

# UNITED THERAPEUTICS CORP

## FORM 10-K (Annual Report)

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Securities and Exchange Commission  
Washington, DC 20549

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**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, 2003**

**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**

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**United Therapeutics Corporation**

*(Exact name of Registrant as specified in its charter)*

**Delaware**  
*(State or Other Jurisdiction of  
Incorporation or Organization)*

**52-1984749**  
*(IRS Employer  
Identification No.)*

**1110 Spring Street**  
**Silver Spring, MD**  
*(Address of principal executive offices)*

**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, 2003 as reported by the Nasdaq National Market was approximately \$431.5 million. <sup>(1)</sup>

The number of shares outstanding of the registrant's Common Stock, par value \$0.01 per share, as of March 1, 2004 was 21,332,444 shares.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's definitive proxy statement for the registrant's 2004 annual shareholders meeting are incorporated by reference in Part III of this Form 10-K.

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<sup>(1)</sup> Excludes 1,226,424 shares of common stock held by directors and officers, and any stockholders whose ownership exceeds ten percent of the shares outstanding at June 30, 2003. 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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### EXHIBITS

EX-10.34	Real Estate Purchase Agreement dated October 31, 2003 by and between Unither Pharmaceuticals, Inc. and Montgomery County, Maryland
EX-21	Subsidiaries of the Registrant
EX-23.1	Consent of Ernst & Young LLP
EX-23.2	Consent of KPMG LLP
EX-31.1	Rule 13a-14(a) Certification of CEO
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EX-32.1	Section 1350 Certification of CEO
EX-32.2	Section 1350 Certification of CFO

## PART I

### Item 1. *Business*

United Therapeutics is a biotechnology company focused on the development and commercialization of unique therapeutics to treat chronic and life-threatening diseases. United Therapeutics is active in three therapeutic areas — cardiovascular medicine, infectious disease and oncology — 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 Canada and Israel for similar uses;
- *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® cardiac event recorder; 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 June 1996 in Delaware under the name Lung Rx, Inc. The company changed its name to United Therapeutics Corporation in December 1997. United Therapeutics' corporate headquarters are located at 1110 Spring Street, Silver Spring, Maryland 20910.

## United Therapeutics' Products

United Therapeutics' product portfolio includes the following:

Product	Mode of Delivery	Indication/Market	Current Status	UT Territory
Remodulin	Continuous subcutaneous	Pulmonary arterial hypertension	Commercial in U.S., Canada and Israel; Preapproval in Switzerland and Australia; France review ongoing	Worldwide
Arginine Formulations	Oral dietary supplement	Vascular function	Commercial	Worldwide
CardioPAL and Decipher Recorder	Telemedical	Arrhythmias and angina	Commercial	Worldwide
CardioPAL AI	Telemedical	Cardiac arrhythmias	Pre-commercial	Worldwide
Remodulin	Intravenous	Pulmonary arterial hypertension	sNDA in review in U.S.	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
BrevaRex®	Intravenous	Multiple myeloma/breast cancer	Phase I	Worldwide*
Beraprost® SR	Oral	Peripheral vascular disease	Phase I	U.S./ Canada
UT-15 Sustained Release	Oral	Pulmonary arterial hypertension and peripheral vascular disease	Phase I	Worldwide
Glycobiology Antiviral Agents	Oral	Hepatitis B, dengue 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. Remodulin, United Therapeutics' main product, was approved by the FDA in May 2002 in the United States and in October 2002 in Canada and Israel.

### ***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 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.

United Therapeutics believes Remodulin provides patients with a convenient and less invasive alternative 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 is 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 Flolan 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. Remodulin causes infusion site pain and infusion site reaction in most patients in varying degrees.

In March 2000, United Therapeutics completed an international, randomized, placebo-controlled, double-blind study of 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 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 disease subsets of pulmonary arterial hypertension and is the only pulmonary arterial hypertension treatment approved for patients with NYHA class II (early-stage) symptoms.

United Therapeutics agreed with the FDA that it would perform a post-marketing Phase IV clinical study to further assess the clinical benefits of Remodulin. The study was originally to have been completed by May 2004 and involve 100 patients. In mid-2003, the FDA agreed to extend the due date of the final study report to December 2005 and reduce the number of patients to 39, with the possibility of concluding the trial after 21 patients have completed the study. As of February 2004, approximately 11 patients have been enrolled in the Phase IV study.

On October 7, 2002, the Canadian Therapeutics Products Directorate approved Remodulin for long term subcutaneous treatment of pulmonary arterial hypertension in NYHA class III and IV patients who do not respond adequately to conventional therapy. On October 31, 2002, the Israeli Ministry of Health, Drug Registration Department, approved Remodulin for the treatment of primary pulmonary arterial hypertension, pulmonary arterial hypertension associated with connective tissue disorders and pulmonary arterial hypertension associated with congenital systemic to pulmonary shunts. In December 2003, Switzerland and Australia announced that they would approve Remodulin pending final labeling and a commitment to perform a drug interaction study in Switzerland. A marketing authorization application for the approval of Remodulin in France is under review. Additional European filings will be made following approval in France.



### *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 in pulmonary arterial hypertension. The sNDA is currently under review.

While intravenous Remodulin would not possess all the safety and convenience benefits as subcutaneously delivered Remodulin, it would eliminate the infusion site pain and reaction currently experienced by most patients using Remodulin subcutaneously. In addition, it could serve as an alternative to intravenous Flolan, since Flolan must be continuously refrigerated, including during infusion, whereas Remodulin does not require any refrigeration. Furthermore, the active ingredient in Flolan is highly unstable and only remains active in the body for approximately two 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.

### *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 vascular 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 has commenced a pre-pivotal clinical study of Remodulin for critical limb ischemia. There are currently 12 patients enrolled in this 30 patient placebo-controlled trial.

### *UT-15 Sustained Release*

United Therapeutics is currently in the early stage of development of a longer-acting prostacyclin analog, known as UT-15 Sustained Release. UT-15 Sustained Release will be developed as an oral therapy for vascular diseases, including pulmonary arterial hypertension and peripheral vascular disease. A longer-acting prostacyclin analog could enable patients to take fewer doses per day. A Phase I study in healthy human volunteers to assess bioavailability was conducted during 2003. United Therapeutics is currently testing tablet and capsule dosage forms in healthy volunteers to determine which formulation is most suitable for Phase II studies.

### *Metastatic Cancer*

United Therapeutics has tested the anti-cancer capabilities of Remodulin in laboratory experiments. These *in vitro* studies showed that Remodulin has an anti-metastatic effect at the same dose given to pulmonary hypertension patients. In addition, there are many published reports of the anti-cancer effects of various analogs of the prostacyclin molecule. Much of the excitement regarding prostacyclin as an anti-cancer molecule has to do with prostacyclin's ability to block an endothelial cell receptor (called the PPAR receptor) which is believed to be needed for tumor growth. Given the potency of Remodulin, and its relative ease of use, United Therapeutics believes there may be anti-cancer potential in this lead product and further development may be initiated in the future.

### *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 seven people as of December 2003 and is expected to continue growing in 2004. 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 Strategic Alliances* 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 \$45.1 million, \$21.2 million and \$493,000 of revenues were earned from the sales of Remodulin in 2003, 2002 and 2001, respectively.

