Medical Corp. OvaRex MAb is the lead product and is currently being studied in two identical Phase III clinical trials in advanced ovarian cancer patients. These studies, which commenced in January 2003, are being conducted at approximately 60 centers throughout the United States and are expected to be fully enrolled in the next 12 to 18 months. These studies could take up to two years to complete following full enrollment, depending on trial patients' relapse rates. United Therapeutics incurred expenses of approximately \$7.3 million, \$10.0 million and \$6.4 million during the years ended December 31, 2004, 2003 and 2002, respectively, on OvaRex development. Approximately \$23.7 million from inception to date has been incurred on OvaRex development.

### ***Infectious Disease Projects***

United Therapeutics' infectious disease program includes glycobiology antiviral drug candidates in the preclinical and clinical stages of testing. The drugs in this program are being developed for hepatitis C, hepatitis B and other infectious diseases. The first candidate for hepatitis C, UT-231B, completed acute and chronic Phase I clinical dosing studies to assess safety in healthy volunteers in early 2003. Phase II clinical studies in patients infected by hepatitis C were initiated in July 2003 and were completed in October 2004. In that trial, UT-231B did not demonstrate efficacy against hepatitis C in a population of patients that previously failed conventional treatments. United Therapeutics is now planning a trial in patients who responded positively to conventional treatments in order to determine if UT-231B can prevent disease relapse in such patients. United Therapeutics incurred expenses of approximately \$3.3 million, \$7.1 million, and \$6.9 million during the years ended December 31, 2004, 2003 and 2002, respectively, for its infectious disease programs. Approximately \$31.7 million from inception to date has been incurred for infectious disease programs.

### ***Project Risks***

Due to the inherent uncertainties involved in the drug development, regulatory review and approval processes, the anticipated completion dates, the cost of completing the research and development and the period in which material net cash inflows from these projects are expected to commence are not known or estimable. There are many risks and uncertainties associated with completing the development of the products discussed above, including the following:

- Products may fail in clinical studies;
- Hospitals, physicians and patients may not be willing to participate in clinical studies;
- The drugs may not be safe and effective or may not be perceived as safe and effective;
- Other approved or investigational therapies may be viewed as safer, more effective or more convenient;
- Patients may experience severe side effects during treatment;
- Patients may die during the clinical study because their disease is too advanced or because they experience medical problems that are not related to the drug being studied;
- Patients may not enroll in the studies at the rate United Therapeutics expects;
- The FDA and foreign regulatory authorities may delay or withhold approvals to commence clinical trials or to manufacture drugs;
- The FDA and foreign regulatory authorities may request that additional studies be performed;
- Higher than anticipated costs may be incurred due to the high cost of contractors for drug manufacture, research and clinical trials;
- Drug supplies may not be sufficient to treat the patients in the studies; and
- The results of preclinical testing may cause delays in clinical trials.

If these projects are not completed in a timely manner, regulatory approvals would be delayed and United Therapeutics' operations,

liquidity and financial position could suffer. Without regulatory approvals, United Therapeutics could not commercialize and sell these products and, therefore, potential revenues and profits from these products would be delayed or impossible to achieve.



## Financial Position

Cash, cash equivalents and marketable investments (including all unrestricted and restricted amounts) at December 31, 2004 were approximately \$139.1 million, as compared to approximately \$117.3 million at December 31, 2003. The increase of approximately \$21.8 million is due primarily to cash provided by operating activities of approximately \$20.8 million and proceeds from the exercise of stock options totaling approximately \$7.1 million, offset by \$5.2 million used to purchase property, plant and equipment. Restricted cash and marketable investments pledged to secure United Therapeutics' obligations under the synthetic operating lease discussed below under *Off Balance Sheet Arrangement* at December 31, 2004 totaled approximately \$10.1 million, as compared to none at December 31, 2003.

Accounts receivable, net of allowances for doubtful accounts, at December 31, 2004 were approximately \$13.7 million, as compared to approximately \$10.2 million at December 31, 2003. The increase of approximately \$3.5 million was due primarily to increased sales of Remodulin in the last quarter of 2004 as compared to sales of Remodulin in the last quarter of 2003.

Prepaid expenses at December 31, 2004 were approximately \$3.2 million, as compared to approximately \$1.9 million at December 31, 2003. The increase of approximately \$1.3 million was due primarily to a greater level of prepayments for research and development related goods and services at December 31, 2004.

Property, plant and equipment at December 31, 2004 was approximately \$17.8 million, as compared to \$15.2 million at December 31, 2003. The increase was due primarily to the purchase of a lot adjacent to United Therapeutics' headquarters for \$2.9 million.

Other non-current assets at December 31, 2004 were approximately \$1.2 million, as compared to approximately \$3.1 million at December 31, 2003. Included in this amount at December 31, 2003 was an escrow of approximately \$2.8 million which was used in June 2004 to purchase a lot adjacent to United Therapeutics' headquarters on which construction of the new laboratory facility has commenced.

Total liabilities at December 31, 2004 were approximately \$15.5 million, as compared to total liabilities of approximately \$11.7 million at December 31, 2003 and consisted primarily of trade payables, accrued expenses and amounts due to affiliates. The increase was due primarily to a guarantee of approximately \$839,000 related to the laboratory construction and lease arrangements discussed below under *Off Balance Sheet Arrangement*, and increases of approximately \$2.0 million in accrued expenses for Medicaid rebates and royalty liabilities.

Total stockholders' equity at December 31, 2004 was approximately \$191.6 million, as compared to \$167.8 million at December 31, 2003. The increase in stockholders' equity of approximately \$23.8 million was due primarily to net income earned during the year ended December 31, 2004 and the proceeds from exercises of stock options of approximately \$7.1 million.

## Results Of Operations

### *Years ended December 31, 2004 and 2003*

	Revenues for the Year Ended (in thousands)	
	December 31, 2004	December 31, 2003
Remodulin	\$ 66,050	\$ 45,121
Telemedicine services and products	5,346	4,161
Other products	2,194	4,059
Total revenues	<u>\$ 73,590</u>	<u>\$ 53,341</u>

Revenues for the year ended December 31, 2004 were approximately \$73.6 million, as compared to approximately \$53.3 million for the year ended December 31, 2003. The increase of approximately \$20.3 million was due primarily to growth in patients using Remodulin and the price increase discussed below. The impact of the price change was to increase revenues from Remodulin by approximately \$13.7 million for the year ended December 31, 2004.

Total revenues are reported net of estimated government rebates, prompt pay discounts and fees due to a distributor for services. Government rebates are paid to state Medicaid agencies that pay for Remodulin. United Therapeutics estimates its liability for such rebates based on the volume of Remodulin dispensed to Medicaid patients as reported to United

Therapeutics by its distributors and the expected rebate per unit of Remodulin as determined by United Therapeutics in accordance with federal guidelines. Prompt pay discounts are offered on sales of Remodulin if the related invoices are paid in full generally within 60 days from the date of sale. United Therapeutics estimates its liability for prompt pay discounts based on historical payment patterns. Fees paid to a distributor for services are estimated based on contractual rates for specific services applied to estimated units of service provided by the distributor for the period.

A roll forward of the liability accounts associated with estimated government rebates, prompt pay discounts and fees to a distributor for services as well as the net amount of reductions to revenues for these items are presented as follows (in thousands):

	Year Ended	
	December 31, 2004	December 31, 2003
Liability accounts, at beginning of period	\$ 936	\$ 654
Additions to liability	7,642	2,992
Payments	(6,457)	(2,710)
Liability accounts, at end of period	\$ 2,121	\$ 936
Net reductions to revenues	\$ 7,642	\$ 2,992

Remodulin is sold to distributors in the United States at an agreed-upon discount from the published average wholesale price (AWP) and to international distributors at an agreed-upon transfer price. In 2003, the published AWP of Remodulin was \$65.00 per milligram (mg) for the 1.0 mg, 2.5 mg and 5.0 mg concentrations and \$39.00 per mg for the 10.0 mg concentration. In the first quarter of 2004, the published AWP for the 10.0 mg concentration was increased to \$65.00 per mg to achieve uniform pricing. Also during the first quarter of 2004, United Therapeutics informed prescribers of Remodulin that based on laboratory studies completed in late 2003, vials containing Remodulin remain stable for up to 30 days from their first use. Previously, the period of stability had been established at 14 days. Furthermore, in November 2004, the FDA approved package insert for Remodulin was updated to reflect the 30 day stability. Therefore, patients are expected to use Remodulin vials for longer than 14 days and, accordingly, consume fewer vials annually. The increase in the period of stability may result in decreased future net sales of Remodulin.

During 2004, approximately one-quarter of all reimbursable Remodulin patients were beneficiaries under Medicare. During most of 2004, Medicare was reimbursing distributors for Remodulin sold to Medicare patients at a payment level that was significantly less than the acquisition price paid by these distributors to United Therapeutics. This under-reimbursement by Medicare was occurring with respect to approximately one-half of the Medicare patients, comprising only those patients using the 10.0 mg/mL concentration vials across all four Medicare payment regions and all patients in one of the Medicare payment regions. As a result of this under-reimbursement, distributors were generally incurring losses on their sales of Remodulin related to Medicare beneficiaries. On October 29, 2004, the Centers for Medicare and Medicaid Services (CMS) issued CMS Manual System, Pub. 100-20 One-Time Notification, Transmittal 123 ("Transmittal") with an effective date of January 1, 2004. The Transmittal directed CMS' regional contractors known as Durable Medical Equipment Regional Coordinators (DMERCs) to reimburse all units of Remodulin at the payment limit established by CMS in January 2004. That payment limit is \$61.75 per milligram which is higher than the acquisition price paid by the distributors. In addition, the Transmittal also requires the DMERCs to retroactively adjust claims brought to their attention. Accordingly, United Therapeutics now believes that the under-reimbursement situation has been favorably resolved.

United Therapeutics' distributors endeavor to maintain levels of Remodulin inventories sufficient to satisfy existing and new demand for the product. Inventory levels held by United States-based distributors (as reported to United Therapeutics by such distributors) at December 31, 2004 were approximately \$14.0 million based on United Therapeutics' selling price. The inventory levels at December 31, 2003 were approximately \$13.6 million. As Remodulin is not yet approved in the European Union, inventory levels outside of the United States were not significant. Product returns were due to arginine products and totaled approximately \$33,000 and \$192,000 during the years ended December 31, 2004 and 2003, respectively.

Research and development expenses consist primarily of salaries and related expenses, costs to acquire pharmaceutical products and product rights for development and amounts paid to contract research organizations, hospitals and laboratories for the provision of services and materials for drug development and clinical trials. Research and development expenses were approximately \$30.6 million for the year ended December 31, 2004, as compared to approximately \$35.4 million for the year ended December 31, 2003. During the year ended December 31, 2004, expenses for Remodulin-related programs increased by approximately \$2.7 million while expenses for the infectious disease and cancer

programs were reduced by approximately \$3.8 million and \$2.7 million, respectively, as compared to 2003. The remaining decrease in total research and development expenses of approximately \$1.0 million was related to reduced expenses in other programs. See *Major Research and Development Projects* above, for additional information.

Selling, general and administrative expenses consist primarily of salaries, travel, office expenses, insurance, professional fees, provision for doubtful accounts receivable, depreciation and amortization. Selling, general and administrative expenses were approximately \$21.6 million for the year ended December 31, 2004, as compared to approximately \$22.7 million for the year ended December 31, 2003. The decrease was due primarily to decreases of approximately \$1.2 million in sales and marketing expenses related mostly to arginine products and approximately \$871,000 in travel expenses. These decreases were offset by increases of approximately \$495,000 in professional fees expenses and \$526,000 in insurance expenses.

Cost of sales consists of the cost to manufacture or acquire products that are sold to customers. Cost of service sales consists of the salaries and related overhead necessary to provide services to customers. Cost of product sales was approximately 9% of product sales for the year ended December 31, 2004, which is consistent with approximately 10% for the year ended December 31, 2003. Cost of service sales was approximately 47% of service sales for the year ended December 31, 2004, which is consistent with the cost of service sales of approximately 49% for the year ended December 31, 2003.

Interest income for the year ended December 31, 2004 was approximately \$3.0 million, as compared to interest income of approximately \$2.4 million for the year ended December 31, 2003. The increase is due primarily to an increase in cash available for investing during 2004.

Equity loss in affiliate represents United Therapeutics' share of Northern Therapeutics, Inc.'s losses. At December 31, 2004, United Therapeutics owned approximately 68% of Northern Therapeutics. The equity loss in affiliate was approximately \$785,000 for the year ended December 31, 2004, which is consistent with approximately \$953,000 for the year ended December 31, 2003. Northern Therapeutics, Inc.'s loss is due primarily to expenditures for its autologous (non-viral vector) gene therapy research for pulmonary hypertension and sales and marketing activities for Remodulin in Canada.

#### *Years ended December 31, 2003 and 2002*

	Revenues for the Year Ended (in thousands)	
	December 31, 2003	December 31, 2002
Remodulin	\$ 45,121	\$ 21,174
Telemedicine services and products	4,161	3,887
Other products	4,059	5,059
Total revenues	<u>\$ 53,341</u>	<u>\$ 30,120</u>

Revenues for the year ended December 31, 2003 were approximately \$53.3 million, as compared to approximately \$30.1 million for the year ended December 31, 2002. The increase of approximately \$23.2 million was due primarily to growth in patients using Remodulin.

A roll forward of the liability accounts associated with estimated government rebates, prompt pay discounts and fees to a distributor for services as well as the net amount of reductions to revenues for these items are presented as follows (in thousands):

	Year Ended	
	December 31, 2003	December 31, 2002
Liability accounts, at beginning of period	\$ 654	\$ —
Additions to liability	2,992	987
Payments	(2,710)	(333)
Liability accounts, at end of period	<u>\$ 936</u>	<u>\$ 654</u>
Net reductions to revenues	<u>\$ 2,992</u>	<u>\$ 987</u>

Product returns were due to arginine products and totaled approximately \$192,000 and \$83,000 during the years ended December 31, 2003 and 2002, respectively.

Research and development expenses were approximately \$35.4 million for the year ended December 31, 2003, as compared to approximately \$26.8 million for the year ended December 31, 2002. The increase of approximately \$8.6 million was due primarily to increased expenses of approximately \$5.1 million for Remodulin-related programs and increased expenses of approximately \$3.5 million for the OvaRex program. See — *Major Research and Development Projects* , above for additional information.

Selling, general and administrative expenses were approximately \$22.7 million for the year ended December 31, 2003, as compared to approximately \$15.9 million for the year ended December 31, 2002. The increase of approximately \$6.8 million was due primarily to increased expenses of approximately \$4.5 million for salaries, travel and related expenses due to expanded selling and marketing efforts, increased expenses of approximately \$1.2 million in professional fees related to regulatory and intellectual property matters, and an increase in other operating expenses, such as rent, telephone, office supplies and depreciation expense, of approximately \$850,000.

Cost of product sales was approximately 10% of product sales for the year ended December 31, 2003, as compared to approximately 14% in 2002. The decrease in cost of product sales as a percentage of product sales was due primarily to the commercial launch of Remodulin in May 2002 which has a lower cost of sales than other United Therapeutics products. Cost of service sales was approximately 49% of service sales for the year ended December 31, 2003, which is consistent with the cost of service sales of approximately 49% for the year ended December 31, 2002.

Interest income for the year ended December 31, 2003 was approximately \$2.4 million, as compared to approximately \$5.0 million for the year ended December 31, 2002. This decrease of approximately \$2.6 million was attributable primarily to lower yields in 2003 and a decrease in the amount of cash available for investing as compared to 2002.

The write-down of investment for the year ended December 31, 2003 was none, as compared to a loss of approximately \$2.9 million for the year ended December 31, 2002. The investment write-down in 2002 represents a loss due to an other-than-temporary decline in value of the investment in AltaRex Medical Corp. For the six-month period ended September 30, 2002, the quoted market price of AltaRex's common stock was consistently less than United Therapeutics' cost. This was determined to be an other-than-temporary decline in the value of AltaRex's common stock held by United Therapeutics. As a result, the investment in AltaRex was written down to its fair value as determined by quoted market prices in September 2002. The fair value of this investment as determined by quoted market prices on December 31, 2004 and 2003 was equivalent to the amount reported in the consolidated balance sheets.

The loss on marketable investments for the year ended December 31, 2003 was none, as compared to a loss of approximately \$7.4 million for the year ended December 31, 2002. In March 2002, United Therapeutics reported a \$538,000 write-down due to an other-than-temporary decline in value of one of its marketable investments. In June 2002, United Therapeutics began reassessing its investment program in light of increasingly adverse conditions in the bond markets. As a result, all marketable debt investments were sold in July 2002. A write-down of investments totaling approximately \$3.6 million was necessary to adjust the value of United Therapeutics' marketable investments to their fair value based on quoted market prices at June 30, 2002. In July 2002, United Therapeutics recorded an additional realized loss of approximately \$3.3 million as a result of the liquidation of the investment portfolio.

The equity loss in affiliate was approximately \$953,000 for the year ended December 31, 2003, as compared to approximately \$209,000 for the year ended December 31, 2002. The increase was due primarily to increased expenditures by Northern Therapeutics related to its autologous (non-viral vector) gene therapy research for pulmonary hypertension and increased sales and marketing activities for Remodulin in Canada.

### ***In-Process Research & Development***

During 2000, a subsidiary of United Therapeutics acquired the assets of Medicomp, Inc. in a purchase transaction that resulted in a write-off of in-process research and development related to in-process projects that had not yet reached technological feasibility and had no alternative future uses. At the acquisition date, Medicomp was conducting design, development, engineering and testing activities associated with the completion of a number of new technological innovations for next-generation products. Medicomp completed the development of its automatic trigger heart monitor during 2004. The new CardioPAL AI monitor utilizes this technology and was launched in 2004. Medicomp was also pursuing development of a wireless heart monitor system. During 2004, United Therapeutics determined that alternative wireless technologies existed that could be utilized more feasibly than the technology acquired from Medicomp. Therefore, the wireless heart monitor project as acquired from Medicomp will not be completed but will, instead, utilize third-party wireless technologies. This

change is not expected to have a material impact on United Therapeutics.

## **Liquidity And Capital Resources**

Until June 1999, United Therapeutics financed its operations principally through private placements of common stock. On June 17, 1999, United Therapeutics completed its initial public offering. Net proceeds to United Therapeutics from the initial public offering and sale of the over-allotment shares, after deducting underwriting commissions and offering expenses, were approximately \$56.4 million. In 2000, United Therapeutics issued common stock in two private placements and received aggregate net proceeds of approximately \$209.0 million. Until 2002, United Therapeutics funded the majority of its operations from such net proceeds of equity. During 2004, United Therapeutics funded the majority of its operations from revenues, mainly Remodulin related, and this is expected to continue.

In addition, on February 10, 2005, United Therapeutics filed a primary shelf registration statement with the SEC to enable United Therapeutics to offer and sell up to five million shares of its common stock from time to time in one or more offerings. The shelf registration statement will provide United Therapeutics the flexibility to take advantage of future financing opportunities on terms that United Therapeutics considers advantageous, which terms would be established at the time of any such offering. The SEC has not as of the date of filing this Annual Report on Form 10-K declared such registration statement effective.

United Therapeutics' working capital at December 31, 2004 was approximately \$96.6 million, as compared to approximately \$79.1 million at December 31, 2003. The increase is primarily due to an increase in cash flow from operations and stock option exercises. Current liabilities at December 31, 2004 were approximately \$13.9 million, as compared to approximately \$10.6 million at December 31, 2003. The increase is due primarily to an increase in Remodulin-related Medicaid rebates and royalty liabilities due to increased sales of Remodulin. United Therapeutics' debt at December 31, 2004 was approximately \$26,000 and consisted of equipment leases as compared with \$798,000 at December 31, 2003. At December 31, 2003, total debt included a mortgage note totaling approximately \$750,000 which was paid off in January 2004.

Net cash provided by operating activities was approximately \$20.8 million for the year ended December 31, 2004 as compared to net cash used in operating activities of approximately \$8.6 million for the year ended December 31, 2003. The increase in cash provided by operating activities is due primarily to growth in sales and collections from Remodulin. For the years ended December 31, 2004 and 2003, United Therapeutics invested approximately \$5.2 million and \$7.0 million, respectively, in cash for property, plant and equipment. These amounts were used primarily to acquire land and buildings in 2004 and 2003.

United Therapeutics made milestone payments totaling \$20,000 pursuant to existing license agreements during the year ended December 31, 2004. United Therapeutics is obligated to make royalty payments on sales of Remodulin which exceed annual net sales of \$25.0 million and on all arginine products. Royalties on sales of all products currently marketed will range up to 10.0 percent of sales of those products.

In December 2000, a subsidiary of United Therapeutics acquired the assets of Medicomp, Inc. and Telemedical Procedures, LLC (together referred to as Medicomp). Under terms of the acquisition agreement, United Therapeutics was required to issue additional shares to the sellers because the average closing price of United Therapeutics' common stock over the 30 calendar days prior to the third anniversary of the acquisition was less than \$70.00 per share. In August 2004, 591,832 shares of United Therapeutics' common stock were issued to the sellers in satisfaction of this obligation.

United Therapeutics believes that its existing revenues, together with existing capital resources (comprised primarily of unrestricted cash, cash equivalents and marketable investments), will be adequate to fund its operations through 2007. Factors that could cause actual results of operations to differ from these expectations include the following:

- Continued regulatory approval of Remodulin in the United States and other countries;
- Size, scope, timely completion and outcome of the Remodulin post-marketing Phase IV clinical study;
- Additional regulatory approvals of Remodulin in other countries;
- Retention and growth of reimbursable patients treated with Remodulin;
- Impact of infusion site pain and infusion site reaction and other Remodulin side effects;
- Changes in the current Remodulin pricing and dosing;
- Changes in the length of time that Remodulin vials may be used by patients;
- Reimbursement of Remodulin by public and private payers and the level of reimbursement;
- Impact of other approved and investigational competitive products and changes in their pricing;

- Changes in prescribers' opinions about Remodulin;
- Impact of medical and scientific opinion on United Therapeutics' products;

- Cost, timing and outcomes of regulatory reviews;
- Rate of technological advances;
- Continued performance by Remodulin distributors under existing agreements;
- Development of manufacturing resources or the establishment, continuation or termination of third-party manufacturing arrangements;
- Development of sales and marketing resources or the establishment, continuation or termination of third-party sales and marketing arrangements;
- Establishment, continuation or termination of third-party clinical trial arrangements;
- Defending and enforcing intellectual property rights;
- Future milestone and royalty payments;
- Risks associated with acquisitions, including the ability to integrate acquired businesses;
- Actual expenses incurred in future periods;
- Establishment of additional strategic acquisitions or licensing arrangements; and
- Ability of United Therapeutics to maintain and grow its telemedicine and arginine revenues.

United Therapeutics did not incur income tax expense for the year ended December 31, 2004 generally due to the availability of deductions for tax purposes which will offset any net income for these periods. As of December 31, 2004, United Therapeutics had available approximately \$109.9 million in net operating loss carryforwards and approximately \$27.0 million in business tax credit carryforwards for federal income tax purposes that expire at various dates through 2024. United Therapeutics is currently conducting a study to determine whether any limitations under Section 382 of the Internal Revenue Code have been triggered. Preliminary results of this study indicate that a limitation occurred in November 2004. As a result, portions of these carry forward items that were generated prior to November 2004 will be subject to certain limitations on their use. United Therapeutics does not believe that these limitations will cause the net operating loss and general business credit carryforwards to expire unused.

#### **Off Balance Sheet Arrangement**

In June 2004, United Therapeutics entered into a synthetic operating lease and related agreements with Wachovia Development Corporation and its affiliates (Wachovia) to fund the construction of a laboratory facility in Silver Spring, Maryland. Under these agreements, Wachovia will fund up to \$32.0 million towards the construction of the laboratory facility on ground owned by United Therapeutics. The construction phase commenced in 2004 and is expected to be completed in early 2006. Following construction, Wachovia will lease the laboratory facility to United Therapeutics with a term ending in May 2011. Under the 99-year ground lease, Wachovia will pay fair value rent to United Therapeutics for use of the land both during the construction phase and after the laboratory lease is terminated. During the term of the laboratory lease, Wachovia will pay \$1 per year to United Therapeutics for use of the land.

Upon completion of the construction, Wachovia will receive rents from United Therapeutics generally based on applying the 30-day LIBOR rate plus approximately 55 basis points to the amount funded by Wachovia towards the construction of the laboratory. These rents will be paid monthly from the time that the laboratory construction is completed until the termination of the lease in May 2011. Upon termination of the lease, United Therapeutics will generally have the option of renewing the lease (subject to approval of both parties), purchasing the laboratory at a price approximately equal to the funded construction cost or selling it and repaying Wachovia the cost of its construction. United Therapeutics has guaranteed that if the laboratory is sold, Wachovia will receive at least 86 percent of the amount it funded towards the construction.

In addition, United Therapeutics agreed to pledge, as collateral, a portion of its marketable investments to secure its lease obligations. At December 31, 2004, approximately \$10.1 million of marketable investments and cash were pledged as collateral and are reported as restricted marketable investments and cash in the consolidated balance sheets.

This arrangement allows United Therapeutics to construct its laboratory facility without using its own working capital. United Therapeutics will manage the construction and incur construction costs. Wachovia will then reimburse these construction costs each month as they are incurred. United Therapeutics will make rent payments to Wachovia starting when construction of the facility is completed and through the lease termination in May 2011. There will not be any depreciation expense associated with the laboratory facility, since these improvements will be owned by Wachovia. The amount of rent to be paid to Wachovia will vary as it is tied to the then current 30-day LIBOR rate plus approximately 55 basis points. As this rate increases, so will the rents to be paid. Similarly, if this rate decreases, then the amount of rent to be paid to Wachovia will also decrease.





United Therapeutics anticipates that rent payments will commence in early 2006, after completion of construction, and continue through termination of the lease in May 2011. Based on construction costs of up to approximately \$32.0 million and the current effective rate of approximately 2.95 percent (equivalent to the current 30-day LIBOR rate plus approximately 55 basis points at December 31, 2004), the rents to be paid could approximate \$944,000 annually. In addition, Wachovia has paid to United Therapeutics ground rent totaling an aggregate of approximately \$307,000 that will be recognized in income ratably through May 2011.

United Therapeutics has guaranteed a minimum residual value of the laboratory facility. This guaranteed residual is generally equal to 86 percent of the amount funded by Wachovia towards construction. If, at the end of the lease term, United Therapeutics does not renew the lease or purchase the improvements, then the building will be sold to a third party. In that event, United Therapeutics has guaranteed that Wachovia will receive at least this residual value amount. The maximum potential amount of this guarantee is approximately \$27.5 million, equivalent to 86 percent of expected total construction costs of \$32.0 million. United Therapeutics has estimated the fair value of this guarantee liability at approximately \$839,000 and this amount is classified as a non-current liability in its balance sheet at December 31, 2004.

The lease and other agreements with Wachovia require that, among other things, United Therapeutics maintain a consolidated current ratio of not less than 1.2:1.0 and a consolidated net worth of at least \$70.0 million. The agreements contain other covenants and conditions with which United Therapeutics must comply throughout the construction and lease periods and upon termination of the lease. If United Therapeutics was unable to comply with these covenants and conditions, the agreements could terminate if the noncompliance was uncured and the parties could not agree otherwise. A termination of these agreements could result in United Therapeutics acquiring the improvements from Wachovia or the loss of its liquid collateral. If the agreements are terminated during the construction period due to United Therapeutics' default, then United Therapeutics could be required to purchase the improvements. During construction, the amount United Therapeutics would be required to pay is limited to 89.9 percent of the construction costs.

### Contractual Obligations

At December 31, 2004, United Therapeutics had contractual obligations coming due approximately as follows (in thousands):

	Payment Due In				
	Total	2005	2006 to 2008	2009 to 2010	2011 and Later
Capital lease obligations	\$ 26	\$ 16	\$ 10	\$ —	\$ —
Operating lease obligations (1)	9,801	1,115	5,545	2,593	548
Purchase obligations	—	—	—	—	—
Other long-term liabilities reflected in the statement of financial position (1)	839	—	—	—	839
Milestone payments (2)	9,765	20	4,685	3,040	2,020
	<u>\$ 20,431</u>	<u>\$ 1,151</u>	<u>\$ 10,240</u>	<u>\$ 5,633</u>	<u>\$ 3,407</u>

- (1) Operating lease obligations include the estimated lease payments on the laboratory facility being constructed in Silver Spring, Maryland. The lease is expected to commence in early 2006 and will expire in May 2011. The lease payments will generally be equal to applying the current 30-day LIBOR rate plus approximately 55 basis points (approximately 2.95 percent at December 31, 2004) to the cost of the construction of the laboratory. Upon termination of the lease, United Therapeutics will generally have the option of renewing the lease, purchasing the laboratory or selling it and repaying Wachovia the cost of its construction. United Therapeutics has guaranteed that if the laboratory is sold, Wachovia will receive at least 86 percent of the amount it funded towards the construction. It is estimated that the laboratory will cost approximately \$32.0 million to construct and the guarantee is estimated at approximately \$27.5 million. The estimated fair value of the guarantee is included in other long-term liabilities reflected in the statement of financial position. See “ — *Off Balance Sheet Arrangement*” for additional information.
- (2) United Therapeutics has licensed certain products from other companies under certain license agreements. These agreements generally include milestone payments to be paid in cash by United Therapeutics upon the achievement of certain product development and commercialization goals set forth in each license agreement. Total milestone payments under these license agreements have been estimated based on the estimated timing of these development and commercialization goals.

## Summary of Critical Accounting Policies

### *Remodulin Revenue Recognition*

Product sales of Remodulin are recognized when delivered to distributors, which are United Therapeutics' customers for Remodulin. Product sales of Remodulin delivery pumps and related supplies are recognized when delivered to distributors on a gross basis in accordance with EITF Issue No. 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent*. Title to these products passes upon delivery. Had the net basis been applied, the amounts of revenues and cost of product sales reported in the consolidated financial statements would have been lower, but there would have been no impact on net income or losses. Prompt payment discounts, government rebates and fees to a distributor (customer) are estimated and recognized as reductions of revenue in the same period that revenues are recognized. Had these discounts, rebates and fees not been reported as reductions of revenue, the amounts reported as revenues and selling expenses would have been higher, but there would have been no impact on net income or losses. Return policies provide that product that has expired or become damaged in shipment may be replaced, but not returned. Therefore, reserves for exchanges are not recorded unless product expiration or damage occurs. The shelf life of Remodulin is two years from the date of its manufacture. United Therapeutics relies on its distributors to report damage in shipment or expirations of Remodulin product.

One of United Therapeutics' Remodulin distribution agreements stipulates minimum quarterly purchases by the distributor. The distribution agreement, however, does not permit the distributor to return Remodulin product solely based on the distributor's ability or inability to resell the product. As such, revenues from sales to this distributor are recognized in the period that the Remodulin product is delivered to the distributor. During the twelve month periods ended December 31, 2004, 2003 and 2002, approximately \$3.1 million, \$2.0 million, and none of Remodulin products were sold to this distributor and recognized as revenue, respectively.

### *Intangible Assets*

United Therapeutics adopted the provisions of Statement of Financial Accounting Standards No. 142, *Goodwill and Other Intangible Assets* (SFAS No. 142), on January 1, 2002, which eliminated the amortization of goodwill. Rather, goodwill is subject to at least an annual assessment for impairment by applying a fair value-based test that is performed on October 1<sup>st</sup> of each year. United Therapeutics continually evaluates whether events and circumstances have occurred that indicate that the remaining value of goodwill may not be recoverable. At December 31, 2004, management believed that goodwill was not impaired and therefore no impairment losses have been recorded. This conclusion is based on management's judgment, taking into consideration expectations regarding future profitability and the status of the reporting units which have reported goodwill. However, changes in strategy or adverse changes in market conditions could impact this judgment and require an impairment loss to be recognized for the amount that the carrying value of goodwill exceeds its fair value.

### *Marketable Investments*

Currently, United Therapeutics invests portions of its cash in debt securities issued by federally sponsored agencies. Due to United Therapeutics' intent and ability to hold these marketable debt investments until their maturities, these investments are reported at their amortized cost. United Therapeutics believes that it is able to hold these investments to maturity, due to the significant level of cash and cash equivalents it has. If United Therapeutics did not have the ability and intent to hold these investments to maturity, it would have reported them in the consolidated balance sheets at their fair market values. At December 31, 2004, the amortized cost of these debt securities was approximately \$56.2 million and their fair values were approximately \$55.3 million.

### *Earnings (Loss) per Share*

In accordance with SFAS No. 128, *Earnings Per Share*, for the periods with net income, the dilutive effect of outstanding stock options is included in the calculation of dilutive earnings per share using the treasury stock method. For periods with a net loss, the effect of outstanding stock options is antidilutive and is excluded from the calculation of dilutive loss per share.

### *Stock Options*

United Therapeutics applies the principles of APB No. 25, *Accounting for Stock Issued to Employees*, in accounting for its stock options issued to its employees. The following table details the pro forma results had United Therapeutics

applied the fair value principles of SFAS No. 123, *Accounting for Stock-Based Compensation* , for its employee options (in thousands):

	Years Ended December 31,		
	2004	2003	2002
Net income (loss), as reported	\$ 15,449	\$ (9,969)	\$(23,651)
Less total stock-based employee compensation expense determined under fair value based method for all awards	(8,072)	(12,964)	(18,082)
Pro forma net income (loss)	<u>\$ 7,377</u>	<u>\$ (22,933)</u>	<u>\$(41,733)</u>

#### *Investments in Affiliates*

The equity method of accounting is used to account for most of United Therapeutics' investments in affiliates. The equity method of accounting generally requires United Therapeutics to report its share of the affiliates' net losses or profits in its financial statements, but does not require that assets, liabilities, revenues and expenses of the affiliates be consolidated with United Therapeutics' consolidated financial statements. The equity method of accounting is being applied generally due to the lack of control over these affiliates and the levels of ownership held by United Therapeutics. Although United Therapeutics' investment in Northern Therapeutics exceeds 50 percent, minority shareholders possess substantive participating rights that preclude Northern Therapeutics' financial statements from being consolidated.

Other investments in affiliates are accounted for on the cost method generally due to the lack of significant influence over these affiliates and a less than 20 percent ownership by United Therapeutics. The cost method of accounting does not require that United Therapeutics report its share of the affiliates' net losses or profits in its financial statements, nor are affiliates' assets, liabilities, revenues and expenses consolidated with United Therapeutics' consolidated financial statements.

The investment in ViRexx Medical Corporation (formerly AltaRex Medical Corp.) is accounted for as an available-for-sale security because its stock is publicly traded. Available-for-sale securities are reported at their fair values in the balance sheet. Changes in their fair values are reported as other comprehensive income or loss. Declines in values that are considered other-than-temporary are reported as losses in the statement of operations. For the year ended December 31, 2004, the fair value of the investment in ViRexx increased by approximately \$1.0 million as compared to an increase in fair market value of approximately \$1.7 million for the year ended December 31, 2003 based on quoted market prices. These increases were reported as other comprehensive income. During 2002, a reduction in the fair value of the investment in ViRexx was considered other-than-temporary and the \$2.9 million decline was reported as a loss in the statement of operations.

#### *Options Issued in Exchange for License*

In June 2000, in connection with the license from Toray Industries for the sustained release formulation of beraprost (an oral prostacyclin analog), United Therapeutics agreed to grant options to purchase 500,000 shares of common stock to Toray upon Toray's adequate documentation of sustained release beraprost in humans and its transfer of clinical trial material for use in clinical trials in the United States. These options will not be priced until Toray has met this milestone. If and when the milestone is met, the options would be granted at the fair market value of United Therapeutics' common stock at that time. Before Toray can produce the clinical trial material, it will need to complete formulation, preclinical testing and early clinical studies. Due to the uncertainties in drug development, it is not yet known if Toray will provide the appropriate clinical trial material. Therefore, in accordance with EITF Issue No. 96-18, *Accounting for Equity Instruments that are Issued to Other than Employees* , these options are measured at their lowest aggregate fair value at each interim reporting date, which amount has been zero. As a result, no expense related to these options has been recorded in the consolidated financial statements.

#### *Lease of Laboratory Facility*

In June 2004, United Therapeutics entered into a synthetic operating lease and related agreements with Wachovia to fund the construction of a laboratory facility in Silver Spring, Maryland. The total amount of the construction is expected to be \$32.0 million. The laboratory facility will be owned by Wachovia, which will act as the lessor, and United Therapeutics will be the lessee and pay rents to Wachovia once the facility is completed. This arrangement is a form of off-balance sheet financing under which Wachovia will fund 100 percent of the costs for the construction of the property and lease the laboratory facility to United Therapeutics. United Therapeutics has provided a residual value guarantee which guarantees Wachovia that the residual value of the leased assets will be at least equal to a specified amount at lease termination.