### *Arginine*

In December 2000, United Therapeutics expanded its cardiovascular focus when it acquired the assets and certain liabilities of Cooke Pharma, Inc., the exclusive manufacturer 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, which is critical for maintaining vascular function and Unither Pharma owns the exclusive patent rights to make these claims. Although arginine is broadly sold as a nutritional supplement in pill form, there are no existing arginine products, other than HeartBar, that can deliver 6 grams of arginine in a single dose. Individual pills generally contain only 500 milligrams of arginine or one-twelfth the amount in one HeartBar. HeartBar products are sold in several flavors of protein rich bars and drink mixes.

Presently, the HeartBar and related line of products is marketed directly to consumers via independent distributors and the Internet. Approximately \$2.3 million, \$1.4 million and \$542,000 of revenues were earned from the sales of HeartBar and related products in 2003, 2002 and 2001, respectively.

### *Telemedicine Services*

United Therapeutics provides telemedicine services to detect cardiac arrhythmias and ischemic heart disease through its wholly owned subsidiary, Medicomp, Inc. 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 Decipher miniaturized digital holter recorder/analyzer and CardioPAL event monitor. In addition, the CardioPAL AI, a next-generation event recorder, is currently in final testing.

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 \$4.2 million,

\$3.9 million and \$2.8 million from the sales of telemedicine products and services were earned in 2003, 2002 and 2001, respectively.

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

In April 2002, Unither Pharmaceuticals, Inc., a wholly owned subsidiary of United Therapeutics, entered into an agreement with AltaRex Corp. (now 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 ovarian, prostate, lung, breast, multiple myeloma, gastrointestinal and other forms of cancer. 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.

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 at approximately 60 centers throughout the United States and are expected to be fully enrolled in approximately two to three years. 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.

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

In March 2000, Unither Pharmaceuticals, Inc. 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, 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. A Phase II proof-of-concept study for UT-231B in patients infected with hepatitis C who have failed conventional therapies is currently being enrolled with an anticipated completion date of late 2004.

### ***Beraprost SR***

In June 2000, United Therapeutics obtained from Toray Industries, Inc. the exclusive right to develop and market the oral prostacyclin beraprost in the 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 dilates blood vessels, prevents platelet aggregation and prevents 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 (non-viral vector) gene therapy for the treatment of pulmonary arterial hypertension and other conditions. In Canada, Northern Therapeutics is developing the gene therapy and also is distributing certain United Therapeutics' products, 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.

### **The Medtronic MiniMed Strategic Alliance**

Medtronic MiniMed partnered with United Therapeutics for the use of its 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 and MiniMed have established a Management Committee comprised of two representatives from each company to oversee implementation of the agreement. United Therapeutics acquires Medtronic MiniMed products and resells these products to its distributors at their acquisition cost. Approximately \$1.7 million, \$3.7 million and \$1.1 million of revenues were earned from the resales of MiniMed pumps and supplies in 2003, 2002 and 2001, respectively.

### **Domestic Strategic Alliances**

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 known as 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 2009 (subject to extension — see *Patent Term Extensions* below) and until various dates from September 2009 to August 2013 in nine other countries. For congestive heart failure, the patent does not expire until May 2011 in the United States and from May 2011 to March 2012 in five 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, which was granted in August 2002. 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 three pending patent applications with respect to additional Remodulin synthesis improvements.

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

In April 2002 and August 2003, Unither Pharmaceuticals, Inc. (UPI), a wholly owned subsidiary of United Therapeutics, entered into license agreements with AltaRex Corp. (now AltaRex Medical 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 of which, 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 2018. 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.

#### ***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. The issued patents have expiration dates ranging from 2008 to 2017.

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 will receive 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.

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. For instance, under Waxman-Hatch, the United States patents relating to Remodulin could be extended by up to five years, giving the product patent protection until as late as October 2014. In addition, patent extensions are available under similar laws in Europe. 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 is pending.

### **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 2003, 2002 and 2001 totaled approximately \$35.4 million, \$26.8 million and \$32.6 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 manufactures treprostinil, the bulk active ingredient in Remodulin. Baxter Healthcare Corporation (formerly Cook Imaging Corporation) formulates Remodulin for United Therapeutics. The agreement with Baxter expires in October 2004 and is renewable for successive eighteen month terms. An analytical testing laboratory, Cardinal Health (formerly Magellan Laboratories, Inc.), tests the purity of each batch of manufactured Remodulin. Medtronic MiniMed provides the delivery device used to administer Remodulin to patients.

UT-231B, OvaRex, arginine and telemedicine products are currently manufactured by contract manufacturers. 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.

### **Competition**

Many drug companies engage in research and development to commercialize products to treat cardiovascular, infectious and oncological diseases. United Therapeutics is aware of two existing treatments already approved in the United States for pulmonary arterial hypertension with which Remodulin competes. One is Flolan, an intravenously delivered prostacyclin marketed by GlaxoSmithkline, PLC, and the other is Tracleer, an oral endothelin antagonist marketed by Actelion, Ltd. Additional investigational drugs are being

developed, including the following: sitaxsentan in the United States, an oral endothelin antagonist being developed by Encysive Pharmaceuticals, Inc.; iloprost, an inhaled prostacyclin analog being developed by CoTherix, Inc. in the United States and marketed in Europe by Schering AG; sildenafil, an oral vasodilator being developed by Pfizer, Inc. internationally; and ambrisentan, an oral endothelin antagonist being developed by Myogen, Inc. in the United States. In addition, competitors may develop and commercialize other products that compete with United Therapeutics' products and may do so more rapidly than United Therapeutics. As of December 31, 2003, United Therapeutics estimated that there were approximately 3,000 patients on prostacyclin therapy (either Flolan or Remodulin) in the United States, of which approximately 15% were using Remodulin.

In late 2001, the FDA approved Tracleer®, an oral treatment for pulmonary arterial hypertension in patients with NYHA Class III — IV symptoms. Tracleer is the first drug in a class of drugs known as endothelin antagonists. Endothelin constricts blood vessels and is elevated in patients with pulmonary arterial hypertension. Tracleer and other endothelin antagonists are being used in combination with Remodulin or Flolan 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 of the largest competitors 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 competitors 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, 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 has 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.

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 or issue a not approvable letter, outlining the deficiencies in the submission and often requiring additional testing or information.

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.

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. 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 any of its drugs are 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 during the FDA regulatory review period for the related product. This period is generally one-half the time between the effective date of an investigational new drug application and the submission date of a new drug application, plus 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 is pending.

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 approval for the use of Remodulin for pulmonary arterial hypertension under the decentralized procedure and filed its first Marketing Authorization Application in France in February 2001. That review is currently ongoing. 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 filed in 2001 and 2002, respectively, and preliminary indications of approval were received in December 2003.

Arginine and telemedicine products are manufactured at contract facilities that are regulated by the FDA and required to follow the FDA's current *Good Manufacturing Practices*. Telemedicine products are subject to FDA regulation as medical devices. The devices, manufactured and sold by Medicomp, have received marketing approval from the FDA under Section 510(k) of the Food, Drug and Cosmetic Act.

## **Employees**

United Therapeutics had approximately 160 employees as of March 1, 2004. 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 16 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 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: 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 United Therapeutics' products; the existence, capabilities and activities of competitors; the adequacy of owned or leased facilities for operations; the expectation not to pay dividends on common stock in the foreseeable future; the extent of United Therapeutics' exposure to market risk; the ability to hold debt instrument investments to maturity; the statements identified as forward-looking statements in "Item 7 — Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this Annual Report on Form 10-K; and statements preceded by, followed by or that include the words "believes", "expects", "anticipates", "intends", "estimates", "may" or similar expressions. 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.