In accordance with the guidance in Statement of Financial Accounting Standards No. 13, *Accounting for Leases*, EITF Issue No. 97-1, *Implementation Issues in Accounting for Lease Transactions, Including Those Involving Special-Purpose Entities*, EITF Issue No. 97-10, *The Effect of Lessee Involvement in Asset Construction*, and FASB Interpretation No. 46, *Consolidation of Variable Interest Entities*, United Therapeutics has determined that the lease is properly classified as an operating lease for accounting purposes. Furthermore, United Therapeutics has determined that Wachovia has sufficient substance such that it can be treated as an unrelated entity to United Therapeutics and, accordingly, does not require consolidation into United Therapeutics' financial statements.

Operating leases of assets do not require that the leased asset and the related rent obligation be reported in the lessee's balance sheet, but rather be disclosed. In contrast, capital leases do require that the leased asset and rent obligations be reported in the lessee's balance sheet as assets and debt. Changes in the equity participation by Wachovia and its affiliates under the agreements could affect the classification of the lease from operating to capital. In that event, United Therapeutics would include both the assets and debt associated with the laboratory facility on its balance sheet.

## **Recent Accounting Pronouncements**

### *Stock-Based Compensation*

On December 16, 2004, the Financial Accounting Standards Board (FASB) issued a revision of Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment* (Statement 123(R)), which is a revision of FASB Statement No. 123, *Accounting for Stock-Based Compensation*. Statement 123(R) supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and amends FASB Statement No. 95, *Statement of Cash Flows*. Generally, the approach in Statement 123(R) is similar to the approach described in Statement 123. Statement 123(R) will be adopted by United Therapeutics on July 1, 2005.

As permitted by Statement 123, United Therapeutics currently accounts for share-based payments to employees using Opinion 25's intrinsic value method and, as such, generally recognizes no compensation cost for employee stock options. However, Statement 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values over the expected period of service. Accordingly, the adoption of Statement 123(R)'s fair value method will have a significant impact on our result of operations, although it will have no impact on our overall financial position.

The full impact of adoption of Statement 123(R) cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had United Therapeutics adopted Statement 123(R) in prior periods, the impact of that standard would have approximated the impact of Statement 123 as described in the disclosure of pro forma net income and earnings per share in Note 2 to the consolidated financial statements. Statement 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption. United Therapeutics is unable to estimate what those amounts will be in the future because they depend on, among other things, when employees exercise stock options.

### *Other-than-Temporary Impairment*

In March 2004, the Emerging Issues Task Force (EITF) reached a consensus on Issue No. 03-01, "*The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments*." EITF Issue No. 03-01 provides guidance on other-than-temporary impairment models for marketable debt and equity securities accounted for under SFAS No. 115, "*Accounting for Certain Investments in Debt and Equity Securities*," and SFAS No. 124, "*Accounting for Certain Investments Held by Not-for-Profit Organizations*," and non-marketable equity securities accounted for under the cost method. The EITF developed a basic three-step model to evaluate whether an investment is other-than-temporarily impaired. The effective date of the recognition and measurement provisions of EITF Issue No. 03-01 has been delayed by the FASB. United Therapeutics does not expect the adoption of EITF Issue No. 03-01 to have a significant impact on our results of operations and financial condition.

### *Inventory Costs*

In December 2004, the FASB issued SFAS Statement No. 151 *Inventory Cost*, which is an amendment to Accounting Research Bulletin No. 43, "*Restatement and Revision of Accounting Research Bulletins*". SFAS 151 clarifies the accounting treatment of certain expenses for inventory costing. The new standard will be effective for the first fiscal year beginning after June 15, 2005. United Therapeutics has not yet assessed the impact of adopting this new standard.

## ITEM 7A: QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

At December 31, 2004, a substantial portion of United Therapeutics' assets were comprised of debt securities issued by federally sponsored agencies. The market value of these investments fluctuates with changes in current market interest rates. In general, as rates increase, the market value of a debt investment would be expected to decrease. Likewise, as rates decrease, the market value of a debt investment would be expected to increase. To minimize such market risk, United Therapeutics holds such instruments to maturity at which time these instruments will be redeemed at their stated or face value. At December 31, 2004, United Therapeutics had approximately \$56.2 million in debt securities issued by federally sponsored agencies with a weighted average stated interest rate of approximately 3.6 percent maturing through March 2012 and callable annually. The fair market value of this portfolio at December 31, 2004 was approximately \$55.3 million.

In June 2004, United Therapeutics entered into a synthetic operating lease and related agreements with Wachovia Development Corporation and its affiliates (Wachovia) to fund the construction of a laboratory facility in Silver Spring, Maryland. Under these agreements, United Therapeutics will pay rents to Wachovia generally based on applying the 30-day LIBOR rate plus approximately 55 basis points to the amount funded by Wachovia towards the construction of the laboratory. The total amount of construction is estimated to be approximately \$32.0 million. At December 31, 2004, the total amount incurred related to the construction was approximately \$4.1 million. Rents will be paid monthly from the time that the laboratory construction is completed until the termination of the lease in May 2011. These rents, therefore, are subject to the risk that LIBOR will increase or decrease during the period until termination in May 2011. At December 31, 2004, the 30-day LIBOR was approximately 2.4 percent. For every movement of 100 basis points (1 percent) in the 30-day LIBOR rate, the rents under this lease could increase or decrease by approximately \$320,000 on an annualized basis.

**ITEM 8: FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

**UNITED THERAPEUTICS CORPORATION**

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

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Consolidated Statements of Stockholders' Equity for the years ended December 31, 2004, 2003 and 2002	F-7
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## Report of Independent Registered Public Accounting Firm

The Board of Directors  
United Therapeutics Corporation:

We have audited the accompanying consolidated balance sheet of United Therapeutics Corporation as of December 31, 2004 and 2003, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the two year period ended December 31, 2004. Our audits also included the financial statement schedules listed in the Index at Item 15 (a)(2). These financial statements and schedules are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedules based on our audits.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of United Therapeutics Corporation at December 31, 2004 and 2003, and the consolidated results of their operations and their cash flows for each of the years in the two year period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedules referred to above, when considered in relation to the basic financial statements taken as a whole, present fairly in all material respects the information set forth therein.

We also have audited, in accordance with the Standards of the Public Company Accounting Oversight Board (United States), the effectiveness of United Therapeutics Corporation's internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 18, 2005 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

McLean, Virginia  
February 18, 2005

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**Report of Independent Registered Public Accounting Firm on  
Internal Control over Financial Reporting**

The Board of Directors  
United Therapeutics Corporation:

We have audited management's assessment, included in the accompanying Management's Report on Internal Control Over Financial Reporting, that United Therapeutics Corporation maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). United Therapeutics Corporation's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that United Therapeutics Corporation maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, United Therapeutics Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2004 consolidated financial statements of United Therapeutics Corporation and our report dated February 18, 2005 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

McLean, Virginia  
February 18, 2005

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## Report of Independent Registered Public Accounting Firm

The Board of Directors  
United Therapeutics Corporation:

We have audited the accompanying consolidated statements of operations, stockholders' equity, and cash flows for the year ended December 31, 2002 of United Therapeutics Corporation and subsidiaries (the Company). In connection with our audit, we also have audited the financial statement schedule listed in the Index at Item 15(a)(2). These consolidated financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements and schedule based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the results of operations and cash flows of United Therapeutics Corporation and subsidiaries for the year ended December 31, 2002, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the financial statement schedule referred to above, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

As discussed in note 15 to the consolidated financial statements, effective January 1, 2002, the Company adopted the provisions of SFAS No. 142, *"Goodwill and Other Intangible Assets"*.

/s/ KPMG LLP

McLean, Virginia  
February 28, 2003

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**UNITED THERAPEUTICS CORPORATION**  
**Consolidated Balance Sheets**  
(In thousands, except share and per share data)

	<u>December 31,</u>	
	<u>2004</u>	<u>2003</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 82,586	\$ 68,362
Marketable investments	200	200
Accounts receivable, net of allowance of \$23 for 2004 and \$119 for 2003	13,743	10,151
Interest receivable	499	461
Due from affiliate	524	81
Prepaid expenses	3,230	1,874
Inventories, net	8,014	8,116
Other current assets	<u>1,696</u>	<u>476</u>
Total current assets	110,492	89,721
Marketable investments	46,233	48,775
Marketable investments and cash - restricted	10,121	—
Goodwill, net	7,465	7,465
Other intangible assets, net	5,967	6,446
Property, plant, and equipment, net	17,799	15,225
Investments in affiliates	7,444	7,221
Notes receivable from affiliate and employee	446	1,570
Other assets	<u>1,191</u>	<u>3,079</u>
Total assets	<u>\$ 207,158</u>	<u>\$ 179,502</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 6,098	\$ 4,244
Accounts payable to affiliates and related parties	29	82
Accrued expenses	7,689	5,459
Due to affiliates and related parties	32	1
Current portion of notes and leases payable	16	773
Other current liabilities	<u>—</u>	<u>59</u>
Total current liabilities	13,864	10,618
Notes and leases payable, excluding current portion	10	25
Due to affiliates	—	946
Other liabilities	<u>1,648</u>	<u>148</u>
Total liabilities	<u>15,522</u>	<u>11,737</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, par value \$.01, 10,000,000 shares authorized, no shares issued	—	—
Series A junior participating preferred stock, par value \$ .01, 100,000 authorized, no shares issued	—	—
Common stock, par value \$.01, 100,000,000 shares authorized, 22,955,129 and 21,836,342 shares issued at December 31, 2004 and 2003, respectively, and 22,428,529 and 21,309,742 outstanding at December 31, 2004 and 2003, respectively	229	218
Additional paid-in capital	375,945	368,537
Accumulated other comprehensive income	2,677	1,674
Treasury stock at cost, 526,600 shares	(6,874)	(6,874)
Accumulated deficit	<u>(180,341)</u>	<u>(195,790)</u>
Total stockholders' equity	<u>191,636</u>	<u>167,765</u>
Total liabilities and stockholders' equity	<u>\$ 207,158</u>	<u>\$ 179,502</u>

See accompanying notes to consolidated financial statements.

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**UNITED THERAPEUTICS CORPORATION**  
**Consolidated Statements of Operations**  
(In thousands, except share and per share data)

	For Years Ended December 31,		
	2004	2003	2002
Revenues:			
Net product sales	\$ 69,539	\$ 49,715	\$ 26,677
Service sales	4,051	3,626	3,443
Total revenue	73,590	53,341	30,120
Operating expenses:			
Research and development	30,602	35,417	26,778
Selling, general and administrative	21,529	22,667	15,889
Cost of product sales	6,347	4,994	3,757
Cost of service sales	1,903	1,789	1,699
Total operating expenses	60,381	64,867	48,123
Income (loss) from operations	13,209	(11,526)	(18,003)
Other income (expense):			
Interest income	2,986	2,435	4,954
Interest expense	(4)	(112)	(117)
Equity loss in affiliate	(785)	(953)	(209)
Other, net	43	187	45
Write-down of investment	—	—	(2,893)
Loss on marketable investments	—	—	(7,428)
Total other income (expense)	2,240	1,557	(5,648)
Net income (loss) before income tax	15,449	(9,969)	(23,651)
Income tax	—	—	—
Net income (loss)	<u>\$ 15,449</u>	<u>\$ (9,969)</u>	<u>\$ (23,651)</u>
Net income (loss) per common share – basic	<u>\$ 0.71</u>	<u>\$ (0.47)</u>	<u>\$ (1.15)</u>
Net income (loss) per common share – diluted	<u>\$ 0.66</u>	<u>\$ (0.47)</u>	<u>\$ (1.15)</u>
Weighted average number of common shares outstanding – basic	<u>21,725,871</u>	<u>21,134,607</u>	<u>20,644,308</u>
Weighted average number of common shares outstanding – diluted	<u>23,351,167</u>	<u>21,134,607</u>	<u>20,644,308</u>

See accompanying notes to consolidated financial statements.

**UNITED THERAPEUTICS CORPORATION**  
**Consolidated Statements of Stockholders' Equity**  
(In thousands, except share data)

	Common Stock		Additional	Accumulated	Treasury	Accumulated	Total
	Shares	Amount	Paid-in	Other	Stock	Deficit	
			Capital	Comprehensive			
				Income			
Balance, December 31, 2001	20,751,820	\$ 208	\$365,235	\$ —	\$(6,874)	\$ (162,170)	\$196,399
Net loss	—	—	—	—	—	(23,651)	(23,651)
Foreign currency translation adjustments	—	—	—	8	—	—	8
Total other comprehensive income (loss)	—	—	—	8	—	(23,651)	(23,643)
Options issued in exchange for services	—	—	323	—	—	—	323
Exercise of stock options	28,648	—	244	—	—	—	244
Settlement of escrow items with sellers of Cooke Pharma	669,002	7	(1,672)	—	—	—	(1,665)
Balance, December 31, 2002	21,449,470	215	364,130	8	(6,874)	(185,821)	171,658
Net loss	—	—	—	—	—	(9,969)	(9,969)
Foreign currency translation adjustments	—	—	—	13	—	—	13
Unrealized gain on available-for-sale securities	—	—	—	1,653	—	—	1,653
Total other comprehensive income (loss)	—	—	—	1,666	—	(9,969)	(8,303)
Options issued in exchange for services	—	—	325	—	—	—	325
Exercise of stock options	386,872	3	4,082	—	—	—	4,085
Balance, December 31, 2003	21,836,342	218	368,537	1,674	(6,874)	(195,790)	167,765
Net income	—	—	—	—	—	15,449	15,449
Foreign currency translation adjustments	—	—	—	48	—	—	48
Unrealized gain on available-for-sale securities	—	—	—	955	—	—	955
Total other comprehensive income	—	—	—	1,003	—	15,449	16,452
Options issued in exchange for services	—	—	329	—	—	—	329
Exercise of stock options	526,955	5	7,085	—	—	—	7,090
Settlement of shares due to sellers of Medicomp	591,832	6	(6)	—	—	—	—
Balance, December 31, 2004	<u>22,955,129</u>	<u>\$ 229</u>	<u>\$375,945</u>	<u>\$ 2,677</u>	<u>\$(6,874)</u>	<u>\$ (180,341)</u>	<u>\$191,636</u>

See accompanying notes to consolidated financial statements.

**UNITED THERAPEUTICS CORPORATION**  
**Consolidated Statements of Cash Flows**  
(In thousands)

	Years Ended December 31,		
	<u>2004</u>	<u>2003</u>	<u>2002</u>
Cash flows from operating activities:			
Net income (loss)	\$ 15,449	\$ (9,969)	\$ (23,651)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization	2,381	2,363	2,022
Loss on disposals of equipment	—	108	—
Provisions for bad debt and write downs	37	425	68
Stock and options issued in exchange for services	329	325	323
Write-down of investment	—	—	2,893
Provisions for inventory obsolescence and write downs	487	325	477
Amortization of premiums and discounts on marketable investments	(105)	(38)	1,113
Loss on sales of marketable investments	—	—	7,428
Equity loss in affiliate	785	953	209
Changes in operating assets and liabilities:			
Accounts receivable	(3,630)	(927)	(8,267)
Interest receivable	(38)	(451)	2,763
Inventories	(385)	(1,202)	(1,867)
Prepaid expenses	(1,356)	(639)	(318)
Other current assets	(1,221)	668	(1,023)
Other noncurrent assets	2,781	(2,556)	(1,506)
Due from affiliate	680	(81)	(433)
Accounts payable	1,854	1,338	(3,361)
Accrued expenses	2,230	1,007	997
Due to affiliate and related parties	(21)	(206)	(112)
Other liabilities	521	(5)	(13)
Net cash provided by (used in) operating activities	<u>20,778</u>	<u>(8,562)</u>	<u>(22,258)</u>
Cash flows from investing activities:			
Purchases of property, plant and equipment	(5,217)	(7,004)	(3,581)
Proceeds from disposals of property, plant and equipment	821	336	1
Investment in Northern Therapeutics, Inc.	(1,000)	(2,500)	(500)
Investment in AltaRex Medical Corp.	—	—	(4,914)
Acquisition of patent rights	—	(300)	—
Purchases of marketable investments and short-term investments	(37,474)	(44,911)	(11,218)
Sales and maturities of marketable investments	<u>30,000</u>	<u>6,641</u>	<u>140,567</u>
Net cash provided by (used in) investing activities	<u>(12,870)</u>	<u>(47,738)</u>	<u>120,355</u>
Cash flows from financing activities:			
Proceeds from exercise of stock options	7,090	4,085	245
Payments of principal on notes payable	(750)	(1,982)	(22)
Principal payments under capital lease obligations	<u>(24)</u>	<u>(96)</u>	<u>(38)</u>
Net cash provided by financing activities	<u>6,316</u>	<u>2,007</u>	<u>185</u>
Net increase (decrease) in cash and cash equivalents	14,224	(54,293)	98,282
Cash and cash equivalents, beginning of year	<u>68,362</u>	<u>122,655</u>	<u>24,373</u>
Cash and cash equivalents, end of year	<u>\$ 82,586</u>	<u>\$ 68,362</u>	<u>\$122,655</u>
Supplemental schedule of noncash investing and financing activities:			
Notes payable issued for building and land	<u>\$ —</u>	<u>\$ 974</u>	<u>\$ —</u>
Supplemental cash flow information — cash paid for interest	<u>\$ 2</u>	<u>\$ 87</u>	<u>\$ 129</u>

See accompanying notes to consolidated financial statements.



# UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements — (Continued)

### 1. Organization and Business Description

United Therapeutics Corporation (United Therapeutics) is a biotechnology company focused on the development and commercialization of unique products for patients with chronic and life-threatening cardiovascular, cancer and infectious diseases. United Therapeutics was incorporated on June 26, 1996 under the laws of the State of Delaware and has the following wholly owned subsidiaries: Lung Rx, Inc., Unither Pharmaceuticals, Inc. (UPI), Unither Telemedicine Services Corp. (UTSC), Unither.com, Inc., United Therapeutics Europe, Ltd., Unither Pharma, Inc., Medicomp, Inc., Unither Nutraceuticals, Inc. and Lung Rx, Ltd.

United Therapeutics' lead product is Remodulin®. On May 21, 2002, the United States Food and Drug Administration (FDA) approved Remodulin (treprostinil sodium) Injection for the treatment of pulmonary arterial hypertension in patients with NYHA class II-IV symptoms to diminish symptoms associated with exercise. United Therapeutics was required by the FDA to perform a post-marketing Phase IV clinical study to further assess the clinical benefits of Remodulin. Continued FDA approval of Remodulin is subject to the diligent and timely completion of the Phase IV trial, as well as its outcome. International applications for the approval of Remodulin are pending.