### *Risks Related to Our Business*

#### **Actual Revenues And Net Losses May Differ From United Therapeutics' Projections.**

United Therapeutics has made public its projections of its estimated Remodulin annual revenue run rates, estimated average monthly net losses, a range of potential 2004 consolidated revenues and a projection of achieving profitability in 2004. These projections were based on numerous factors and assumptions taken into consideration at the time the estimates were made, which factors and assumptions are inherently subject to a degree of uncertainty. As a result, the actual revenues and net losses may be greater or less than projected. Even small differences in the factors and assumptions can lead to significant changes in United Therapeutics' stock price. United Therapeutics had net losses of approximately \$10.0 million in 2003, \$23.7 million in 2002 and \$37.3 million in 2001.

Factors that could affect the accuracy of United Therapeutics' expectations of revenues and profits include the following:

- Retention of current patients;
- Addition of new patients to replace patients who discontinue Remodulin therapy;
- Remodulin side effects, including impact of infusion site pain and reaction;
- Changes in the current pricing and dosing of Remodulin;
- Willingness of private insurance companies, Medicare and Medicaid to reimburse Remodulin at current pricing levels;
- Continued regulatory approval of Remodulin;
- Additional regulatory approvals in other countries for Remodulin;

- Outcome of the Phase IV post-marketing study of Remodulin;
- Impact of other approved and investigational competitive products;
- Continued performance by current Remodulin distributors;
- Unforeseen expenses;
- Actual growth in sales of telemedicine and arginine products;
- Actual expenses incurred in future periods; and
- Establishment of additional strategic acquisitions or licensing arrangements.

Factors that could affect the accuracy of United Therapeutics' estimated net loss and capital requirements include the following:

- Continued regulatory approval of Remodulin;
- Retention and growth of patients treated with Remodulin;
- Collection of accounts receivable;
- Size, scope and outcome of the Remodulin post-marketing Phase IV clinical study;
- 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;
- Recovery of goodwill, intangible assets and investments in affiliates;
- Status of competitive products;
- 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; and
- Establishment of additional strategic acquisitions or licensing arrangements.

#### **United Therapeutics Has A History Of Losses And May Never Become Profitable.**

United Therapeutics has lost money since its inception in 1996, and its accumulated deficit was approximately \$195.8 million at December 31, 2003. United Therapeutics had net losses of approximately \$10.0 million, \$23.7 million and \$37.3 million in 2003, 2002 and 2001, respectively. United Therapeutics expects to incur additional losses and may never become profitable. United Therapeutics expects its quarterly and annual operating results to fluctuate, depending primarily on the following factors:

- 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; and
- Establishment of additional strategic acquisitions or licensing arrangements.

Most of United Therapeutics' pharmaceutical products are in clinical studies. United Therapeutics might not maintain or obtain new regulatory approvals for its pharmaceutical products and may not be able to sell its

pharmaceutical products commercially. Even if United Therapeutics sells its products, United Therapeutics may never be profitable and may not be able to sustain any profitability it achieves.

**If United Therapeutics Cannot Maintain Regulatory Approvals For Its Products, It Cannot Sell Those Products And Its 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 United Therapeutics receives 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 United Therapeutics' agreement 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 results of that trial. If approvals are withdrawn for a product, United Therapeutics cannot sell that product and its revenues will suffer. In addition, if product approvals are withdrawn, governmental authorities could seize United Therapeutics' products or force United Therapeutics to recall its products. Finally, United Therapeutics and its officers and directors could be subject to civil and criminal penalties for failure to comply with these regulatory requirements.

**If United Therapeutics' Products Fail In Clinical Studies, United Therapeutics Will Not Be Able To Obtain FDA And Foreign Approvals And Will Not Be Able To Sell Those Products.**

In order to sell its pharmaceutical products, United Therapeutics must receive regulatory approvals. To obtain those approvals, United Therapeutics must conduct clinical studies demonstrating that the drug and the delivery mechanism for the drug are safe and effective. If United Therapeutics cannot obtain approval from the United States Food and Drug Administration for a product, that product cannot be sold, and United Therapeutics' revenues will suffer.

On May 21, 2002, the 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 agreed to perform a post-marketing Phase IV clinical study to further assess the clinical benefits of Remodulin. The Phase IV study must be completed by December 2005, and continued FDA approval is conditioned on the completion and outcome of the Phase IV study. As of February 2004, approximately 11 patients had been enrolled in the 39 patient Phase IV study. Additionally, United Therapeutics has initiated a pre-pivotal clinical study of Remodulin in critical limb ischemia. The lead glycobiology antiviral agent, UT-231B, has completed acute and chronic Phase I clinical dosing studies in normal volunteers and is currently enrolling a Phase II, proof-of-concept study. United Therapeutics is also currently conducting two Phase III pivotal studies of OvaRex for the treatment of metastatic ovarian cancer. United Therapeutics is still completing or planning pre-clinical studies for its other products. United Therapeutics' 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;
- Other investigational or approved therapies are viewed as more effective by physicians;
- Patients experience severe side effects during treatment;
- 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;
- Patients do not enroll in the studies at the rate United Therapeutics expects;
- 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 United Therapeutics has demonstrated that its products are safe and effective.

**United Therapeutics' Products May Not Be Commercially Successful Because Physicians And Patients May Not Accept Them.**

Even if regulatory authorities approve United Therapeutics' products, these products may not be commercially successful. United Therapeutics expects that most of its products, including Remodulin, which is already approved by the United States Food and Drug Administration, will be very expensive. Patient acceptance of and demand for United Therapeutics' products will depend largely on the following factors:

- Acceptance by physicians and patients of United Therapeutics' products as safe and effective therapies;
- 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 United Therapeutics' products; and
- Prevalence and severity of side effects associated with United Therapeutics' products, including the infusion site pain and reaction associated with use of Remodulin.

**Discoveries Or Developments Of New Technologies By Others May Make United Therapeutics' Products Obsolete.**

Other companies may conduct research, make discoveries or introduce new products that render all or some of United Therapeutics' 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 United Therapeutics' products are intended. In addition, alternative approaches to treating chronic diseases, such as gene therapy, may make United Therapeutics' products obsolete or noncompetitive. One therapy approved in the United States in 2001 is Tracleer, an oral endothelin antagonist developed by Actelion, Ltd. which competes with Remodulin. United Therapeutics is aware that other endothelin antagonists are being developed, such as sitaxsentan by Encysive Pharmaceuticals, Inc. and ambrisentan by Myogen, Inc. United Therapeutics is also aware that sildenafil, being developed by Pfizer, Inc., is being studied for use in pulmonary hypertension. Also, iloprost, developed by Schering AG and approved in 2003 in Europe for pulmonary hypertension, is also being developed in the United States for pulmonary hypertension by CoTherix, Inc. Sildenafil and iloprost are currently approved for the treatment of other diseases.

**If Third-Party Payers Will Not Reimburse Patients For United Therapeutics' Drug Products Or If Third-Party Payers Limit the Amount of Reimbursement, Sales Will Suffer.**

United Therapeutics' commercial success will depend in part on third-party payers, such as Medicare, Medicaid and private insurance companies, agreeing to reimburse patients for the costs of United Therapeutics' pharmaceutical products. Third-party payers frequently challenge the pricing of new drugs. Remodulin and the associated infusion pump and supplies are very expensive. United Therapeutics believes its 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. Third-party payers may not approve United Therapeutics' new products for reimbursement or continue to approve Remodulin for reimbursement. If third-party payers do not approve a United Therapeutics' product for reimbursement or limit the amount of reimbursement, sales will suffer, as patients will opt for a competing product that is approved for reimbursement.

**United Therapeutics Relies On Third Parties To Develop, Market, Distribute And Sell Most of Its Products And Those Third Parties May Not Perform.**

United Therapeutics is currently marketing products in three of its 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. United Therapeutics does not have the ability to independently conduct clinical studies, obtain regulatory approvals, market, distribute or sell most of its products and intends to rely substantially on experienced third parties to perform all of those functions. United Therapeutics 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, United Therapeutics will be unable to obtain marketing approvals and will be unable to sell its products. Medtronic MiniMed is United Therapeutics' exclusive partner for the subcutaneous delivery of Remodulin using the MiniMed microinfusion device for pulmonary arterial hypertension. United Therapeutics is relying on Medtronic MiniMed's experience, expertise and performance. Similarly, United Therapeutics is relying on Accredo Therapeutics, Inc., Priority Healthcare Corporation and Caremark, Inc. to market, distribute, and sell Remodulin in the United States. If United Therapeutics' partners in the United States and internationally are unsuccessful in their efforts, United Therapeutics' revenues will suffer.

#### **United Therapeutics May Not Successfully Compete With Established Drug Companies.**

United Therapeutics competes with established drug companies during product development for, among other things, funding, access to licenses, expertise, personnel and third-party collaborators. United Therapeutics will also compete with these companies following approval of its 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 United Therapeutics.

United Therapeutics is aware of existing treatments that compete with its products. For the treatment of pulmonary arterial hypertension, approved products that compete with Remodulin include the intravenous prostacyclin, Flolan, marketed by GlaxoSmithkline PLC, and Tracleer, an oral endothelin antagonist marketed by Actelion, Ltd. With respect to the prostacyclin segment of the pulmonary arterial hypertension market, United Therapeutics estimates that approximately 15% of the patients being treated with prostacyclin in the United States are using Remodulin. Products that are being developed that may also compete with Remodulin include sitaxsentan being developed by Encysive Pharmaceuticals, Inc., ambrisentan, being developed by Myogen, Inc. and iloprost, being developed by CoTherix, Inc. Sildenafil, being developed by Pfizer, Inc., is currently approved for the treatment of a disease other than pulmonary arterial hypertension. Iloprost is currently approved for pulmonary hypertension and other diseases in Europe. 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 United Therapeutics' immunotherapeutic monoclonal antibody platform and glycobiology antiviral agents platform.

#### **If The Licenses And Assignments United Therapeutics Depends On Are Breached Or Terminated, United Therapeutics Would Lose Its Right To Develop And Sell The Products Covered By The Licenses And Assignments.**

United Therapeutics' 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 its product license agreements, United Therapeutics retains 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 United Therapeutics, subject to the terms of each assignment agreements. In addition, United Therapeutics has obtained and will be required to obtain licenses to other third-party technology to conduct its business, including licenses for its products and an agreement for the use of the MiniMed microinfusion device for the administration of Remodulin. This dependence has the following risks:

- United Therapeutics may not be able to obtain future licenses and assignments at a reasonable cost or at all;

- If any of United Therapeutics' licenses or assignments are terminated, United Therapeutics will lose its rights to develop and market some or all of its products;
- The licenses and assignments that United Therapeutics holds generally provide for termination by the licensor or assignor in the event United Therapeutics breaches 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) or Pfizer (formerly Pharmacia) terminate their assignment agreements (see *Patents and Proprietary Rights — Glaxo Wellcome Assignment and Pharmacia License*), United Therapeutics will have no further rights to utilize the assigned patents or trade secrets to develop and commercialize Remodulin. In the twelve-month period ended December 31, 2003, sales of Remodulin accounted for approximately 85% of United Therapeutics' revenues. GlaxoSmithkline or Pfizer could seek to terminate the assignment in the event that United Therapeutics failed to pay royalties based on sales of Remodulin; and
- If licensors fail to maintain the intellectual property licensed or assigned to United Therapeutics as required by most of United Therapeutics' license and assignment agreements, United Therapeutics may lose its rights to develop and market some or all of its products and may be forced to incur substantial additional costs to maintain the intellectual property itself or force the licensor or assignor to do so.

**If United Therapeutics' Patent And Other Intellectual Property Protection Is Inadequate, United Therapeutics' Sales And Profits Could Suffer Or Competitors Could Force United Therapeutics' Products Completely Out Of The Market.**

The United States patent for the method of treating pulmonary hypertension with Remodulin expires in 2009. 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 2018. United Therapeutics may not be able to extend these or any other patents. Competitors may develop products based on the same active ingredients as United Therapeutics' products, including Remodulin, and market those products after the patents expire, or may design around United Therapeutics' existing patents. If this happens, United Therapeutics' sales would suffer and United Therapeutics' profits could be severely impacted.

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

United Therapeutics has been granted a patent in the United States for the synthesis of Remodulin, but pending patent applications, which have been or may be filed by United Therapeutics, may not be issued. The scope of any patent issued may not be sufficient to protect United Therapeutics' technology. The laws of foreign jurisdictions in which United Therapeutics intends to sell its products may not protect United Therapeutics' rights to the same extent as the laws of the United States.

In addition to patent protection, United Therapeutics also relies on trade secrets, proprietary know-how and technology advances. United Therapeutics enters into confidentiality agreements with its employees and others, but these agreements may not be effective in protecting United Therapeutics' proprietary information. Others may independently develop substantially equivalent proprietary information or obtain access to United Therapeutics' know-how.

Litigation, which is very expensive, may be necessary to enforce or defend United Therapeutics' patents or proprietary rights and may not end favorably for United Therapeutics. Any of United Therapeutics' licenses, patents or other intellectual property may be challenged, invalidated, canceled, infringed or circumvented and may not provide any competitive advantage to United Therapeutics. The only current pending litigation to which United Therapeutics is a party relates to suits initiated by United Therapeutics against other parties believed to have violated United Therapeutics' patents related to its arginine products line.

**United Therapeutics Has Limited Experience With Manufacturing And Depends On Third Parties, Who May Not Perform, To Synthesize And Manufacture Many Of Its Products.**

United Therapeutics itself has limited experience with manufacturing. In October 1999, United Therapeutics acquired SynQuest, Inc., a company that manufactured treprostinil, the bulk active ingredient in Remodulin, for United Therapeutics. In December 2000, SynQuest was dissolved and merged into United Therapeutics as its synthesis and manufacturing division. Prior to the acquisition of SynQuest, United Therapeutics had no experience with manufacturing. Even though United Therapeutics retained the employees and managers of SynQuest in connection with the acquisition, United Therapeutics may be unsuccessful in maintaining drug manufacturing operations.