United Therapeutics has generated pharmaceutical revenues from sales of Remodulin and arginine products in the United States, Europe and Asia. In addition, United Therapeutics has generated non-pharmaceutical revenues from telemedicine products and services in the United States.

### 2. Summary of Significant Accounting Policies

#### *Principles of Consolidation*

The consolidated financial statements include the financial statements of United Therapeutics Corporation and its wholly owned subsidiaries. All significant intercompany balances and transactions are eliminated in consolidation.

#### *Cash Equivalents*

Cash equivalents consist of highly liquid investments with original maturities of three months or less. Cash equivalents consist of money market funds, commercial paper, and certificates of deposit and amount to approximately \$82.6 million and \$68.4 million at December 31, 2004 and 2003, respectively. At December 31, 2004 and 2003, approximately \$1.5 million and none, respectively, was held by a bank as a compensating balance in order to reduce fees charged by the bank. However, the agreement with the bank does not restrict United Therapeutics' ability to withdraw such balances.

#### *Inventories*

United Therapeutics manufactures certain compounds and purchases medical supplies for use in its product sales and ongoing clinical trials. United Therapeutics subcontracts the manufacture of cardiac monitoring equipment. United Therapeutics contracts with a third party manufacturer to make the HeartBar® and related products. These inventories are accounted for under the first-in, first-out method and are carried at the lower of cost or market. At December 31, 2004 and 2003, inventories consisted of the following, net of reserves of approximately \$447,000 and \$321,000 at December 31, 2004 and 2003, respectively (in thousands):

	December 31,	
	2004	2003
Remodulin:		
Raw materials	\$ 553	\$ 172
Work in progress	5,428	4,971
Finished goods	960	921
Remodulin delivery pumps and medical supplies	804	1,544
Cardiac monitoring equipment components	—	211
HeartBar and related product lines	269	297
Total inventories	<u>\$ 8,014</u>	<u>\$ 8,116</u>



# UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements — (Continued)

### *Property, Plant and Equipment*

Property, plant and equipment are stated at cost. Depreciation of assets placed in service is computed using the straight-line method over the estimated useful lives of the assets. Estimated useful lives of the assets are as follows:

Buildings	39 years
Building improvements	15-39 years
Furniture, equipment and vehicle	3-15 years
Holter and event cardiac monitoring systems	5 years
Leasehold improvements	Life of the lease or asset, whichever is shorter

Property, plant and equipment consisted of the following (in thousands):

	December 31,	
	2004	2003
Land	\$ 4,477	\$ 1,375
Buildings, building improvements and leasehold improvements	9,116	8,790
Buildings under construction	412	—
Holter and event cardiac monitoring systems	3,307	2,836
Furniture, equipment and vehicle	<u>6,160</u>	<u>6,004</u>
	23,472	19,005
Less — accumulated depreciation	<u>(5,673)</u>	<u>(3,780)</u>
Property, plant and equipment, net	<u>\$17,799</u>	<u>\$15,225</u>

Buildings under construction are for projects unrelated to the construction of the laboratory discussed in Note 9.

In November 2003, United Therapeutics agreed to purchase a lot adjacent to its headquarters for approximately \$2.9 million to be used to construct a new laboratory facility. At December 31, 2003, approximately \$2.8 million was held in an escrow account pending settlement on the acquisition of the lot. This escrow was included in non-current other assets in the accompanying consolidated balance sheet at December 31, 2003. In June 2004, settlement occurred and approximately \$2.9 million was paid from escrow and cash.

### *Research and Development*

Research and product development costs are expensed as incurred. Research and development expenses consist primarily of salaries and related expenses, costs to acquire pharmaceutical products and product rights for development and amounts paid to contract research organizations, hospitals and laboratories for the provision of services and materials for drug development and clinical trials. Acquired in-process research and development is expensed if technological feasibility has not been demonstrated and there is no alternative use for the in-process technology.

Costs incurred in obtaining the license rights to technology in the research and development stage and that have no alternative future uses are expensed as incurred and in accordance with the specific contractual terms of the applicable license agreements.

### *Income Taxes*

Income taxes are accounted for in accordance with SFAS No. 109, *Accounting for Income Taxes*. Under the asset and liability method of SFAS No. 109, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using the tax rates and laws that are expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Valuation allowances are provided against deferred tax assets, including those arising from net operating loss carry forwards, if it is anticipated that some or the entire asset may not be realized through future taxable income. United Therapeutics assesses the likelihood that the deferred tax assets will be recovered from future taxable income and to the extent it believes that recovery is not likely, it establishes a valuation allowance. To the extent United Therapeutics establishes a valuation allowance or changes it in a given period, an income tax expense or benefit (i.e. reduction of expense) is recognized in the statement of operations.

### *Marketable Investments*

United Therapeutics' marketable investments are considered held-to-maturity securities. Held-to-maturity securities are those securities

which United Therapeutics has the ability and intent to hold until maturity and are recorded at amortized cost, adjusted for the amortization or accretion of premiums or discounts. Premiums and discounts are amortized or accreted over the life of the related held-to-maturity security as an adjustment to yield using the effective interest method. Declines in market values below amortized cost that are considered other-than-temporary are reported in the statement of operations as losses.

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# UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements — (Continued)

### Goodwill and Other Intangible Assets

Goodwill represents the excess of purchase price and related costs over the value assigned to the net tangible and intangible assets of the business acquired. Goodwill resulting from the purchase of SynQuest, Inc. was amortized using the straight-line method over five years. Goodwill resulting from the purchase of Medicomp was amortized using the straight-line method over twenty years. United Therapeutics ceased amortizing goodwill upon the adoption of SFAS No. 142, *Goodwill and Other Intangible Assets*, on January 1, 2002. Other intangible assets resulting from these purchases relate to covenants not to compete, employment agreements, technology, patents, and trade names and were determined on the basis of independent valuations. The other intangibles are being amortized over three to eighteen years, consistent with the terms of the underlying agreements.

Goodwill is tested for impairment in October of each year. Intangible assets subject to amortization are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The measurement of possible impairment is based primarily on the ability to recover the balance of the goodwill and other intangible assets from expected future operating cash flows on an undiscounted basis. Impairment losses are recognized when expected future cash flows are estimated to be less than the asset's carrying value. In management's opinion, no impairment exists at December 31, 2004.

Goodwill and other intangible assets were comprised as follows (in thousands):

	As of December 31, 2004			As of December 31, 2003		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Goodwill	<u>\$ 9,072</u>	<u>\$ (1,607)</u>	<u>\$ 7,465</u>	<u>\$ 9,072</u>	<u>\$ (1,607)</u>	<u>\$ 7,465</u>
Intangible assets:						
Noncompete agreements	\$ 273	\$ (273)	\$ —	\$ 273	\$ (273)	\$ —
Trademarks	2,802	(984)	1,818	2,802	(738)	2,064
Technology and patents	6,164	(2,015)	4,149	6,164	(1,782)	4,382
Total intangible assets	<u>\$ 9,239</u>	<u>\$ (3,272)</u>	<u>\$ 5,967</u>	<u>\$ 9,239</u>	<u>\$ (2,793)</u>	<u>\$ 6,446</u>

Total amortization expense for the years ended December 31, 2004, 2003 and 2002 was approximately \$479,000, \$855,000, and \$899,000, respectively. As of December 31, 2004, the aggregate amortization expense related to these intangible assets for each of the five succeeding years is estimated as follows (in thousands):

Year ending December 31,	
2005	\$479
2006	479
2007	432
2008	432
2009	432

### Investments in Affiliates

The investments in affiliates represent United Therapeutics' investments in Northern Therapeutics, Inc. and ViRexx Medical Corp. (formerly AltaRex Medical Corp.). The investment in Northern Therapeutics is being accounted for on the equity method of accounting which requires United Therapeutics to report its share of the affiliates' net losses or profits in its financial statements, but does not require that assets, liabilities, revenues and expenses of the affiliates be consolidated with United Therapeutics' consolidated financial statements. United Therapeutics owns approximately 68 percent of Northern Therapeutics, but only holds 49.9 percent of the voting shares. The equity method is used because the minority shareholders of Northern Therapeutics possess substantive participating rights as defined by EITF Issue No. 96-16, *Investors Accounting for an Investee when the Investor Has a Majority of the Voting Interest but the Minority Shareholders or Shareholders Have Certain Approval or Veto Rights*.

The investment in ViRexx is being accounted for as an available-for-sale security as ViRexx is a publicly traded company. Available-for-sale securities are reported at their fair values in the balance sheet. Changes in their fair values are

## UNITED THERAPEUTICS CORPORATION

### Notes to Consolidated Financial Statements — (Continued)

reported as other comprehensive income or loss. Declines in values that are considered other-than-temporary are reported as losses in the statement of operations. United Therapeutics owns approximately 8.6 percent of ViRexx.

During 2002, the quoted market price of AltaRex's (now ViRexx) common stock was consistently less than cost. This was determined to be an other-than-temporary decline in value. As a result, the investment in AltaRex was written down to its fair value of approximately \$2.0 million as determined by quoted market prices at September 30, 2002. The write-down totaled approximately \$2.9 million. At December 31, 2004 and 2003, the investment in ViRexx's common stock was reported at its fair market value of approximately \$4.6 and \$3.7 million, respectively, and is classified with investments in affiliates. The unrealized gain at December 31, 2004 and 2003 was approximately \$2.6 million and \$1.7 million, respectively, as compared to the adjusted basis of approximately \$2.0 million.

#### *Fair Value of Financial Instruments*

The carrying amounts of cash and cash equivalents, accounts receivables, accounts payable, and accrued expenses, approximate fair value due to their short maturities. The carrying value of marketable investments approximated its fair value based on quoted market prices. The fair values of notes and leases payable approximate their carrying values based on notes that are currently available to United Therapeutics for obligations with similar terms and maturities.

#### *Earnings (Loss) per Common Share*

Basic earnings (loss) per common share are computed by dividing net income or (loss) by the weighted average number of shares of common stock outstanding during the respective periods. Diluted earnings (loss) per common share is computed by dividing net income by the weighted average number of shares of common stock outstanding during the period plus the effects of outstanding stock options that could potentially dilute earnings per share in the future. The effects of potentially dilutive stock options were calculated using the treasury stock method. The effects of outstanding stock options were not included in the computation of diluted loss per share in 2003 and 2002 because to do so would have been antidilutive for the periods presented. As of December 31, 2003 and 2002, those options totaled approximately 998,000 and 201,000 shares, respectively. The components of basic and dilutive earnings (loss) per share are as follows (in thousands, except per share amounts):

	Years ended December 31,		
	2004	2003	2002
Net income (loss) (Numerator)	\$ 15,449	\$ (9,969)	\$ (23,651)
Shares (Denominator):			
Weighted average outstanding shares for basic EPS	21,726	21,135	20,644
Dilutive effect of stock options	1,625	—	—
Adjusted weighted average shares for diluted EPS	<u>23,351</u>	<u>21,135</u>	<u>20,644</u>
Earnings (loss) per share			
Basic	\$ 0.71	\$ (0.47)	\$ (1.15)
Diluted	<u>\$ 0.66</u>	<u>\$ (0.47)</u>	<u>\$ (1.15)</u>

#### *Use of Estimates*

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements. Estimates also affect the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

#### *Stock Option Plan*

United Therapeutics accounts for its stock-based compensation under the intrinsic value method in accordance with the provisions of APB No. 25, *Accounting for Stock Issued to Employees*, and has provided the pro forma disclosures of net income (loss) and net income (loss) per share in accordance with SFAS No. 123, *Accounting for Stock-Based Compensation*, using the fair value method. Under APB No. 25, compensation expense for stock options granted to employees is based on the difference, if any, on the date of the grant between the fair value of United Therapeutics' stock and the exercise price of the option and is recognized ratably over the vesting period of the option. United Therapeutics accounts for equity instruments issued to consultants in accordance with SFAS No. 123 and Emerging Issues Task Force Issue No. 96-18, *Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunction with Selling Goods or Services*.



## UNITED THERAPEUTICS CORPORATION

### Notes to Consolidated Financial Statements — (Continued)

In accordance with SFAS No. 148, *Accounting for Stock-Based Compensation — Transition and Disclosure*, the effect on net income (loss) and net income (loss) per share if United Therapeutics had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation is as follows (in thousands, except per share amounts):

	Years ended December 31,		
	2004	2003	2002
Net income (loss), as reported	\$ 15,449	\$ (9,969)	\$(23,651)
Less total stock-based employee compensation expense determined under fair value based method for all awards	<u>(8,072)</u>	<u>(12,964)</u>	<u>(18,082)</u>
Pro forma net income (loss)	<u>\$ 7,377</u>	<u>\$(22,933)</u>	<u>\$(41,733)</u>
Basic net income (loss) per common share:			
As reported	<u>\$ 0.71</u>	<u>\$ (0.47)</u>	<u>\$ (1.15)</u>
Pro forma	<u>\$ 0.34</u>	<u>\$ (1.09)</u>	<u>\$ (2.02)</u>
Diluted net income (loss) per common share:			
As reported	<u>\$ 0.66</u>	<u>\$ (0.47)</u>	<u>\$ (1.15)</u>
Pro forma	<u>\$ 0.32</u>	<u>\$ (1.09)</u>	<u>\$ (2.02)</u>

The effect of applying SFAS No. 123 on 2004, 2003 and 2002 pro forma net income (loss) and net income (loss) per share as stated above, is not necessarily representative of the effects on reported net income (loss) for future years due to, among other things, the vesting period of the stock options and the fair value of additional stock options that may be granted in future years.

As discussed in Note 16, the Financial Accounting Standards Board has issued a revision to SFAS No. 123 which will become effective beginning July 1, 2005. The revision will have significant impacts on the accounting and disclosure of employee stock options and future operating results.

### **Revenues**

Revenues are recognized in the financial statements only when considered realizable and earned.

Product sales of Remodulin are recognized when delivered to distributors, which are United Therapeutics' customers for Remodulin. Product sales of Remodulin delivery pumps and related supplies are recognized when delivered to distributors on a gross basis in accordance with EITF Issue No. 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent*. Title to these products passes upon delivery. Prompt payment discounts and government rebates are estimated and recognized as reductions of revenue in the same period that revenues are recognized. Return policies provide that product that has expired or become damaged in shipment may be replaced, but not returned.

Service sales from cardiac monitoring analysis services are recognized when the services are performed.

Product sales of cardiac monitoring systems are recognized when delivered to customers and installed.

Product sales from the HeartBar and a related product line are recognized when delivered to customers. If the products are consigned, sales are recognized in the period that the consignee has sold the product. Product sales are recorded net of allowances for estimated returns and rebates.

### **Trade Receivables**

Trade receivables that are deemed collectible and will be held until payment is received are reported in the consolidated balance sheets at the outstanding amounts less an allowance for doubtful accounts. United Therapeutics writes off uncollectible receivables when the likelihood of collection is remote.

### **Treasury Stock**

Treasury stock is reported at cost, including commissions and fees.



## UNITED THERAPEUTICS CORPORATION

### Notes to Consolidated Financial Statements — (Continued)

#### *Employee Health Insurance*

On July 1, 2003, United Therapeutics became self-insured for health insurance claims up to \$60,000 annually per individual and an annual aggregate amount which approximated \$1.5 million at December 31, 2004. United Therapeutics maintains a commercial insurance policy for claims liabilities exceeding these limits. Liabilities of approximately \$591,000 and \$510,000 at December 31, 2004 and 2003, respectively, have been established for known claims and an estimated amount for claims incurred but not yet reported. These amounts are reported as accrued expenses in the accompanying consolidated balance sheets.

#### *Advertising Costs*

Advertising costs are expensed when incurred. Advertising costs expensed during the years ended December 31, 2004, 2003 and 2002 were approximately \$174,000, \$526,000, and \$92,000, respectively.

#### *Reclassifications*

Certain amounts in the 2003 consolidated financial statements were reclassified to conform to the 2004 presentation.

### **3. Related Party Transactions**

#### *Office Leases*

During 2002, a subsidiary of United Therapeutics leased office space from Beacon Projects, Inc., a company owned by the Chairman and CEO of United Therapeutics. During 2002, the total amount paid to Beacon Projects was approximately \$57,000 under this lease.

#### *Research Agreement*

During 1998, United Therapeutics entered into a cooperative drug discovery agreement with William Harvey Research Limited (WHR). The Chairman and CEO of United Therapeutics is an unpaid volunteer President of William Harvey Medical Research Foundation. Payments made to WHR were approximately \$102,000 for the year ended December 31, 2002. This agreement was terminated in June 2002.

#### *Receivable from Employees*

At December 31, 2004 and 2003, United Therapeutics had approximately \$446,000 and \$1,137,000, respectively, in interest and non-interest bearing advances totaling due from employees. The advances are classified as notes receivable from affiliate and employee in the accompanying consolidated balance sheets.

In April 2002, United Therapeutics agreed to loan \$1.3 million to Dr. Roger Jeffs, its President and Chief Operating Officer, to purchase his primary residence. The loan and accrued interest will be due at the end of five years or earlier, in part or in full, if Dr. Jeffs obtains a mortgage on the property, exercises and sells any United Therapeutics stock options, sells any United Therapeutics stock, or sells the property. Interest of 6.5 percent per year accrues on the note. The loan is secured by the property and all United Therapeutics stock that Dr. Jeffs now owns or hereafter acquires. The note receivable and accrued interest are classified as noncurrent assets in the accompanying balance sheets. The Audit Committee and the Compensation Committee of the Board of Directors, as well as the full Board of Directors, approved this transaction. In June 2002, Dr. Jeffs was elected to the Board of Directors by United Therapeutics' shareholders. During the years ended December 31, 2004 and 2003, Dr. Jeffs paid approximately \$749,000 and \$303,000 of outstanding interest and principal on the note, respectively. At December 31, 2004 and 2003, the amount due from Dr. Jeffs was approximately \$445,000 and \$1,137,000, respectively.

#### *Iminosugar Program*

United Therapeutics reported expenses of approximately none, none and \$200,000 to Synergy Pharmaceuticals, Inc. during the years ended December 31, 2004, 2003 and 2002, respectively, for contract research services. From March 2000 until March 2003, United Therapeutics owned approximately 15 percent of Synergy.



## UNITED THERAPEUTICS CORPORATION

### Notes to Consolidated Financial Statements — (Continued)

#### *Marketing and Consulting Agreements*

In February 2003, United Therapeutics entered into an agreement for the development, hosting and maintenance of its website [www.Remodulin.com](http://www.Remodulin.com) with The Medical Learning Company, Inc., a company controlled by Raymond Kurzweil who is one of three non-independent directors on United Therapeutics' eight-person Board of Directors. The Medical Learning Company, Inc., is a joint venture with the American Board of Family Practice, the second largest medical specialty board in the United States, and has extensive experience in the design, development and maintenance of Internet-based information resources for physicians. Pursuant to this Agreement, United Therapeutics will pay The Medical Learning Company \$29,000 and a continuing payment of \$2,000 per month for posting new information to and maintenance of the website. In 2004 and 2003, United Therapeutics incurred approximately \$22,000 and \$29,000, respectively under this agreement.

In September 2002, United Therapeutics entered into a technical services agreement with Kurzweil Technologies, Inc. ("KTI"), a company controlled by Raymond Kurzweil. Pursuant to this agreement, United Therapeutics will pay KTI up to \$40,000 monthly for consulting fees and up to \$1,000 monthly for reimbursement of expenses for certain telemedicine technology development services. In addition, United Therapeutics will pay KTI a five percent royalty on certain sales of products reasonably attributed to and dependent upon technology developed by KTI under the technical services agreement and which are covered by claims of an issued and unexpired United States patent(s). The agreement may be terminated by United Therapeutics upon 30 days advance notice to KTI and by KTI upon 180 days advance notice to United Therapeutics. During the years ended December 31, 2004, 2003 and 2002 United Therapeutics incurred approximately \$520,000, and \$484,000 and \$190,000, respectively, of fees and expenses related to this agreement, of which approximately \$30,000 and \$80,000 were payable to KTI at December 31, 2004 and 2003, respectively.

United Therapeutics entered into an agreement in 2002 with Raymond Kurzweil to provide strategic consulting services in the field of telemedicine. The value of the agreement is \$10,000 annually. In 2002, United Therapeutics entered into an agreement with a company affiliated with Raymond Kurzweil with a total value of \$15,000. United Therapeutics paid a total of \$15,000, \$30,000 and \$25,000 under these agreements during the years ended December 31, 2004, 2003 and 2002, respectively.

#### **4. License Agreements**

##### *Glaxo Wellcome Assignment*

In January 1997, Glaxo Wellcome Inc. (now GlaxoSmithKline PLC) assigned to United Therapeutics patents and patent applications for the use of the stable prostacyclin analog UT-15 (now known as Remodulin) for the treatment of pulmonary hypertension and congestive heart failure. Glaxo Wellcome has a right to negotiate a license from United Therapeutics if United Therapeutics decides to license any part of the marketing rights to a third party. Glaxo Wellcome waived this right with respect to the agreement with MiniMed described below. Under the agreement, Glaxo Wellcome is entitled to certain royalties on sales exceeding a specified threshold from United Therapeutics for a period of ten years from the date of the first commercial sale of any product containing Remodulin. If United Therapeutics grants to a third party any license to Remodulin, Glaxo Wellcome is also entitled to a percentage of all consideration payable to United Therapeutics by such licensee. United Therapeutics is responsible for all patent prosecution and maintenance for Remodulin.

##### *Pharmacia License*

In December 1996, the Pharmacia & Upjohn Company (now Pfizer, Inc.) exclusively licensed to United Therapeutics patents and a patent application for the composition and production of a prostacyclin analog. The Pharmacia agreement required milestone payments of up to \$325,000 for orphan indications of a prostacyclin analog manufactured utilizing technology licensed from Pharmacia and royalties between 2.5% (in the United States) and 5% (in certain other countries) of all net sales, subject to certain offsets, until the later of the expiration of the applicable patent or ten years after the date of the first commercial sale of a product in a country defined as a milestone country under the agreement. In October 2002, United Therapeutics and Pharmacia amended the license agreement to change the royalties to Pharmacia to 4% on annual net sales of Remodulin in excess of \$25.0 million. This 4% royalty is subject to a 50% reduction for royalties due to other parties. Under the amended license agreement, Pharmacia is entitled to these royalties from United Therapeutics for a period of ten years from date of the first commercial sale in the applicable country of any product containing Remodulin.

## UNITED THERAPEUTICS CORPORATION

### Notes to Consolidated Financial Statements — (Continued)

#### *Medtronic MiniMed*

United Therapeutics entered into an agreement with MiniMed (now Medtronic MiniMed) in September 1997 to collaborate in the design, development, and implementation of therapies to treat pulmonary hypertension and peripheral vascular disease utilizing MiniMed products with subcutaneous Remodulin. The term of the agreement is for seven years following the May 2002 FDA approval for Remodulin and will be automatically extended for additional 12-month periods unless otherwise terminated. The agreement is subject to early termination in the event of a material breach or bankruptcy of either party. The guidelines implementing the agreement provide that United Therapeutics will purchase subcutaneous infusion pumps and supplies from Medtronic MiniMed at a discount off of Medtronic MiniMed's list prices from time to time. In the event that there are any discoveries or improvements arising out of work performed under the agreement, the parties will have joint ownership of those discoveries or improvements. The guidelines require United Therapeutics and its distributors to purchase its subcutaneous Remodulin infusion pumps exclusively from Medtronic MiniMed unless Medtronic MiniMed's infusion pumps fail to receive certain government approvals or cannot be appropriately used.

#### *Toray Industries Licenses*

In June 2000, United Therapeutics entered into an agreement with Toray Industries, Inc. obtaining the exclusive right to develop and market sustained release formulations of beraprost in the United States and Canada for the treatment of all vascular indications (including cardiovascular indications). In exchange, United Therapeutics paid Toray \$1.0 million in cash and issued 200,000 shares of common stock valued at approximately \$18.8 million. In addition, United Therapeutics agreed to grant Toray an option to purchase 500,000 shares of common stock upon Toray's adequate documentation of sustained released beraprost in humans and its delivery of clinical trial material with an exercise price based on the average of closing market prices during the month preceding delivery of clinical trial material. Such documentation and delivery has not yet occurred. The sustained release formulation of beraprost is currently in Phase I testing in Japan by Toray. However, the development has been significantly delayed by Toray and United Therapeutics may cancel this agreement prior to granting any options. United Therapeutics also agreed to pay Toray milestone payments of up to \$750,000.

#### *Synergy Pharmaceuticals, Inc.*

In March 2000, UPI entered into a license agreement with Synergy Pharmaceuticals, Inc. (Synergy) to obtain from Synergy the exclusive worldwide rights to certain patents relating to antiviral iminosugar compounds. The iminosugar agreement conditionally required that UPI pay Synergy milestone payments of up to \$22.2 million for each FDA-approved product plus royalties ranging from 6 percent to 12.25 percent, subject to reductions, based on net sales. Additionally, UPI acquired 15 percent of the outstanding stock of Synergy for a total of \$5.0 million.

In March 2003, UPI and Synergy entered into an Assignment and Assumption Agreement and a Redemption and Termination Agreement (together referred to as the Agreements). Under the Agreements, UPI paid approximately \$535,000 to Synergy and assumed responsibility for payment of up to \$190,000 of certain expenses incurred by Synergy. These payments and liabilities totaling \$725,000 were expensed as research and development in 2003 because the licensed agents were in early development and had no alternative future uses. UPI also agreed to the redemption of all the stock it owned in Synergy and the cancellation of all warrants held by UPI to purchase Synergy stock. In return, Synergy assigned to UPI all of its intellectual property rights in the glycobiology antiviral agents and exclusively sublicensed to UPI all of the intellectual property rights that had been licensed to it by third parties, the prosecution and maintenance of which are now the responsibility of UPI. Synergy also released United Therapeutics from all milestone and royalty obligations that would have become due should a product be successfully developed.

#### *Stanford University and New York Medical College*

Unither Pharma, Inc. has exclusively licensed patents related to arginine-based dietary supplements to enhance the level of naturally occurring nitric oxide in the vascular system from Stanford University and New York Medical College. The licenses cover worldwide territories and are valid for the life of the patents. In return, Unither Pharma, Inc. has agreed to pay royalties equal to one percent of net sales of amino acid based products to each licensor respectively, subject to reductions. Minimum annual royalties of \$10,000 are due to each licensor.

#### *ViRexx Medical Corp.*

In April 2002, UPI acquired an option to develop and commercialize a platform of five immunotherapeutic monoclonal antibodies from AltaRex Corp. (now known as AltaRex Medical Corp. and currently a wholly owned subsidiary

## UNITED THERAPEUTICS CORPORATION

### Notes to Consolidated Financial Statements — (Continued)

of ViRexx Medical Corp.) through an agreement to exclusively license certain intellectual property from AltaRex. These products were being developed by AltaRex for use in ovarian, prostate, lung, breast, multiple myeloma and other forms of cancer. UPI will bear the cost of the necessary research and development and has full commercialization rights in all countries other than those in Europe and most of the Middle East. UPI has agreed to pay AltaRex certain amounts based upon the achievement of specified milestones together with royalties based upon sales of products utilizing or incorporating the licensed technology.

In August 2003, the exclusive license was amended to include the commercialization rights in Germany in exchange for a payment to AltaRex of \$250,000 and payment of additional amounts based upon the achievement of certain specified milestones related to the German market. The payment of the \$250,000 license fee was expensed as research and development expense in 2003 because the licensed agents are in clinical development and have no alternative future uses.

As part of the April 2002 transactions, UPI acquired approximately 9.95 percent of the outstanding stock of AltaRex for \$2.5 million and an additional approximately 9.95 percent of the outstanding stock of AltaRex in August 2002 for approximately \$2.1 million. On December 13, 2004, AltaRex was acquired by ViRexx Medical Corp. in an all stock transaction which resulted in AltaRex operating as a wholly owned subsidiary of ViRexx. For every two shares of AltaRex stock, one share of ViRexx stock was received. UPI's ownership in ViRexx at December 31, 2004 and its ownership in AltaRex at December 31, 2003 was approximately 8.6 percent and 17.6 percent, respectively. This investment is being accounted for as an available-for-sale security and is classified with investments in affiliates in the accompanying balance sheets.

Also in August 2002, UPI loaned to AltaRex approximately \$433,000 as a secured convertible debenture due in August 2005 with interest of six percent due quarterly. The note was convertible into AltaRex common stock at a price of \$0.50 per share at any time by UPI. Upon the merger of AltaRex with ViRexx, the note is convertible into ViRexx common stock at a price of \$1.00 per share at any time by UPI.

At December 31, 2004, the closing price of ViRexx' common stock was approximately \$1.01 per share. At December 31, 2003, the closing price of AltaRex' common stock was approximately \$0.40 per share. The note is secured by all intellectual property owned by AltaRex, including intellectual property licensed to UPI by AltaRex.

## 5. Commitments

### *Oxford University*

UPI agreed to fund research conducted by the University of Oxford to develop analogs of the antiviral compounds licensed from Synergy Pharmaceuticals. The research agreement provided for payments of up to approximately \$1.1 million over two years and had an initial term expiring in September 2002 that was renewed until September 2006. Under the agreement, UPI is required to fund the research and pay to the University of Oxford milestone payments for successfully completed clinical trials, and a royalty equal to a percentage of net sales that UPI earns from discoveries and products developed by the University of Oxford. The milestone payments and royalties are subject to reduction depending upon third-party contributions to inventions and/or third party licenses necessary to develop products.

### *Milestone and Royalty Payments*

United Therapeutics has licensed certain products from other companies under license agreements described in Note 4. These agreements generally include milestone payments to be paid in cash by United Therapeutics upon the achievement of certain product development and commercialization goals set forth in each license agreement.

Total milestone payments under these license agreements are expected to come due approximately as follows (in thousands):

## UNITED THERAPEUTICS CORPORATION

### Notes to Consolidated Financial Statements — (Continued)

Year ending December 31,	
2005	\$ 20
2006	20
2007	1,645
2008	3,020
2009 and thereafter	5,060

Additionally, certain agreements described in Note 4 require United Therapeutics to pay royalties. The royalties are generally based on a percentage of net sales or other product fees earned by United Therapeutics. Royalties will become due when sales are generated and will range from 1.0 to 10.0 percent of net product revenues as defined in the respective agreements.

#### 6. Concentrations Of Credit Risk, Suppliers, Products, Revenues and Customers

Financial instruments, which potentially subject United Therapeutics to credit risk, consist primarily of cash, money market funds, commercial paper, marketable investments, and trade receivables. United Therapeutics maintains its cash and money market funds with major financial institutions. The amounts deposited with these institutions exceed the Federal Deposit Insurance Corporation insurance limits. United Therapeutics has not experienced any losses on such bank accounts. United Therapeutics' commercial paper and marketable investments have been issued by companies with high credit ratings or by federally sponsored agencies. At December 31, 2004, trade receivables are due primarily from two customers in the pharmaceutical segment.

If these financial institutions, issuing companies, federal agencies or customers failed to perform their obligations under the terms of these financial instruments, the maximum amount of loss resulting from these credit risks would be approximately equal to the amounts reported in the consolidated balance sheets for cash and cash equivalents, marketable investments, accounts receivable and interest receivable.

United Therapeutics currently relies on a single supplier for stability studies on Remodulin and to analyze other products, and on a single supplier for the delivery device to administer subcutaneous Remodulin to patients. Additionally, Remodulin is formulated, packaged and warehoused by a single formulator. United Therapeutics also relies on a single supplier to produce clinical trial supplies for OvaRex. Although there are a limited number of companies that could replace each of these suppliers, management believes that other suppliers could provide similar services and materials. A change in suppliers, however, could cause a delay in distribution of Remodulin and in the conduct of clinical trials and commercial launch for products in development, which would adversely affect United Therapeutics' research and development efforts and future sales efforts.

During 2004, Remodulin drug sales accounted for approximately 90% of total revenues. Upon FDA approval in 2002, United Therapeutics was required by the FDA to perform a post-marketing Phase IV clinical study to further assess the clinical benefits of Remodulin. Continued FDA approval of Remodulin is subject to the diligent and timely completion of the Phase IV trial, as well as its outcome. The Phase IV clinical trial was required to be one-half enrolled by June 2004 and must be fully enrolled by June 2005; however, the FDA has permitted an interim assessment and opportunity to terminate the Phase IV study after only 21 patients have completed the study. The final study report is required to be submitted in December 2005. To date, only 15 patients have been enrolled in this 39-patient Phase IV trial. Enrolling patients in this study is difficult, in part because it involves randomizing some of the patients to placebo despite the fact that approved drugs are available for these patients.

United Therapeutics is not currently enrolling the Phase IV trial within the time frame specified by the FDA, and therefore is at risk of the FDA at any time instituting a public hearing to withdraw marketing approval for Remodulin. United Therapeutics is in discussions with the FDA about its due diligence in enrolling the Phase IV trial and has made a proposal which United Therapeutics believes will ensure that it is able to provide interpretable results of this trial by the December 2005 final study report delivery deadline. Specifically, United Therapeutics has proposed that the FDA evaluate the results of the Phase IV trial based on the number of patients enrolled through September 15, 2005. The FDA is reviewing this proposal. The FDA could, among other things, accept this proposal, grant an extension of time to continue to enroll the trial, or institute a public hearing to withdraw marketing approval for Remodulin. If a withdrawal hearing were instituted by the FDA, United Therapeutics would pursue the opportunity to participate as it believes that it has exercised good faith due diligence in pursuing enrollment of this trial.

## UNITED THERAPEUTICS CORPORATION

### Notes to Consolidated Financial Statements — (Continued)

The majority of these Remodulin drug sales were made to United States distributors. In the United States, United Therapeutics has contracted with three distributors who purchase and market Remodulin. There are several other qualified distributors that could market Remodulin, if an existing distributor ceased to market Remodulin. If these distributor agreements expire or are terminated, under certain conditions, United Therapeutics may have to repurchase unsold Remodulin inventory held by the distributors.

United Therapeutics relies solely on one manufacturer to manufacture its cardiac monitoring devices. Although there are a limited number of companies that could replace this supplier, management believes that other suppliers could provide similar services and materials. A change in supplier, however, could cause a delay in the manufacture and distribution of cardiac monitoring devices which would adversely affect United Therapeutics' sales efforts.

In 2004, 2003 and 2002, approximately 87 percent, 92 percent and 93 percent of United Therapeutics' revenues were earned from customers located in the United States. In 2004, 2003 and 2002, approximately \$61.3 million, \$39.7 million and \$22.6 million in gross pharmaceutical segment revenues were derived from two Remodulin distributors in the United States, respectively.

## 7. Stockholders' Equity

### *Common Stock*

In December 2000, United Therapeutics acquired certain assets and liabilities of Cooke PH, Inc. (formerly Cooke Pharma, Inc.). In accordance with the acquisition agreement, United Therapeutics was obligated to issue additional shares (subject to certain reductions) to Cooke PH, Inc. as a result of United Therapeutics' stock price falling below a certain level. The asset purchase agreement required United Therapeutics to issue additional shares to Cooke PH if the value of the United Therapeutics' common stock fell below \$90 per share in December 2001 within certain limits defined in the asset purchase agreement. In addition, the parties agreed that United Therapeutics would reduce the number of shares to be issued to Cooke PH, Inc. if the assets it acquired were less or if the liabilities were greater than was represented by the sellers upon the acquisition date ("escrow items"). These escrow items totaled approximately \$1.7 million. In May 2002, United Therapeutics and Cooke PH, Inc. agreed to resolve these aspects of their agreement through the issuance by United Therapeutics of an additional 669,002 shares of its common stock to Cooke PH, Inc. The effect of this issuance was to decrease current assets and additional paid in capital by approximately \$1.7 million and to increase common stock outstanding by 669,002 shares.

In August 2004, 591,832 shares of United Therapeutics' common stock were issued to the sellers of Medicomp, Inc. and Telemedicine Procedures, LLC, as described in Note 12.

### *Shareholder Rights Plan*

In December 2000, United Therapeutics' Board of Directors approved the adoption of a Shareholder Rights Plan designed to discourage takeovers that involve abusive tactics or do not provide fair value to its shareholders. The Shareholder Rights Plan provides for a dividend distribution of one Preferred Share Purchase Right (Rights) for each outstanding share of United Therapeutics' common stock. The dividend distribution was made to shareholders of record on December 29, 2000. The Rights will be exercisable only if a person or group (except for certain exempted persons or groups) acquires 15 percent or more of United Therapeutics' common stock or announces a tender offer which would result in ownership of 15 percent or more of United Therapeutics' common stock. The Rights entitle each holder of one share to purchase one one-thousandth of a share of Series A Junior Participating Preferred Stock (par value \$.01) and will expire on December 29, 2010.

A total of 100,000 shares of Series A Junior Participating Preferred Stock with a par value of \$.01 were authorized in 2000. No Series A Junior Participating Preferred Stock has been issued.