United Therapeutics relies on third parties for the manufacture of all its products other than Remodulin. United Therapeutics relies on Baxter Healthcare Corporation for the formulation of Remodulin. United Therapeutics relies on Cardinal Health to test the purity of each batch of Remodulin and other products that United Therapeutics is developing. United Therapeutics relies on Nellson Nutraceutical and Garden State Nutritionals to manufacture its arginine products. United Therapeutics relies exclusively on Toray Industries, Inc. to manufacture beraprost. United Therapeutics relies on other manufacturers to make its experimental 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 United Therapeutics' research and development efforts, and future sales efforts. United Therapeutics' manufacturing strategy presents the following risks:

- The manufacturing processes for some of United Therapeutics' 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 United Therapeutics' products;
- A long lead time is needed to manufacture Remodulin, and the manufacturing process is complex;
- United Therapeutics and manufacturers of United Therapeutics' products are subject to the FDA's good manufacturing practices regulations and similar foreign standards, and although United Therapeutics controls compliance issues with respect to synthesis and manufacturing conducted internally, United Therapeutics does not have control over compliance with these regulations by its third-party manufacturers;
- If United Therapeutics has to change to another manufacturing contractor or abandon its 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;
- Without satisfactory long-term agreements with its manufacturers, United Therapeutics will not be able to develop or commercialize its products, other than Remodulin, as planned or at all and will have to rely solely on internal manufacturing capacity;
- Without substantial experience in operating a manufacturing facility, United Therapeutics may not be able to successfully continue to manufacture Remodulin; and
- United Therapeutics 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 its products.

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



**United Therapeutics 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 United Therapeutics currently has product liability insurance covering claims up to \$15 million per occurrence, United Therapeutics 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 United Therapeutics' liability insurance coverage, United Therapeutics may go out of business.

**If United Therapeutics' Highly Qualified Management And Technical Personnel Leave United Therapeutics, Its Business May Suffer.**

United Therapeutics is dependent on its current management, particularly its founder and Chief Executive Officer, Martine Rothblatt, Ph.D., its President and Chief Operating Officer, Dr. Roger Jeffs, Ph.D., its Executive Vice President for Business Development and Chief Financial Officer, Fred Hadeed, and its Executive Vice President for Strategic Planning, General Counsel and Corporate Secretary, Paul Mahon, all of whom are employed pursuant to multi-year employment agreements. United Therapeutics does not maintain key person life insurance on these officers. United Therapeutics' success will depend in part on retaining the services of its 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.

**United Therapeutics May Not Have, Or May Have To Share Rights To, Future Inventions Arising From Its Outsourcing Agreements And May Lose Potential Profits Or Savings.**

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

**If United Therapeutics Needs Additional Financing And Cannot Obtain It, Product Development And Sales May Be Limited.**

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

***Risks Related to Owning United Therapeutics' Common Stock***

**United Therapeutics' 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 United Therapeutics' common stock for the periods indicated:

	<b>High</b>	<b>Low</b>
January 1, 2002 – December 31, 2002	\$17.61	\$ 9.10
January 1, 2003 – December 31, 2003	\$24.65	\$14.70

United Therapeutics' 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 and United Therapeutics' projections;
- Rate of product acceptance;
- Public concern as to the safety of products developed by United Therapeutics or by others;
- Announcements by United Therapeutics or others of technological innovations or new products;
- Developments in patent or other proprietary rights;
- Establishment of additional strategic acquisitions or licensing arrangements;
- Future sales of substantial amounts of common stock by existing United Therapeutics' stockholders;
- Future sales of common stock by United Therapeutics' directors or officers;
- Results of clinical trials;
- Maintaining approvals to sell Remodulin;
- Timing and outcome of additional regulatory approvals; and
- General market conditions.

#### **Future Sales Of Shares May Depress The Stock Price.**

If the stockholders sell a substantial number of shares of United Therapeutics' common stock in the public market, or investors become concerned that substantial sales might occur, the market price of the common stock could decrease. Such a decrease could make it difficult for United Therapeutics 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 United Therapeutics' 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 United Therapeutics And The Public Stockholders.**

Certain provisions of United Therapeutics' amended and restated certificate of incorporation, amended and restated 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 United Therapeutics' securities; and
- The replacement or removal of current management by United Therapeutics' stockholders.

For example, United Therapeutics' amended and restated 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.

United Therapeutics has a shareholder rights plan designed to discourage takeovers that involve abusive tactics or do not provide fair value to shareholders. Generally, the shareholder rights plan requires a hostile purchaser to pay a price per share that is substantially higher than the current quoted price of United Therapeutics' common stock.

Provisions of United Therapeutics' amended and restated certificate of incorporation and the shareholder rights plan could discourage or make more difficult, a merger or other change of control transaction, whether or not the transaction is favored by current management or would be favorable to United Therapeutics' stockholders. In addition, these provisions may make removal of current management by United Therapeutics' stockholders more difficult, even if such removal would generally be beneficial to the stockholders.

**Existing Directors And Executive Officers Of United Therapeutics Own A Substantial Block Of Stock And Might Be Able To Direct The Outcome Of Matters Requiring Stockholder Approval.**

United Therapeutics' directors and named executive officers beneficially own approximately 13 percent of its outstanding common stock as of March 1, 2004. Accordingly, these stockholders as a group might be able to direct the outcome of matters requiring approval by United Therapeutics' stockholders, including the election of its directors. Such stockholder control could delay or prevent a change of control of United Therapeutics.

**If Stockholders Do Not Receive Dividends, Stockholders Must Rely On Stock Appreciation For Any Return On Their Investment In United Therapeutics.**

United Therapeutics has never declared or paid cash dividends on any of its capital stock. United Therapeutics currently intends to retain its earnings for future growth and therefore does not anticipate paying cash dividends in the future.

## EXECUTIVE OFFICERS OF THE REGISTRANT

The following is a list, as of March 1, 2004, 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 shareholders, 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 a term of service of five years.

Name	Age	Position
Martine A. Rothblatt, Ph.D., J.D., M.B.A.	49	Chairman, Chief Executive Officer and Director
Roger Jeffs, Ph.D.	42	President, Chief Operating Officer and Director
Paul A. Mahon, J.D.	40	Executive Vice President for Strategic Planning, General Counsel and Corporate Secretary
Fred T. Hadeed	39	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. 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.

*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. 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, Medcomp, 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 also owns three buildings and land adjacent to its corporate

headquarters in Silver Spring, Maryland and has committed to purchasing an additional adjacent lot. 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***

The Federal Trade Commission (FTC), through the staff of the FTC's Division of Advertising Practices, has reviewed certain advertising and promotional claims made by Unither Pharma, Inc., a wholly owned subsidiary of United Therapeutics, about the HeartBar product line, including claims made prior to United Therapeutics' acquisition of HeartBar and certain other assets and liabilities of Cooke PH, Inc. (formerly Cooke Pharma, Inc.) in December 2000. As a result of the review, on July 20, 2003, the FTC issued a final consent order based upon a settlement agreement with United Therapeutics and Unither Pharma, Inc. relating to certain advertising and promotional claims made about the HeartBar product line. The order prohibits the making of claims concerning the beneficial cardiovascular effects of L-arginine supplementation therapy without supporting competent and reliable scientific evidence. It also prohibits the making of any unsubstantiated claims about the health benefits, performance, or efficacy of any food, medical food, or dietary supplement used in or marketed for the treatment, cure, or prevention of cardiovascular disease. The settlement contains certain notice and enforcement obligations. Violation of the terms of the settlement may result in fines, penalties and other restrictions that could adversely affect the assets and operations of United Therapeutics. United Therapeutics does not believe that the settlement agreement will have a material adverse effect on United Therapeutics' assets and operations.