### *Options Issued in Exchange for Services*

United Therapeutics issued options to consultants for services during 2004, 2003 and 2002. The options generally vest over a period of up to one year. The fair value of these options is being recognized as expense over the performance period which is typically one year. The grant activity is summarized as follows:

# UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements — (Continued)

	<u>Number of Options Granted</u>	<u>Weighted Average Grant Price</u>
For the year ended December 31,		
2004	14,334	\$ 29.77
2003	21,001	\$ 19.03
2002	44,334	\$ 11.70

### *Employee Options*

United Therapeutics' Board of Directors adopted an equity incentive plan (the Plan) effective in November 1997. In April 1999, the Board of Directors and stockholders approved an amendment and restatement of the Plan to increase the total number of shares of common stock that may be issued pursuant to the Plan to 14,939,517 shares, including 7,939,517 shares reserved for issuance to the CEO under her employment agreement. The Plan provides for the grant of awards, including options, stock appreciation rights, restricted stock awards and other rights as defined in the Plan, to eligible participants. Options granted under the Plan are not transferable and must generally be exercised within 10 years. The price of all options granted under the Plan must be at least equal to the fair market value of the common stock on the date of grant. With respect to any participant who owns 10 percent or more of United Therapeutics' outstanding common stock on the date of grant, the exercise price of any incentive stock option granted to that participant must equal or exceed 110 percent of the fair market value of the common stock on the date of grant and the option must not be exercisable for longer than five years.

Options granted under this Plan were as follows:

	<u>Number of Options Granted</u>	<u>Weighted Average Grant Price</u>
For the year ended December 31,		
2004	654,692	\$ 34.82
2003	552,816	\$ 20.58
2002	595,950	\$ 13.72

Options are also granted outside of the Plan described above (non-Plan awards) as inducements to new employees. Prior to July, 2003, non-Plan grants were also made to employees and consultants in order to incentivize performance or procure services. All non-Plan grants were awarded pursuant to specific approvals of the Compensation Committee of the Board of Directors. These grants were made at the fair market value of United Therapeutics' common stock on the date of grant. Board members and executive officers did not participate in these non-Plan option awards.

Non-Plan options were awarded as follows:

	<u>Number of Options Granted</u>	<u>Weighted Average Grant Price</u>
During the year ended December 31,		
2004	17,500	\$ 23.89
2003	212,420	\$ 21.72
2002	593,605	\$ 15.20

The fair value of each option is estimated on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions generally used for grants in 2004, 2003 and 2002:

	<u>Years ended December 31,</u>		
	<u>2004</u>	<u>2003</u>	<u>2002</u>
Dividend yield	0 percent	0 percent	0 percent
Expected volatility	63.68 percent	73.00 percent	92.86 percent
Risk free interest rate	3.16 percent	2.14 percent	3.82 percent
Expected lives	3.77 years	3.75 years	3.85 years

# UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements — (Continued)

A summary of the status of United Therapeutics' employee stock options as of December 31, 2004, 2003 and 2002, and changes during the years then ended is presented below:

	2004		2003		2002	
	Shares	Weighted-Average Exercise Price	Shares	Weighted-Average Exercise Price	Shares	Weighted-Average Exercise Price
Outstanding at beginning of period	4,313,222	\$ 26.81	4,032,871	\$ 26.13	3,083,246	\$ 29.98
Granted	672,192	34.53	765,236	20.90	1,189,555	14.46
Exercised	(485,687)	13.42	(388,616)	10.60	(28,648)	8.54
Forfeited	(50,427)	18.79	(95,335)	17.08	(211,282)	18.35
Canceled	(731,932)	66.79	(934)	3.00	—	—
Outstanding at end of period	3,717,368	\$ 21.54	4,313,222	\$ 26.81	4,032,871	\$ 26.13
Options exercisable at end of period	2,445,493	\$ 18.68	3,033,647	\$ 30.09	2,598,873	\$ 31.19
Weighted-average fair value of options granted during the period	\$ 17.12		\$ 10.83		\$ 9.17	

In November 2001, the Compensation Committee of the Board of Directors approved a plan to allow employees to voluntarily permit a limited portion of their outstanding options to be canceled. In exchange for each canceled option, United Therapeutics granted a new option in May 2002. The new options were granted at the fair market value of United Therapeutics' common stock on the date that the replacement awards were issued. Approximately 453,000 options were canceled with a weighted average exercise price of \$56.80. The canceled options were replaced with options priced at \$12.69, the NASDAQ closing price on the award date of May 10, 2002. The program ended in May 2002. Each of the employees who participated did not have any options granted to them in the six months prior to notification of intent to cancel. Furthermore, each of the employees who participated agreed to forgo receiving any new options for a period of six months following the cancellation. No guarantees or other promises of remuneration were made to the employees who agreed to participate. In accordance with FASB Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation*, no compensation expense was required to be recognized upon the grant of the replacement awards.

In July 2004, the Compensation Committee of the Board of Directors individually negotiated with certain employees to voluntarily cancel a portion of their outstanding options. In exchange for each canceled option, United Therapeutics granted a new option in January 2005. Approximately 560,000 options with a weighted average exercise price of \$85.79 were canceled. The new options were granted at the fair market price of United Therapeutics' common stock on the date that the replacement options were issued. The canceled options were replaced with options with a weighted average exercise price of \$43.56. Each of the employees who participated did not have any options granted to them in the six months prior to the cancellation. Furthermore, each of the employees who participated agreed to forgo receiving any new options for a period of six months following the cancellation. No guarantees or other promises of remuneration were made to the employees who agreed to participate. In accordance with FASB Interpretation No. 44, no compensation expense was recognized upon the grant of the replacement options in 2005.

The following table summarizes information about employee stock options outstanding at December 31, 2004:

Exercise Prices	Options Outstanding			Options Exercisable	
	Number	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Number	Weighted-Average Exercise Price
\$ 3.00 — 10.00	48,673	5.8	\$ 8.01	39,423	\$ 7.66
10.01 — 20.00	2,112,812	6.2	15.02	1,796,650	14.93
20.01 — 30.00	1,051,100	8.2	23.56	459,306	24.53
30.01 — 40.00	13,750	8.0	34.28	5,000	35.75
40.01 — 50.00	447,927	8.8	44.17	107,008	42.36
50.01 — 60.00	21,378	5.2	56.98	21,378	56.98
60.01 — 70.00	1,900	5.4	60.57	1,900	60.57
70.01 — 80.00	9,502	5.1	71.74	4,502	71.93
80.01 — 90.00	7,126	5.5	84.81	7,126	84.81
90.01 — 116.38	3,200	5.2	99.68	3,200	99.68
\$ 3.00 — \$116.38	3,717,368	7.1	\$ 21.54	2,445,493	\$ 18.68

During the year ended December 31, 2004 and 2003, options to purchase a total of 485,687 and 388,616 shares of common stock were exercised. The proceeds from these exercises totaled approximately \$6.5 million and \$4.1 million.





# UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements — (Continued)

### 8. Income Taxes

A reconciliation of tax benefit computed at the statutory federal tax rate on income (loss) from operations before income taxes to the actual income tax expense is approximately as follows (in thousands):

	Years Ended December 31,		
	2004	2003	2002
Federal tax provision (benefit) computed at the statutory rate	\$ 5,197	\$ (3,567)	\$ (8,041)
State tax provision (benefit), net of federal tax provision (benefit)	807	(554)	(1,249)
Change in the valuation allowance for deferred tax assets allocated to tax expenses	(1,480)	946	9,865
General business credits generated	(2,030)	(1,354)	(4,590)
Other	(3,348)	3,932	—
Nondeductible expenses	854	597	4,015
Total income tax expense	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

Deferred income taxes reflect the net effect of net operating loss carryforwards and the temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of United Therapeutics' net deferred tax asset as of December 31, 2004 and 2003, respectively, are approximately as follows (in thousands):

	December 31,	
	2004	2003
Deferred tax assets:		
Net operating loss carryforwards	\$ 43,165	\$ 45,343
General business credits	26,971	24,940
Impairment losses on investments	3,260	3,260
Realized losses on marketable investments	2,675	2,675
License fees capitalized for tax purposes	7,214	8,230
In-process research and development capitalized for tax purposes	4,859	5,301
Other	3,094	3,002
Total deferred tax assets	<u>91,238</u>	<u>92,751</u>
Deferred tax liabilities:		
Furniture and equipment principally due to differences in depreciation	(334)	(367)
Total deferred tax liabilities	<u>(334)</u>	<u>(367)</u>
Net deferred tax asset before valuation allowance	90,904	92,384
Valuation allowance	(90,904)	(92,384)
Net deferred tax asset	<u>\$ —</u>	<u>\$ —</u>

In assessing the realizability of its net deferred tax asset, management considers whether it is more likely than not that some portion or all of the net deferred tax asset is realizable. Based on the weight of available evidence, management has determined that the deferred tax asset amount may not be realized at this time. This is due primarily to the uncertainty of the levels of future product sales and profitability. The valuation allowance for deferred tax assets decreased by approximately \$1.5 million for the year ended December 31, 2004 and increased by approximately \$946,000 for the year ended December 31, 2003.

At December 31, 2004, United Therapeutics had net operating loss carryforwards of approximately \$109.9 million and business tax credit carryforwards of approximately \$27.0 million for federal income tax purposes which expire at various dates from 2012 through 2024. Business tax credits can offset future tax liabilities and arise from qualified research expenditures. United Therapeutics may be subject to alternative minimum tax or state income taxes, even though it has significant net operating loss and credit carryforwards. United Therapeutics is currently conducting a study to determine whether any limitations under Section 382 of the Internal Revenue Code have been triggered. Preliminary results of this study indicate that a limitation occurred in November, 2004. As a result, portions of these

## UNITED THERAPEUTICS CORPORATION

### Notes to Consolidated Financial Statements — (Continued)

carryforward items that were generated prior to November 2004 will be subject to certain limitations on their use. United Therapeutics does not believe that the potential limitations will cause the net operating loss and general business credit carryforwards to expire unused.

#### 9. Notes and Leases Payable

##### *Notes Payable*

In January 2003, United Therapeutics purchased a building and land adjacent to its Silver Spring, Maryland headquarters. United Therapeutics paid approximately \$171,000 in cash and issued a non-interest bearing note payable for \$1.0 million due to the seller in January 2004. The note payable was recorded at its present value using an imputed interest rate of approximately 2.6%, which represents the estimated borrowing rate for similar funding from commercial sources. The discount is being amortized using the effective interest method. In September 2003, an early payment of \$250,000 was made against this note payable. The note payable is included in the current portion of notes and leases payable in the December 31, 2003 consolidated balance sheet and was paid in January 2004.

United Therapeutics had two 30-year adjustable rate mortgage notes payable issued in the amount of approximately \$1.8 million and secured by building and property located at 1106 and 1110 Spring Street in Silver Spring Maryland and a certificate of deposit. These notes payable had an interest rate of approximately 5.7 percent during 2003. These notes payable were paid off in October 2003.

##### *Laboratory Operating Lease*

In June 2004, United Therapeutics entered into a synthetic operating lease and related agreements with Wachovia Development Corporation and its affiliates (Wachovia) to fund the construction of a laboratory facility in Silver Spring, Maryland for use in the Remodulin and OvaRex programs. Under these agreements, Wachovia will fund up to \$32.0 million towards the construction of the laboratory facility on ground owned by United Therapeutics. The construction phase has commenced and is expected to be completed in early 2006. Following construction, Wachovia will lease the laboratory facility to United Therapeutics with a term ending in May 2011. Under the 99-year ground lease, Wachovia will pay fair value rent to United Therapeutics for use of the land both during the construction phase and after the laboratory lease is terminated. During the term of the laboratory lease, Wachovia will pay \$1 per year to United Therapeutics for use of the land.

Upon completion of the construction, Wachovia will receive rents from United Therapeutics generally based on applying the 30-day LIBOR rate plus approximately 55 basis points to the amount funded by Wachovia towards the construction of the laboratory. These rents will be paid monthly from the time that the laboratory construction is completed until the termination of the lease in May 2011. Upon termination of the lease, United Therapeutics will generally have the option of renewing the lease (subject to the approval of both parties), purchasing the laboratory at a price approximately equal to the funded construction cost or selling it and repaying Wachovia the cost of its construction. United Therapeutics has guaranteed that if the laboratory is sold, Wachovia will receive at least 86 percent of the amount it funded towards the construction, as further discussed below.

In addition, United Therapeutics agreed to pledge, as collateral, a portion of its marketable investments to secure its lease obligations. At December 31, 2004, approximately \$10.1 million of marketable investments and cash were pledged as collateral and are reported as restricted marketable investments and cash in the consolidated balance sheets.

United Therapeutics anticipates that rent payments will commence in early 2006, after completion of construction, and continue through termination of the lease in May 2011. In addition, pursuant to the 99 year ground lease, Wachovia has paid to United Therapeutics ground rent totaling approximately \$307,000 that will be recognized in other income ratably through May 2011.

The lease and other agreements with Wachovia require that, among other things, United Therapeutics maintain a consolidated current ratio of not less than 1.2:1.0 and a consolidated net worth of at least \$70.0 million. The agreements contain other covenants and conditions which must be complied with by United Therapeutics throughout the construction and lease periods and upon termination of the lease. If United Therapeutics is unable to comply with these covenants and conditions, the agreements could terminate if the noncompliance was uncured and the parties could not agree otherwise.

If, at the end of the lease term, United Therapeutics does not renew the lease or purchase the improvements, then the facility will be sold to a third party. In that event, United Therapeutics has guaranteed that Wachovia will receive a

# UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements — (Continued)

guaranteed minimum residual value for the laboratory facility. This guaranteed residual is generally equal to 86 percent of the amount funded by Wachovia towards construction. The maximum potential amount of this guarantee is approximately \$27.5 million, equivalent to 86 percent of expected total construction costs of \$32.0 million.

FASB Interpretation No. 45 (FIN 45), *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*, requires that the fair value of the residual value guarantee be reported as a liability in United Therapeutics' consolidated balance sheet, regardless of whether an event triggering the payment of the guarantee has occurred. In accordance with FIN 45, United Therapeutics has reported this guarantee as a non-current asset (prepaid rent) and non-current liability (other liability). The prepaid rent and guarantee liability will be amortized in a straight-line manner over the term of the lease. The value of the guarantee reported in the balance sheet was approximately \$839,000. At December 31, 2004, approximately \$4.1 million towards the laboratory's development had been incurred and funded by Wachovia.

United Therapeutics has concluded that it is not required to consolidate Wachovia pursuant to FASB Interpretation No. 46 (FIN 46), *Consolidation of Variable Interest Entities* as United Therapeutics does not have a controlling financial interest in Wachovia. In accordance with the guidance in Statement of Financial Accounting Standards No. 13, *Accounting for Leases*, EITF No. 97-1, *Implementation Issues in Accounting for Lease Transactions, Including Those Involving Special-Purpose Entities*, EITF No. 97-10, *The Effect of Lessee Involvement in Asset Construction*, and FIN 46, United Therapeutics has determined that the lease is properly classified as an operating lease for accounting purposes.

### Capital Leases

United Therapeutics also leased certain equipment under capital leases with interest rates of approximately 12.6 percent and terms up to 5 years.

Future minimum payments under notes and leases payable are as follows (in thousands):

Year ending December 31,	Capital Leases
2005	\$ 16
2006	10
2007	—
2008	—
2009	—
2010 and thereafter	—
	<u>26</u>
Less amounts representing interest	(1)
Less current portion	<u>(16)</u>
	<u>\$ 9</u>

At December 31, 2004 and 2003, the carrying value of equipment under capital leases approximated \$75,000 and \$99,000, respectively, and accumulated depreciation approximated \$54,500 and \$53,000, respectively. Amortization of equipment under capital leases is included within depreciation expense.

### Other Operating Leases

United Therapeutics leases various office and production space generally under noncancelable agreements with terms expiring through 2011. United Therapeutics also leases automobiles for certain employees.

Approximate minimum annual rent payments to be paid under these noncancelable operating leases are as follows (in thousands):

Year ending December 31,	
2005	\$ 1,115
2006	2,221
2007	1,807
2008	1,517
2009	1,414



# UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements — (Continued)

These minimum annual rent payments shown above include estimated amounts for the synthetic operating lease described above and are based on LIBOR rates in effect at December 31, 2004. Total rent expense for the years ended December 31, 2004, 2003, and 2002 was approximately \$1.4 million, \$1.4 million and \$1.0 million, respectively.

### 10. Comprehensive Income (Loss)

SFAS No. 130, *Reporting Comprehensive Income*, establishes standards for the reporting and display of comprehensive income (loss) and its components. SFAS No. 130 requires, among other things, that unrealized gains and losses on available-for-sale securities and foreign currency translation adjustments be included in other comprehensive income (loss). The following statement presents comprehensive income (loss) for the years ended December 31, 2004, 2003 and 2002 (in thousands):

	December 31,		
	2004	2003	2002
Net income (loss)	\$ 15,449	\$ (9,969)	\$ (23,651)
Other comprehensive income:			
Foreign currency translation adjustments	48	13	8
Unrealized gain on available-for-sale securities	955	1,653	—
Comprehensive income (loss)	<u>\$ 16,452</u>	<u>\$ (8,303)</u>	<u>\$ (23,643)</u>

### 11. Marketable Investments

At December 31, 2004 and 2003, United Therapeutics' investments consisted of several federally-sponsored debt securities that are classified as non-current marketable investments. The amortized cost approximates fair value of these investments at December 31, 2004 and 2003. Certain marketable investments have been pledged as collateral to Wachovia Development Corporation under the laboratory lease described in Note 9, and are classified as restricted marketable investments and cash on the consolidated balance sheet.

Marketable investments held to maturity were as follows (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Agency notes at December 31, 2004	\$ 56,192	\$ 2	\$ (891)	\$ 55,303
Agency notes at December 31, 2003	\$ 48,775	\$ 22	\$ (480)	\$ 48,317

The following table summarizes maturities of United Therapeutics' marketable investment securities at December 31, 2004 (in thousands):

	Amortized Cost	Fair Value
Less than one year	\$ —	\$ —
Due in one to two years	2,894	2,854
Due in three to five years	17,460	17,352
Due after five years	<u>35,838</u>	<u>35,097</u>
Total	<u>\$ 56,192</u>	<u>\$ 55,303</u>

United Therapeutics' gross proceeds, realized gains and realized losses from its marketable investments are as follows (in thousands):

	Year Ended December 31,		
	2004	2003	2002
Gross proceeds	\$30,000	\$6,000	\$128,329
Realized gains	\$ —	\$ —	\$ 384
Realized losses	\$ —	\$ —	\$ 7,273

## UNITED THERAPEUTICS CORPORATION

### Notes to Consolidated Financial Statements — (Continued)

In March 2002, United Therapeutics reported a \$538,000 write-down due to an other-than-temporary decline in value of one of its marketable investments. In June 2002, United Therapeutics began reassessing its investment program in light of increasingly adverse conditions in the bond markets. As a result, all marketable debt investments were sold in July 2002. A write-down of investments totaling approximately \$3.6 million was necessary to adjust the value of United Therapeutics' marketable investments to their fair value based on quoted market prices at June 30, 2002. In July 2002, United Therapeutics recorded an additional realized loss of approximately \$3.3 million as a result of the liquidation of the investment portfolio.

#### 12. Acquisitions and Investments in Affiliates

##### *Medicomp, Inc. and Telemedical Procedures, LLC*

In December 2000, UTSC acquired all of the assets of Medicomp, Inc. and Telemedical Procedures, LLC (together referred to as Medicomp), related cardiac monitoring companies based in Florida. The total cost of this acquisition was approximately \$20.0 million, including transaction costs. Cash and shares of United Therapeutics' common stock, subject to adjustment, was paid to the sellers as consideration.

United Therapeutics agreed to register all of these shares for resale by Medicomp. Approximately 129,000 of the shares issued to Medicomp were placed in escrow for up to three years for unknown liabilities, indemnifications, warranties and a stock adjustment (described below) pursuant to the terms of an Escrow Agreement. In December 2002, the shares in escrow were reduced to approximately 26,000 shares. These shares are still being held in escrow.

Under terms of the acquisition agreement, Medicomp was entitled to receive additional shares from United Therapeutics since the average closing price of United Therapeutics' common stock over the 30 calendar days prior to the third anniversary of the acquisition was less than \$70.00 per share. In August 2004, 591,832 shares of United Therapeutics' common stock were issued to the sellers in satisfaction of this obligation.

##### *Northern Therapeutics, Inc.*

In December 2000, Lung Rx formed a new company in Canada, Northern Therapeutics, Inc. (Northern Therapeutics), with the inventor of a new form of autologous (non-viral vector) gene therapy for pulmonary hypertension and other diseases. The purpose of Northern Therapeutics is to develop the gene therapy and also to distribute Remodulin and other United Therapeutics products in Canada. Lung Rx received approximately 59 percent of the initial outstanding common stock of Northern Therapeutics in exchange for \$5.0 million in cash. United Therapeutics agreed to provide the services of its Chief Executive Officer as Chairman of the Northern Therapeutics' Board. During 2001, Northern Therapeutics' CEO resigned and since December 2001, United Therapeutics' CEO has been serving as the acting CEO of Northern Therapeutics. In January 2002, Northern Therapeutics purchased and retired shares of one of the initial founders. This increased Lung Rx's ownership of Northern Therapeutics to approximately 68 percent.

Northern Therapeutics is incorporated as a Canadian Controlled Private Corporation. Lung Rx may appoint only two of the company's seven board seats. Substantially all important decisions require unanimous board votes in favor of the proposal. The decisions requiring unanimous board votes include decisions related to personnel selection and compensation and establishment of operating and capital budgets. Therefore, the minority owners of Northern Therapeutics have substantive participating rights as discussed in Emerging Issues Task Force Issue No. 96-16, *Investors' Accounting for an Investee when the Investor has a Majority of the Voting Interest but the Minority Shareholder or Shareholders Have Certain Approval or Veto Rights*. As a result of these substantive participating rights, Lung Rx does not control Northern Therapeutics and consolidation, therefore, is prohibited. The equity method of accounting is used to account for Lung Rx's investment in Northern Therapeutics. At December 31, 2004, Lung Rx's investment in Northern Therapeutics was reported at approximately \$2.8 million, which is comprised of \$5.0 million paid in cash, net of Lung Rx's share of Northern Therapeutics' losses since its formation. Lung Rx's equity in the underlying net assets was approximately \$1.9 million at December 31, 2004. The difference between Lung Rx's investment in Northern Therapeutics and its equity in the underlying net assets is accounted for as goodwill.

## UNITED THERAPEUTICS CORPORATION

### Notes to Consolidated Financial Statements — (Continued)

Summarized financial information for Northern Therapeutics is as follows (in thousands):

	<u>As of and for the year ended December 31,</u>		
	<u>2004</u>	<u>2003</u>	<u>2002</u>
Total assets	\$ 2,874	\$ 3,660	\$ 4,233
Total liabilities	\$ 140	\$ 75	\$ 52
Net loss	\$ (1,148)	\$ (1,394)	\$ (305)

#### 13. Employees' Retirement Plan

Effective January 1, 1999, United Therapeutics adopted the United Therapeutics Corporation Employees' Retirement Plan (the Plan), a salary reduction 401(k) Plan. Employees employed on or after July 15, 1999 are eligible to participate in the Plan. The Plan provides for annual discretionary employer contributions. Employees may also contribute to the Plan at their discretion subject to statutory limitations. Beginning January 1, 2004, United Therapeutics began matching qualifying employee contributions at a rate of 20 percent, subject to certain limitations. For the year ended December 31, 2004, United Therapeutics contributed and expensed \$207,000 to the plan as a result of this matching.

#### 14. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	<u>December 31,</u>	
	<u>2004</u>	<u>2003</u>
Professional fees	\$ 126	\$ 163
Research	856	524
Payroll related	1,876	1,638
Royalties and rebates	3,565	1,552
Contracted services	564	706
Other	702	876
Total	<u>\$ 7,689</u>	<u>\$ 5,459</u>

# UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements — (Continued)

### 15. Segment Information

United Therapeutics has two reportable business segments. The pharmaceutical segment includes all activities associated with the research, development, manufacture, and commercialization of therapeutic products. The telemedicine segment includes all activities associated with the research, design, and delivery of patient monitoring services. The telemedicine segment is managed separately because diagnostic services require different technology and marketing strategies.

Segment information as of and for the year ended December 31, 2004 was as follows (in thousands):

	<u>Pharmaceutical</u>	<u>Telemedicine</u>	<u>Consolidated Totals</u>
Revenues from external customers	\$ 68,244	\$ 5,346	\$ 73,590
Net income (losses)	16,633	(1,184)	15,449
Interest income	2,977	9	2,986
Interest expense	(2)	(2)	(4)
Depreciation and amortization	(1,565)	(816)	(2,381)
Equity loss in affiliate	(785)	—	(785)
Total investments in equity method investees	2,813	—	2,813
Expenditures for long-lived assets	(4,654)	(563)	(5,217)
Goodwill, net	1,287	6,178	7,465
Total assets	197,044	10,114	207,158

Segment information as of and for the year ended December 31, 2003 was as follows (in thousands):

	<u>Pharmaceutical</u>	<u>Telemedicine</u>	<u>Consolidated Totals</u>
Revenues from external customers	\$ 49,180	\$ 4,161	\$ 53,341
Net losses	(6,639)	(3,330)	(9,969)
Interest income	2,427	8	2,435
Interest expense	(108)	(4)	(112)
Depreciation and amortization	(1,243)	(1,120)	(2,363)
Equity loss in affiliate	(953)	—	(953)
Total investments in equity method investees	3,544	—	3,544
Expenditures for long-lived assets	(6,747)	(257)	(7,004)
Goodwill, net	1,287	6,178	7,465
Total assets	169,734	9,768	179,502

Segment information as of and for the year ended December 31, 2002 was as follows (in thousands):

	<u>Pharmaceutical</u>	<u>Telemedicine</u>	<u>Consolidated Totals</u>
Revenues from external customers	\$ 26,234	\$ 3,886	\$ 30,120
Net losses	(20,690)	(2,961)	(23,651)
Interest income	4,943	11	4,954
Interest expense	(111)	(6)	(117)
Depreciation and amortization	(529)	(1,493)	(2,022)
Write-down of investments	(7,428)	—	(7,428)
Equity loss in affiliate	(209)	—	(209)
Total investments in equity method investees	4,367	—	4,367
Expenditures for long-lived assets	(3,384)	(197)	(3,581)
Goodwill, net	1,287	6,178	7,465
Total assets	173,462	11,104	184,566



## UNITED THERAPEUTICS CORPORATION

### Notes to Consolidated Financial Statements — (Continued)

The segment information shown above equals the consolidated totals when combined. These consolidated totals equal the amounts reported in the consolidated financial statements without further reconciliation for those categories which are reported in the consolidated financial statements.

The accounting policies of the segments are the same as those described in the summary of significant accounting policies in Note 2. There are no inter-segment transactions.

#### 16. Recent Accounting Pronouncements

##### *Stock-Based Compensation*

On December 16, 2004, the Financial Accounting Standards Board (FASB) issued a revision of Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment (Statement 123(R)), which is a revision of FASB Statement No. 123, Accounting for Stock-Based Compensation. Statement 123(R) supersedes APB Opinion No. 25, Accounting for Stock Issued to Employees, and amends FASB Statement No. 95, Statement of Cash Flows. Generally, the approach in Statement 123(R) is similar to the approach described in Statement 123. Statement 123(R) will be adopted by United Therapeutics on July 1, 2005.

As permitted by Statement 123, United Therapeutics currently accounts for share-based payments to employees using Opinion 25's intrinsic value method and, as such, generally recognizes no compensation cost for employee stock options. However, Statement 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values over the expected period of service. Accordingly, the adoption of Statement 123(R)'s fair value method will have a significant impact on our result of operations, although it will have no impact on our overall financial position.

The full impact of adoption of Statement 123(R) cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had United Therapeutics adopted Statement 123(R) in prior periods, the impact of that standard would have approximated the impact of Statement 123 as described in the disclosure of pro forma net income and earnings per share in Note 2 to the consolidated financial statements. Statement 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption. United Therapeutics is unable to estimate what those amounts will be in the future because they depend on, among other things, when employees exercise stock options.

##### *Other-than-Temporary Impairment*

In March 2004, the Emerging Issues Task Force (EITF) reached a consensus on Issue No. 03-01, The Meaning of *Other-Than-Temporary Impairment and Its Application to Certain Investments*. EITF 03-01 provides guidance on other-than-temporary impairment models for marketable debt and equity securities accounted for under SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, and SFAS No. 124, *Accounting for Certain Investments Held by Not-for-Profit Organizations*, and non-marketable equity securities accounted for under the cost method. The EITF developed a basic three-step model to evaluate whether an investment is other-than-temporarily impaired. The effective date of the recognition and measurement provisions of EITF 03-01 has been delayed by the FASB. United Therapeutics does not expect the adoption of EITF 03-01 to have a significant impact on our results of operations and financial condition.

##### *Inventory Costs*

In December 2004, the FASB issued SFAS Statement No. 151 *Inventory Cost*, which is an amendment to Accounting Research Bulletin No. 43, *Restatement and Revision of Accounting Research Bulletins*. SFAS 151 clarifies the accounting treatment of certain expenses for inventory costing. The new standard will be effective for the first fiscal years beginning after June 15, 2005. United Therapeutics has not yet assessed the impact of adopting this new standard.

# UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements — (Continued)

### 17. Quarterly Financial Information (Unaudited)

The following presents certain quarterly financial information for each of the years ended December 31, 2004 and 2003 (in thousands, except per share amounts):

	Quarters Ending During 2004			
	December 31, 2004	September 30, 2004	June 30, 2004	March 31, 2004
Net sales	\$ 21,613	\$ 19,995	\$18,299	\$ 13,683
Gross profit	19,361	17,835	16,256	11,888
Net income (loss)	6,890	6,266	4,140	(1,847)
Income (loss) per share – basic	\$ 0.31	\$ 0.29	\$ 0.19	\$ (0.09)
Income (loss) per share – diluted	\$ 0.28	\$ 0.27	\$ 0.18	\$ (0.09)
	Quarters Ending During 2003			
	December 31, 2003	September 30, 2003	June 30, 2003	March 31, 2003
Net sales	\$ 13,590	\$ 15,035	\$13,977	\$ 10,739
Gross profit	12,310	13,282	11,957	9,009
Net loss	(3,220)	(1,341)	(2,384)	(3,024)
Loss per share – basic and diluted	\$ (0.15)	\$ (0.06)	\$ (0.11)	\$ (0.14)

**United Therapeutics Corporation**  
**Schedule II – Valuation and Qualifying Accounts**  
**Years Ended December 31, 2004, 2003, and 2002**  
(in thousands)

	<b>Allowance for Doubtful Accounts Receivable</b>			
	<b>Balance at Beginning of Year</b>	<b>Additions charged to expenses</b>	<b>Deductions</b>	<b>Balance at End of Year</b>
Year ended December 31, 2004	\$ 119	\$ 24	\$ (120)	\$ 23
Year ended December 31, 2003	\$ 268	\$ 228	\$ (377)	\$ 119
Year ended December 31, 2002	\$ 198	\$ 110	\$ (40)	\$ 268

	<b>Reserve for Inventory Obsolescence</b>			
	<b>Balance at Beginning of Year</b>	<b>Additions charged to expenses</b>	<b>Deductions</b>	<b>Balance at End of Year</b>
Year ended December 31, 2004	\$ 321	\$ 316	\$ (190)	\$ 447
Year ended December 31, 2003	\$ 421	\$ 93	\$ (193)	\$ 321
Year ended December 31, 2002	\$ —	\$ 421	\$ —	\$ 421

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## ITEM 9: CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURES

None.

### ITEM 9A. CONTROLS AND PROCEDURES

#### *Disclosure Controls and Procedures*

Based on their evaluation, as of December 31, 2004, United Therapeutics' Chief Executive Officer and Chief Financial Officer have concluded that United Therapeutics' disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) are effective.

#### *Management's Report on Internal Control Over Financial Reporting*

The management of United Therapeutics is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended). United Therapeutics' internal control over financial reporting was designed to provide reasonable assurance to United Therapeutics' management and board of directors regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. All internal controls over financial reporting, no matter how well designed, have inherent limitations. As a result of these inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those internal controls determined to be effective can provide only reasonable assurance with respect to reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

United Therapeutics' management assessed the effectiveness of United Therapeutics' internal control over financial reporting as of December 31, 2004 based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control — Integrated Framework*. Management's assessment included an evaluation of the design of United Therapeutics' internal control over financial reporting and testing of the operational effectiveness of United Therapeutics' internal control over financial reporting. Based on this assessment, United Therapeutics' management concluded that, as of December 31, 2004, United Therapeutics' internal control over financial reporting was effective.

Ernst & Young LLP, an independent registered public accounting firm, has issued an audit report on management's assessment of United Therapeutics' internal control over financial reporting. The report of Ernst & Young LLP is contained in Item 8 of this Annual Report on Form 10-K.

There have been no changes in United Therapeutics' internal control over financial reporting that occurred during the three months ended December 31, 2004 that have materially affected, or are reasonably likely to materially affect, such internal control over financial reporting.

### ITEM 9B. RECENT DEVELOPMENTS

In February 2005, United Therapeutics was granted a five-year patent term extension by the United States Patent and Trademark Office for its patent covering the method of treating pulmonary hypertension using Remodulin. U.S. Patent Number 5,153,222, titled "Method of Treating Pulmonary Hypertension with Benzidine Prostaglandins," was originally scheduled to expire on October 6, 2009. It will now expire on October 6, 2014. The five-year Hatch-Waxman Act extension is the maximum extension allowed under 35 U.S.C. §156.

## PART III

### ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

Information required by Item 10 regarding nominees and directors appearing under *Election of Directors* in United Therapeutics' definitive proxy statement for its 2005 annual shareholders meeting (the "2005 Proxy Statement") is hereby incorporated herein by this reference. Information regarding executive officers of United Therapeutics appears in Part I of this Form 10-K under the heading *Executive Officers*. Information regarding the Audit Committee's financial expert appearing

under *Board Meetings and Committees – Audit Committee* in the 2005 Proxy Statement is hereby incorporated herein by this reference.

Information appearing under *Section 16(a) Beneficial Ownership Reporting Compliance* in the 2005 Proxy Statement is hereby incorporated herein by this reference.

United Therapeutics has a written Code of Conduct and Ethics that applies to its principal executive officer, principal financial officer and its principal accounting officer and every other director, officer and employee of United Therapeutics. The Code of Conduct and Ethics is available on United Therapeutics' Internet website at [www.unither.com](http://www.unither.com). A copy of the Code of Conduct and Ethics will be provided free of charge by making a written request and mailing it to United Therapeutics' corporate headquarters offices to the attention of Vice President, Investor Relations. If any amendment to, or a waiver from, a provision of the Code of Conduct and Ethics that applies to the principal executive officer, principal financial officer and principal accounting officer is made, such information will be posted on United Therapeutics' Internet website at [www.unither.com](http://www.unither.com).

## ITEM 11. EXECUTIVE COMPENSATION

Information concerning executive compensation required by Item 11 appears under *Management* in the 2005 Proxy Statement and is hereby incorporated herein by this reference.

## ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information regarding beneficial ownership of United Therapeutics capital stock required by Item 12 appears under *Security Ownership of Certain Beneficial Owners and Management* in the 2005 Proxy Statement and is hereby incorporated herein by this reference.

### Securities Authorized for Issuance Under Equity Compensation Plans

The following table presents information as of December 31, 2004 regarding United Therapeutics' securities authorized for issuance under equity compensation plans:

Plan category	Number of securities to be issued upon exercise of outstanding options (a)	Weighted average exercise price of outstanding options (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plan approved by security holders	2,637,117	\$ 23.08	11,498,786
Equity compensation plans not approved by security holders	1,278,248	\$ 18.87	none
Total	3,915,365	\$ 21.71	11,498,786

United Therapeutics has one equity compensation plan approved by security holders. In addition, United Therapeutics granted options to employees and consultants outside of the plan approved by security holders (non-plan options). Information regarding the security holder approved plan and the non-plan options is contained in Note 7 in the *Notes to the Consolidated Financial Statements* in this Annual Report. United Therapeutics does not have any warrants or rights that are outstanding or available for issuance as described in Regulation S-K Item 201 (d). Securities issued pursuant to the non-plan awards were made under standard agreements generally consistent with the form contained in Exhibits 10.27 and 10.43.

### **ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

Information concerning related party transactions required by Item 13 appears under *Certain Relationships and Related Transactions* in the 2005 Proxy Statement and is hereby incorporated herein by this reference.

### **ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

Information required by this item, concerning the principal accounting fees paid by the Registrant and the Audit Committee's pre-approval policies and procedures, is incorporated by reference to the information under *Independent Auditors* in the 2005 Proxy Statement and is hereby incorporated by reference.