**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:

	2003		2002	
	High	Low	High	Low
January 1 – March 31	\$17.24	\$14.70	\$13.46	\$ 9.10
April 1 – June 30	\$23.24	\$16.57	\$15.31	\$11.50
July 1 – September 30	\$24.65	\$18.14	\$17.01	\$10.35
October 1 – December 31	\$23.49	\$18.29	\$17.61	\$14.00

As of March 1, 2004, there were 99 holders of record of common stock. United Therapeutics estimates that included within the holders of record are approximately 3,000 beneficial owners of common stock. As of March 1, 2004, the closing price for the common stock was \$21.06.

#### Dividend Policy

United Therapeutics has never paid and does not intend to pay any dividends on the common stock in the foreseeable future but intends to retain any earnings for use in its business operations.

#### Recent Sales of Unregistered Securities

At various times throughout 2003, United Therapeutics issued options to consultants in exchange for services pursuant to Section 4(2) of the Securities Act of 1933. The aggregate number of these options was 7,667. 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 preceding the grant of each of these options. The exercise prices ranged from \$16.17 to \$17.10 and these options vest over a period of up to one year.

## 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,				
	2003	2002	2001	2000	1999
<b>Consolidated Statements of Operations Data:</b>					
Revenues	\$ 53,341	\$ 30,120	\$ 5,731	\$ 2,049	\$ 436
Operating expenses:					
Research and development	35,417	26,778	32,590	70,188	30,715
Selling, general and administrative	22,667	15,889	16,943	11,736	4,978
Cost of sales	6,783	5,456	3,137	1,626	164
Total operating expenses	64,867	48,123	52,670	83,550	35,857
Loss from operations	(11,526)	(18,003)	(46,939)	(81,501)	(35,421)
Other income (expense):					
Interest income	2,435	4,954	10,021	10,693	1,925
Interest expense	(112)	(117)	(173)	(120)	(58)
Equity loss in affiliate	(953)	(209)	(257)	—	—
Write-down of investment	—	(2,893)	—	(4,790)	—
Loss on marketable investments	—	(7,428)	—	—	—
Other, net	187	45	60	109	50
Total other income (expense), net	1,557	(5,648)	9,651	5,892	1,917
Net loss before income tax	(9,969)	(23,651)	(37,288)	(75,609)	(33,504)
Income tax	—	—	—	—	(3)
Net loss	\$ (9,969)	\$ (23,651)	\$ (37,288)	\$ (75,609)	\$ (33,507)
Net loss per common share — basic and diluted (1)	\$ (0.47)	\$ (1.15)	\$ (1.84)	\$ (3.93)	\$ (2.51)
Weighted average number of common shares outstanding — basic and diluted	21,135	20,644	20,286	19,237	13,374
<b>As of December 31,</b>					
	2003	2002	2001	2000	1999
<b>Consolidated Balance Sheet Data:</b>					
Cash, cash equivalents and marketable investments	\$ 117,337	\$ 132,655	\$ 172,299	\$ 215,419	\$ 51,596
Total assets	179,502	184,566	212,121	250,645	59,943
Notes and leases payable (2)	798	1,878	1,938	1,907	1,841
Accumulated deficit	(195,790)	(185,821)	(162,170)	(124,882)	(49,273)
Total stockholders' equity	167,765	171,658	196,399	234,738	53,566

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

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



## **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 and the Private Securities Litigation Reform Act of 1995 concerning, among other things, the pricing of Remodulin, the rate of patient consumption of Remodulin, the impacts of price changes and changes in patient consumption of Remodulin on future revenues, the funding of operations from future revenues, the expectation of continued losses, expectations concerning milestone and royalty payments in 2004, the use of net operating loss carryforwards and business tax credit carryforwards, the completion of in-process research and development products, the 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 2006, the timing and level of spending to construct a laboratory production facility, the potential impacts of new accounting standards, 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 therapeutic products to treat chronic and life-threatening cardiovascular, infectious and oncological 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 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 agreed with the FDA that it would perform a post-marketing Phase IV clinical study to further assess the clinical benefits of Remodulin. The Phase IV study commenced in late 2002 and the final study report must be submitted to the FDA by December 2005. Continued FDA approval is conditioned on the completion and outcome of the Phase IV study. In 2002, Remodulin was approved for use in Canada and Israel. In December 2003, Switzerland and Australia announced that they would approve Remodulin pending final labeling and a commitment to perform a drug interaction study in Switzerland. A marketing authorization application for the approval of Remodulin in France is under review.

United Therapeutics has generated pharmaceutical revenues from sales of Remodulin and arginine-enriched nutritional products in the United States and Europe. In addition, United Therapeutics has generated non-pharmaceutical revenues from telemedicine products and services in the United States primarily designed for patients with cardiac arrhythmias and ischemic heart disease. 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 dangerous 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. As of December 31, 2003, approximately 670 patients were receiving Remodulin therapy worldwide, of whom approximately 555 (approximately 575 at January 31, 2004) were paying for Remodulin (reimbursable patients). Virtually all of the patients who do not yet pay for Remodulin (non-reimbursable patients) reside in countries where Remodulin has not yet been approved.

### ***Future Prospects***

United Therapeutics has incurred net losses each year since inception and has an accumulated deficit of approximately \$195.8 million at December 31, 2003. United Therapeutics expects to continue to incur net losses and cannot provide assurances that, in the future, it will become profitable. Future profitability will depend on many factors, including the pricing and sales of Remodulin and other currently commercialized products, 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***

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 FDA approval is that a Phase IV clinical study must be completed with a final study report submitted to the FDA by December 2005. The Phase IV study is currently being enrolled. Remodulin was also approved in Canada and Israel in October 2002 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.

Remodulin is also being developed for the treatment of critical limb ischemia (the advanced stage of vascular disease affecting blood vessels in the legs). United Therapeutics has completed one Phase II clinical study and an additional clinical study is underway. United Therapeutics is also developing Remodulin as an intravenous therapy for pulmonary arterial hypertension. 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 February 2004, United Therapeutics filed a supplemental New Drug Application (sNDA) with the FDA for intravenous use of Remodulin in pulmonary hypertension. The sNDA is under review. Additionally, United Therapeutics is in very early stages of developing other formulations of Remodulin. United Therapeutics incurred expenses of approximately \$13.5 million, \$8.8 million, and \$22.5 million during the years ended December 31, 2003, 2002 and 2001, respectively, on Remodulin development. Approximately \$124.6 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 commenced in January 2003 and are expected to require two to three years to become fully enrolled. United Therapeutics incurred expenses of approximately

\$10.0 million and \$6.4 million during the years ended December 31, 2003 and 2002, respectively, on OvaRex development. Approximately \$16.4 million from inception to date has been incurred on OvaRex development.

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

United Therapeutics' infectious disease program includes 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 are expected to become fully enrolled in 2004. United Therapeutics incurred expenses of approximately \$7.1 million, \$6.9 million, and \$5.7 million during the years ended December 31, 2003, 2002 and 2001, respectively, for its infectious disease programs. Approximately \$28.4 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 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 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 at December 31, 2003 were approximately \$117.3 million, as compared to approximately \$132.7 million at December 31, 2002. The decrease of approximately \$15.4 million is due primarily to cash used by operating activities of approximately \$8.6 million and approximately \$7.0 million used to purchase property, plant and equipment.

Property, plant and equipment at December 31, 2003 was approximately \$15.2 million, as compared to \$9.1 million at December 31, 2002. The increase of approximately \$6.1 million was due primarily to the purchases of a building and land adjacent to United Therapeutics' headquarters, building improvements and equipment.