## PART IV

### ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K.

- (a)(1) The financial statements of United Therapeutics filed as part of this report on Form 10-K are set forth in the Index to Consolidated Financial Statements under Part II, Item 8 of this Form 10-K.
- (a)(2) The Schedule II – Valuation and Qualifying Accounts is filed as part of this Form 10-K. All other schedules are omitted because they are not applicable or not required, or because the required information is included in the consolidated statements or notes thereto.
- (a)(3) Exhibits filed as a part of this Form 10-K:

<b>Exhibit No.</b>	<b>Description</b>
3.1	Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
3.2	Amended and Restated Bylaws of the Registrant, incorporated by reference to Exhibit 3.2 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
4.1	Reference is made to Exhibits 3.1 and 3.2.
4.2	Form of Purchase Agreement dated as of December 22, 1999, incorporated by reference to Exhibit 4.6 of the Registrant's Registration Statement on form S-1 (Registration No. 333-93853).
4.3	Registration Rights Agreement, dated as of June 27, 2000 by and between the Registrant and Toray Industries, Inc., incorporated by reference to Exhibit 4.7 of the Registrant's Registration Statement on Form S-3 (Registration No. 333-40598).
4.4	Stock Option Grant issued on June 27, 2000 to Toray Industries, Inc., incorporated by reference to Exhibit 4.8 of the Registrant's Registration Statement on Form S-3 (Registration No. 333-40598).
4.5	Form of Stock Purchase Agreement dated July 13, 2000 incorporated by reference to Exhibit 99.2 of the Registrant's Current Report on Form 8-K filed July 14, 2000.
4.6	Rights Agreement, dated as of December 17, 2000 between Registrant and The Bank of New York, as Rights Agent, incorporated by reference to Exhibit 4 of Registrant's Form 8-K dated December 17, 2000.
10.1 **	Amended and Restated Equity Incentive Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
10.2	Form of Scientific Advisor Compensation Agreement, incorporated by reference to Exhibit 10.2 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
10.3 **	Executive Employment Agreement (as amended) dated as of April 2, 1999, between the Registrant and Martine A. Rothblatt, incorporated by reference to Exhibit 10.3 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
10.4 **	Amendment dated December 21, 2000 to the Employment Agreement between the Registrant and Martine A. Rothblatt, which appears as Exhibit 10.5 to Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2002, which exhibit is incorporated herein by reference.
10.5 **	Employment Agreement dated June 16, 2001 between the Registrant and Paul A. Mahon, which appears as Exhibit 10.4 to Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2002, which exhibit is incorporated herein by reference.
10.6 **	Employment Agreement dated December 29, 2000 between the Registrant and Ricardo A. Balda, which appears as Exhibit 10.2 to Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2002, which exhibit is incorporated herein by reference.
10.7 *	Exclusive License Agreement dated as of December 3, 1996, between the Registrant and an affiliate of Pharmacia & Upjohn Company, incorporated by reference to Exhibit 10.8 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
10.8 *	Assignment Agreement dated as of January 31, 1997, between the Registrant and affiliates of Glaxo Wellcome Inc., incorporated by reference to Exhibit 10.9 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
10.9 *	Cooperation and Strategic Alliance Agreement dated as of September 3, 1997, between Registrant and MiniMed Inc., incorporated

by reference to Exhibit 10.10 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).

10.10 \* Exclusive License Agreement dated as of September 24, 1998, between the Registrant and Toray Industries, Inc., incorporated by reference to Exhibit 10.11 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).



- 10.11 \*\* Employment Agreement dated January 3, 2000 between the Registrant and Fred T. Hadeed, which appears as Exhibit 10.6 to Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2002, which exhibit is incorporated herein by reference.
- 10.12 \*\* Amendment dated August 16, 2001 to the Employment Agreement between the Registrant and Fred T. Hadeed, which appears as Exhibit 10.7 to Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2002, which exhibit is incorporated herein by reference.
- 10.13 \* Exclusive License Agreement dated as of March 15, 1999, between the Registrant and Toray Industries, Inc., incorporated by reference to Exhibit 10.14 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
- 10.14 \*\* Employment Agreement dated November 29, 2000 between the Registrant and Roger Jeffs, which appears as Exhibit 10.9 to Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2002, which exhibit is incorporated herein by reference.
- 10.15 Agreement and Plan of Merger dated as of October 7, 1999, among the Registrant, SQ Acquisition, Inc., Robert M. Moriarty, Ph.D., Raju Penmasta, Ph.D., Liang Guo, Ph.D., George W. Davis, Esq., David Moriarty and SynQuest, Inc., incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the period ended September 30, 1999.
- 10.16 Form of Indemnification Agreement between the Registrant and each of its Directors, incorporated by reference to Exhibit 10.19 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
- 10.17 Guidelines to Govern the Strategic Activities, Co-Development and Related Activities of the Parties dated as of November 1, 1999, between the Registrant and MiniMed, Inc., incorporated by reference to Exhibit 10.20 of the Registrant's Amended Registration Statement on Form S-1/A (Registration No. 333-93853).\*
- 10.18 Short Form Commercial and Apartment House Real Estate Purchase Agreement, accepted as of August 4, 1999 between the Registrant and 1106 Spring Street Associates, incorporated by reference to Exhibit 10.21 of the Registrant's Form 10-K for the year ended December 31, 2000.
- 10.19 Exclusive License Agreement dated as of June 23, 2000 between the Registrant and Toray Industries, Inc., incorporated by reference to Exhibit 10.1 of the Registrant's Registration Statement on Form S-3 (Registration No. 333-40598).
- 10.20 Asset Purchase Agreement dated as of December 28, 2000 among the Registrant, UTSC Sub Acquisition, Inc., Medcomp, Inc., and Telemedical Procedures, LLC, incorporated by reference to Exhibit 2.1 of the Registrant's Form 8-K/A dated December 28, 2000.
- 10.21 Asset Purchase Agreement dated as of December 15, 2000 among the Registrant, UP Subsidiary Corporation, and Cooke Pharma, Inc., incorporated by reference to Exhibit 2.1 of the Registrant's Form 8-K/A dated December 15, 2000.
- 10.22 Amendment No. 1 to Exclusive License Agreement, effective as of December 3, 1996, made as of October 1, 2002 by and between Pharmacia & Upjohn Company and the Registrant, which appears as Exhibit 10.25 to Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2002, which exhibit is incorporated herein by reference.
- 10.23 Technical Services Agreement dated August 27, 2002 between the Registrant and Kurzweil Technologies, Inc., which appears as Exhibit 10.26 to Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2002, which exhibit is incorporated herein by reference.
- 10.24 \*\* Promissory note dated May 8, 2002 between the Registrant and Roger Jeffs, which appears as Exhibit 10.10 to Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2002, which exhibit is incorporated herein by reference.
- 10.25 \*\* Security Agreement dated May 8, 2002 between the Registrant and Roger Jeffs, which appears as Exhibit 10.11 to Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2002, which exhibit is incorporated herein by reference.
- 10.26 \*\*\* Exclusive License Agreement dated April 17, 2002 between AltaRex Corp. and Unither Pharmaceuticals, a subsidiary of the Registrant, which appears as Exhibit 10.12 to Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2002, which exhibit is incorporated herein by reference.
- 10.27 \*\* Standard Non-plan Option Award Agreement used by Registrant incorporated by reference to Exhibit 10.30 to Registrant's Form 10-K for the year ended December 31, 2002.
- 10.28 \*\* Amendment to Employment Agreement dated December 11, 2002 between the Registrant and Roger Jeffs, incorporated by reference to Exhibit 10.31 to the Registrant's Form 10-K for the year ended December 31, 2002.
- 10.29 \*\* Amendment to Employment Agreement dated December 11, 2002 between the Registrant and Fred Hadeed, incorporated by

reference to Exhibit 10.32 to the Registrant's Form 10-K for the year ended December 31, 2002.

- 10.30 \*\* Amendment to Employment Agreement dated December 11, 2002 between the Registrant and Paul Mahon, incorporated by reference to Exhibit 10.33 to the Registrant's Form 10-K for the year ended December 31, 2002.
- 10.31 Real Estate Purchase Agreement dated October 31, 2003 by and between Unither Pharmaceuticals, Inc. and Montgomery County.

- 10.32\*\* United Therapeutics Corporation Amended and Restated Equity Incentive Plan, as amended effective as of September 24, 2004 incorporated by reference to Exhibit 10.1 to the Registrant's Form 10-Q for the quarter ended September 30, 2004.
- 10.33 Lease Agreement dated as of June 28, 2004, by and among United Therapeutics Corporation and Wachovia Development Corporation, incorporated by reference to Exhibit 99.1 of the Registrant's Form 8-K filed on July 6, 2004.
- 10.34 Assignment of Liquid Collateral Account dated June 28, 2004, by and among United Therapeutics Corporation and Wachovia Development Corporation, incorporated by reference to Exhibit 99.2 of the Registrant's Form 8-K filed on July 6, 2004.
- 10.35 Ground Lease dated June 28, 2004, by and among United Therapeutics Corporation and Wachovia Development Corporation, incorporated by reference to Exhibit 99.3 of the Registrant's Form 8-K filed on July 6, 2004.
- 10.36 Participation Agreement dated June 28, 2004, by and among United Therapeutics Corporation, Wachovia Development Corporation, Various Other Banks and Financial Institutions and Wachovia Bank, NA, incorporated by reference to Exhibit 99.4 of the Registrant's Form 8-K filed on July 6, 2004.
- 10.37 Agency Agreement dated June 28, 2004, by and among United Therapeutics Corporation and Wachovia Development Corporation, incorporated by reference to Exhibit 99.5 of the Registrant's Form 8-K filed on July 6, 2004.
- 10.38\*\* Amendment to Executive Employment Agreement between Martine A. Rothblatt and United Therapeutics Corporation, dated April 2, 1999, as previously amended, incorporated by reference to Exhibit 10.1 of the Registrar's Form 8-K filed on December 29, 2004.
- 10.39\*\* Amendment to Employment Agreement between Roger Jeffs, Ph.D. and United Therapeutics Corporation dated November 29, 2000, as previously amended, incorporated by reference to Exhibit 10.2 of the Registrar's Form 8-K filed on December 29, 2004.
- 10.40\*\* Amendment to Employment Agreement between Fred Hadeed and United Therapeutics Corporation dated January 3, 2000, as previously amended, incorporated by reference to Exhibit 10.3 of the Registrar's Form 8-K filed on December 29, 2004.
- 10.41\*\* Amendment to Employment Agreement between Paul A. Mahon and United Therapeutics Corporation dated June 16, 2001, as previously amended, incorporated by reference to Exhibit 10.4 of the Registrar's Form 8-K filed on December 29, 2004.
- 10.42\*\* Form of Employee Stock Option Award Agreement, incorporated by reference to Exhibit 10.1 of the Registrar's Form 8-K filed on December 17, 2004.
- 10.43\*\* Form of Non-Employee Stock Option Award Agreement, incorporated by reference to Exhibit 10.2 of the Registrar's Form 8-K filed on December 17, 2004.
- 16 Letter from KPMG LLP regarding change in certifying accountant, which appears as Exhibit 99.1 to Registrant's Form 8-K filed on September 8, 2003, which exhibit is incorporated herein by reference.
- 21 Subsidiaries of the Registrant.
- 23.1 Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm
- 23.2 Consent of KPMG LLP, Independent Registered Public Accounting Firm.
- 31.1 Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.
- 31.2 Certification of Chief Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.
- 32.1 Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2 Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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\* Confidential treatment has been granted with respect to certain portions of this exhibit pursuant to Rule 406 of the Securities Act of 1933, as amended.

\*\* Designates management contracts and compensation plans.

\*\*\* Confidential treatment has been granted with respect to certain portions of this exhibit pursuant to Rule 24b-2 of the Securities Act of 1934.



## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereto duly authorized.

### UNITED THERAPEUTICS CORPORATION

By: /s/ MARTINE A. ROTHBLATT

Martine A. Rothblatt, Ph.D.

*Chairman of the Board and Chief Executive Officer*

February 25, 2005

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signatures	Title	Date
<u>/s/ MARTINE A. ROTHBLATT</u> Martine A Rothblatt	Chairman of the Board and Chief Executive Officer	February 25, 2005
<u>/s/ ROGER A. JEFFS</u> Roger A. Jeffs	President, Chief Operating Officer and Director	February 25, 2005
<u>/s/ FRED T. HADEED</u> Fred T. Hadeed	Executive Vice President for Business Development and Chief Financial Officer	February 25, 2005
<u>/s/ CHRISTOPHER CAUSEY</u> Christopher Causey	Director	February 25, 2005
<u>/s/ RAYMOND DWEK</u> Raymond Dwek	Director	February 25, 2005
<u>/s/ R. PAUL GRAY</u> R. Paul Gray	Director	February 25, 2005
<u>/s/ RAYMOND KURZWEIL</u> Raymond Kurzweil	Director	February 25, 2005
<u>/s/ CHRISTOPHER PATUSKY</u> Christopher Patusky	Director	February 25, 2005
<u>Louis W. Sullivan</u>	Director	February 25, 2005

SUBSIDIARIES OF THE REGISTRANT

Lung Rx, Inc., a Delaware Corporation

Unither Telemedicine Services Corp., a Delaware Corporation

Unither Pharmaceuticals, Inc., a Delaware Corporation

United Therapeutics Europe, Ltd., a United Kingdom Company

Unither Pharma, Inc., a Delaware Corporation

Medicomp, Inc., a Delaware Corporation

Unither Nutraceuticals, Inc., a Delaware Corporation

Unither.com, Inc., a Delaware Corporation

Lung Rx, Ltd, a United Kingdom Company

Exhibit 23.1  
Consent of Ernst & Young LLP

**Consent of Independent Registered Public Accounting Firm**

The Board of Directors  
United Therapeutics Corporation

We consent to the incorporation by reference in the Registration Statements (Form S-3 Nos. 333-118699 and 333-122703) and in the related Prospectus and the Registration Statements (Form S-8 Nos. 333-108169, 333-56922 and 333-95419) of United Therapeutics Corporation of our report dated February 18, 2005, with respect to the consolidated financial statements and schedules of United Therapeutics Corporation included in this Annual Report (Form 10-K) for the year ended December 31, 2004.

/s/ ERNST & YOUNG LLP

McLean, Virginia  
February 24, 2005

**Consent of Independent Registered Public Accounting Firm**

The Board of Directors  
United Therapeutics Corporation:

We consent to the incorporation by reference in the registration statements (No. 333-95419, No. 333-56922 and No. 333-108169) on Form S-8 and in the registration statements (No. 333-118699 and No. 333-122703) on Form S-3 of United Therapeutics Corporation of our report dated February 28, 2003, with respect to the consolidated statements of operations, stockholders' equity, and cash flows of United Therapeutics Corporation and subsidiaries for the year ended December 31, 2002, and the related financial statement schedule, which report appears in the December 31, 2004 annual report on Form 10-K of United Therapeutics Corporation.

Our report on the consolidated financial statements refers to the Company's adoption of Statement of Financial Accounting Standards No. 142, "*Goodwill and Other Intangible Assets*", effective January 1, 2002.

/s/ KPMG LLP

McLean, Virginia  
February 23, 2005



**CERTIFICATION PURSUANT TO RULE 13a-14(a)**  
**OF THE SECURITIES EXCHANGE ACT OF 1934**

I, Martine A. Rothblatt, certify that:

1. I have reviewed this annual report on Form 10-K of United Therapeutics Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 25, 2005

/s/ Martine A. Rothblatt

By: Martine A. Rothblatt, Ph.D.

Title: Chairman and Chief Executive Officer

**CERTIFICATION PURSUANT TO RULE 13a-14(a)**  
**OF THE SECURITIES EXCHANGE ACT OF 1934**

I, Fred T. Hadeed, certify that:

1. I have reviewed this annual report on Form 10-K of United Therapeutics Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 25, 2005

/s/ Fred T. Hadeed

By: Fred T. Hadeed

Title: Executive Vice President for Business

Development and Chief Financial Officer

CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report of United Therapeutics Corporation (the “Company”) on Form 10-K for the period ended December 31, 2004 as filed with the Securities and Exchange Commission (the “Report”), I, Martine A. Rothblatt, Chief Executive Officer of the Company, certify, to the best of my knowledge, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Martine A. Rothblatt  
Martine A. Rothblatt  
Chairman and Chief Executive Officer  
United Therapeutics Corporation  
February 25, 2005

THE FOREGOING CERTIFICATION IS BEING FURNISHED SOLELY PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002 AND IS NOT BEING FILED AS PART OF THE FORM 10-K OR AS A SEPARATE DISCLOSURE DOCUMENT.

A SIGNED ORIGINAL OF THIS WRITTEN STATEMENT REQUIRED BY SECTION 906, OR OTHER DOCUMENT AUTHENTICATING, ACKNOWLEDGING, OR OTHERWISE ADOPTING THE SIGNATURE THAT APPEARS IN TYPED FORM WITHIN THE ELECTRONIC VERSION OF THIS WRITTEN STATEMENT REQUIRED BY SECTION 906, HAS BEEN PROVIDED TO UNITED THERAPEUTICS CORPORATION AND WILL BE RETAINED BY UNITED THERAPEUTICS CORPORATION AND FURNISHED TO THE SECURITIES AND EXCHANGE COMMISSION OR ITS STAFF UPON REQUEST.

CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report of United Therapeutics Corporation (the "Company") on Form 10-K for the period ended December 31, 2004 as filed with the Securities and Exchange Commission (the "Report"), I, Fred T. Hadeed, Chief Financial Officer of the Company, certify, to the best of my knowledge, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Fred T. Hadeed  
Fred T. Hadeed  
Executive Vice President for Business Development  
and Chief Financial Officer  
United Therapeutics Corporation  
February 25, 2005

THE FOREGOING CERTIFICATION IS BEING FURNISHED SOLELY PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002 AND IS NOT BEING FILED AS PART OF THE FORM 10-K OR AS A SEPARATE DISCLOSURE DOCUMENT.

A SIGNED ORIGINAL OF THIS WRITTEN STATEMENT REQUIRED BY SECTION 906, OR OTHER DOCUMENT AUTHENTICATING, ACKNOWLEDGING, OR OTHERWISE ADOPTING THE SIGNATURE THAT APPEARS IN TYPED FORM WITHIN THE ELECTRONIC VERSION OF THIS WRITTEN STATEMENT REQUIRED BY SECTION 906, HAS BEEN PROVIDED TO UNITED THERAPEUTICS CORPORATION AND WILL BE RETAINED BY UNITED THERAPEUTICS CORPORATION AND FURNISHED TO THE SECURITIES AND EXCHANGE COMMISSION OR ITS STAFF UPON REQUEST.

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**End of Filing**

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