At December 31, 2003, total liabilities were approximately \$11.7 million, as compared to approximately \$12.9 million at December 31, 2002 and consisted primarily of trade payables, accrued expenses and notes payable. The decrease in total liabilities of approximately \$1.2 million was due primarily to paying off both mortgage notes for approximately \$1.7 million and a reduction in the due to affiliates of approximately \$2.7 million, offset by increases in accrued expenses, and the addition of a \$1.0 million note payable resulting from the purchase of a building and land adjacent to United Therapeutics' headquarters. This non-interest bearing note payable was paid in January 2004.

At December 31, 2003, total stockholders' equity was approximately \$167.8 million, as compared to \$171.7 million at December 31, 2002. The decrease in stockholders' equity of approximately \$3.9 million was due primarily to the net loss of approximately \$10.0 million incurred during the year ended December 31, 2003, offset by proceeds totaling approximately \$4.1 million received from the exercise of stock options.

## Results Of Operations

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

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 was due primarily to United Therapeutics' 2003 sales of approximately \$45.1 million of Remodulin and approximately \$1.7 million of pumps and supplies to distributors in connection with Remodulin, as compared to 2002 sales of approximately \$21.2 million of Remodulin and approximately \$3.7 million of pumps and supplies. In addition, 2003 sales of other products and services increased in the aggregate by approximately \$1.3 million to approximately \$6.5 million.

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. Therefore, patients are expected to use Remodulin vials for longer than 14 days and, accordingly, consume fewer vials annually. The 10 mg concentration price increase discussed above could increase future net sales of Remodulin, while the increase in the period of stability could decrease future net sales of Remodulin.

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 \$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 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 \$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 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 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, 2002 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.

Equity loss in affiliate represents United Therapeutics' share of Northern Therapeutics, Inc.'s losses. At December 31, 2003, United Therapeutics owned approximately 68% of Northern Therapeutics. 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.

#### ***Years ended December 31, 2002 and 2001***

Revenues for the year ended December 31, 2002 were approximately \$30.1 million, as compared to approximately \$5.7 million for the year ended December 31, 2001. The increase was due primarily to United Therapeutics' 2002 sales of approximately \$21.2 million of Remodulin and approximately \$3.7 million of pumps and supplies to distributors in connection with Remodulin, as compared to 2001 sales of approximately \$493,000 of Remodulin and approximately \$1.1 million of pumps and supplies. In addition, 2002 sales of other products and services increased in the aggregate by approximately \$1.1 million to approximately \$5.2 million.

Research and development expenses were approximately \$26.8 million for the year ended December 31, 2002, as compared to approximately \$32.6 million for the year ended December 31, 2001. The decrease of approximately \$5.8 million was due primarily to a decrease from 2001 to 2002 in expenses related to patient enrollment in clinical trials of approximately \$12.9 million offset by an increase in 2002 of approximately \$7.8 million related to expenses for United Therapeutics' infectious disease program and the OvaRex program, which was licensed to United Therapeutics in April 2002. See *Major Research and Development Projects* above for additional information.

Selling, general and administrative expenses were approximately \$15.9 million for the year ended December 31, 2002, as compared to approximately \$16.9 million for the year ended December 31, 2001. This decrease of approximately \$1.0 million was due primarily to decreased expenses of approximately \$1.1 million related to the transfer of certain employees and related expenses from third party contract manufacturing activities to internal research and development functions, amortization of goodwill of approximately \$1.1 million for the year ended December 31, 2001 with no corresponding amount in 2002 (due to the adoption of SFAS No. 142 on January 1, 2002 which eliminated goodwill amortization) and decreased advertising expenses of approximately \$1.4 million. These decreases were offset by increases in expenses related primarily to increased salaries and benefits of approximately \$2.1 million.

Cost of product sales was approximately 14% of product sales for the year ended December 31, 2002, as compared to approximately 57% in 2001. 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. In 2001, product sales consisted largely of Remodulin pumps and supplies which were sold to Remodulin distributors at their acquisition cost. Cost of service sales was approximately 49% of service sales for the year ended December 31, 2002, as compared to approximately 55% in 2001. The decrease in the cost of service sales as a percentage of service sales was due primarily to the growth in telemedicine service sales, which generated higher margins than other service sales.

Interest income for the year ended December 31, 2002 was approximately \$5.0 million, as compared to approximately \$10.0 million for the year ended December 31, 2001. This decrease of approximately \$5.0 million was attributable primarily to lower yields in 2002 and a decrease in the amount of cash available for investing as compared to 2001.

The write-down of investment in 2002 represents a loss due to an other-than-temporary decline in value of the investment in AltaRex. 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 write-down totaled approximately \$2.9 million. The fair value of this investment as determined by quoted market prices on December 31, 2002 was equivalent to the amount reported in the consolidated balance sheet.

The loss on marketable investments for the year ended December 31, 2002 was approximately \$7.4 million, as compared to none for the year ended December 31, 2001. 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.

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

During 2000, United Therapeutics acquired the assets and assumed certain liabilities of Cooke Pharma, Inc. in a purchase transaction which resulted in a write-off of in-process research and development (IPR&D) related to in-process projects that had not yet reached technological feasibility and had no alternative future

uses. The projects under development at the valuation date involved HeartBar products and were expected to address the coronary and peripheral arterial disease markets as well as the market of persons that are at risk of developing some form of heart disease. It was anticipated that research and development related to these projects would be completed by 2002. However, United Therapeutics decided to initiate studies of arginine in pulmonary hypertension prior to coronary and peripheral arterial diseases. These studies in pulmonary hypertension commenced in 2002 and were expected to be completed in 2003, but were terminated in April 2003 due to lack of enrollment. Additionally, due to recent discussions with regulatory authorities, United Therapeutics decided that HeartBar products will no longer be marketed as medical foods, which are regulated by the FDA, but instead as nutritional supplements. As a result, studies are no longer necessary to support HeartBar's classification as a medical food. In addition, there are a growing number of medical and scientific individuals and organizations investigating the cardiovascular efficacy of L-arginine, the key active ingredient in HeartBar. Consequently, United Therapeutics' studies in coronary and peripheral arterial diseases are no longer necessary for United Therapeutics' business plan and will not be performed by United Therapeutics.

Also during 2000, United Therapeutics acquired the assets of Medicomp, Inc. in a purchase transaction that resulted in a write-off of IPR&D 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. It was anticipated that completion of these projects would occur in 2001. While some of these have been completed, completion of others is now expected to occur in phases during 2004. This delay 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 2003, United Therapeutics funded the majority of its operations from revenues, mainly Remodulin related, and this is expected to continue.

United Therapeutics' working capital at December 31, 2003 was approximately \$79.1 million, as compared with approximately \$132.6 million at December 31, 2002. The decrease in working capital was due primarily to the net purchase of approximately \$38.7 million of non-current debt securities issued by United States government sponsored agencies and approximately \$7.0 million for the purchases of a building and land, building improvements and equipment. Current liabilities at December 31, 2003 were approximately \$10.6 million, as compared with approximately \$9.3 million at December 31, 2002. United Therapeutics' debt at December 31, 2003 was approximately \$798,000 as compared with \$1.9 million at December 31, 2002 and consisted of equipment leases and one mortgage note secured by the building and property owned by United Therapeutics located at 1100 and 1102 Spring Street in Silver Spring, Maryland. Two mortgage notes totaling approximately \$1.7 million were paid off in October 2003. The one mortgage note totaling approximately \$750,000 remaining at December 31, 2003 came due and was paid off in January 2004.

Net cash used in operating activities was approximately \$8.6 million and \$22.3 million for the years ended December 31, 2003 and 2002, respectively. For the years ended December 31, 2003 and 2002, United Therapeutics invested approximately \$7.0 million and \$3.6 million, respectively, in cash for property, plant and equipment. For the years ended December 31, 2003 and 2002, United Therapeutics invested \$2.5 million and \$500,000, respectively, in Northern Therapeutics, Inc. For the year ended December 31, 2003, United Therapeutics used approximately \$38.1 million of cash to purchase marketable investments, net of sales and maturities. For the year ended December 31, 2002, United Therapeutics generated approximately \$129.3 million of cash from sales and maturities of marketable investments, net of reinvestments. Net cash provided by financing activities for the year ended December 31, 2003 and 2002 were approximately \$2.0 million and

\$185,000, respectively. The cash provided by financing activities was due primarily from the exercise of stock options, less amounts used to repay notes payable.

United Therapeutics believes that sales of Remodulin to distributors for use by the current base of approximately 555 reimbursable patients at December 31, 2003 (575 reimbursable patients at January 31, 2004) in the US and Europe could provide an average annual revenue to United Therapeutics of approximately \$55.0 million based on current pricing and dosing levels. United Therapeutics believes that its total revenues, together with existing capital resources (comprised primarily of cash, cash equivalents and marketable investments) will be adequate to fund its operations through 2006. Factors that could cause actual results of operations to differ from these expectations include the following:

- Continued regulatory approval of Remodulin;
- Expansion of existing regulatory approvals of Remodulin to include intravenously delivered Remodulin;
- Additional regulatory approvals in other countries for Remodulin;
- 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;
- Impact of medical and scientific opinion on all United Therapeutics' products;
- Size, scope and outcome of Remodulin post-marketing Phase IV clinical studies;
- Cost, timing and outcomes of regulatory reviews;
- Rate of technological advances;
- Continued performance by current Remodulin distributors;
- 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.

As of December 31, 2003, United Therapeutics had available approximately \$124.2 million in net operating loss carryforwards and approximately \$29.3 million in business tax credit carryforwards for federal income tax purposes that expire at various dates through 2023. The portions of these carryforward items that were generated prior to June 1999 are subject to certain limitations. United Therapeutics does not believe that the limitations will cause the net operating loss and general business credit carryforwards to expire unused.



In October 2003, United Therapeutics agreed to purchase for approximately \$2.9 million a lot adjacent to its Silver Spring, Maryland headquarters to construct laboratory facilities and United Therapeutics expects that this purchase will close in 2004. United Therapeutics currently expects to spend an estimated \$30.0 million over the next three years to construct this facility and it is currently in the planning phase. United Therapeutics is investigating various financing alternatives for the construction project. United Therapeutics expects to make milestone payments totaling \$20,000 pursuant to existing license agreements during 2004. United Therapeutics will make royalty payments on sales of Remodulin which exceed annual net sales of \$25.0 million and on all arginine products during 2004. Royalties on sales of all products in 2004 will range up to 10.0% of sales of those products.

In December 2000, a subsidiary of United Therapeutics acquired the assets of Medcomp, Inc. and Telemedical Procedures, LLC (together referred to as Medcomp). Under terms of the acquisition agreement, United Therapeutics is required to issue additional shares to the sellers 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. It is expected that approximately 600,000 shares of United Therapeutics common stock will be issued to the sellers in 2004 in satisfaction of this obligation.

## Contractual Obligations

At December 31, 2003, United Therapeutics had contractual obligations coming due approximately as follows (in thousands):

	Payment Due In				
	Total	Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
Long-term debt obligations	\$ 749	\$ 749	\$ —	\$ —	\$ —
Capital lease obligations	49	24	25	—	—
Operating lease obligations	5,679	1,127	2,402	1,436	714
Purchase obligations(1)	2,880	2,880	—	—	—
Other long-term liabilities reflected in the statement of financial position(2)	1,000	—	1,000	—	—
Milestone payments(3)	7,845	20	315	5,490	2,020
	<u>\$18,202</u>	<u>\$4,800</u>	<u>\$3,742</u>	<u>\$6,926</u>	<u>\$2,734</u>

- (1) Purchase obligations include approximately \$2.9 million related to the purchase in 2004 of a lot adjacent to United Therapeutics headquarters.
- (2) Other long-term liabilities include payments that will be made to Northern Therapeutics to fund United Therapeutics' equity investment in Northern Therapeutics.
- (3) 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 issues 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 the net losses. Prompt payment discounts and government rebates are estimated and recognized as reductions of revenue in the same period that revenues are recognized. Had these discounts and rebates 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 the net losses. Return policies provide that product that has expired or become damaged in shipment may be replaced, but not returned. Therefore, reserves for returns are not recorded unless product expiration or damage occurs.

### ***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 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, 2003, 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, 2003, the amortized cost of these debt securities was approximately \$48.8 million and their fair values were approximately \$48.3 million.

### ***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 which generally does not require that options granted to employees be expensed. Had United Therapeutics applied the fair value principles of SFAS No. 123, *Accounting for Stock-Based Compensation*, for its employee options, its net loss for the years ended December 31, 2003, 2002 and 2001 would have increased to approximately \$22.9 million, \$41.7 million and \$50.3 million, respectively, as compared to approximately \$10.0 million, \$23.7 million and \$37.3 million, respectively. The Financial Accounting Standards Board has indicated it will likely require that companies expense employee options in the future, but it has not yet finalized the timing or methods for such a change.

### ***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%, 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% 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 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, 2003, the investment in AltaRex was increased by approximately \$1.7 million to reflect its fair value at December 31, 2003, based on quoted market prices. This increase was reported as other comprehensive income.

#### ***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.

#### **Recent Accounting Pronouncements**

##### ***Disposal Activities***

In June 2002, the Financial Accounting Standards Board issued SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* (SFAS 146). SFAS 146 addresses the financial accounting and reporting for costs associated with exit or disposal activities and is effective for exit or disposal activities initiated after December 31, 2002. SFAS No. 146 was adopted effective January 1, 2003, and did not have a significant impact on United Therapeutics' financial statements.

##### ***Variable Interest Entities***

In January 2003, the Financial Accounting Standards Board (FASB) issued Interpretation No. 46 (FIN 46), *Consolidation of Variable Interest Entities*. FIN 46 requires that if an entity has a controlling financial interest in a variable interest entity, the assets, liabilities and results of activities of the variable interest entity should be included in the consolidated financial statements of the controlling entity. FIN 46 requires that its provisions are effective immediately for all arrangements entered into after January 31, 2003. For any arrangements entered into prior to January 31, 2003, the provisions of FIN 46 are required to be adopted at the beginning of the first interim or annual period beginning after December 15, 2003. The adoption of FIN 46 on December 15, 2003, did not have a significant impact on United Therapeutics' consolidated financial statements.

##### ***Derivative Instruments and Hedging Activities***

In April 2003, the FASB issued SFAS No. 149, *Amendment of Statement 133 on Derivative Instruments and Hedging Activities*. SFAS No. 149 amends and clarifies certain provisions of SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities* for contracts entered into after June 30, 2003. The adoption

of SFAS No. 149 on June 30, 2003 did not have an impact on United Therapeutics' consolidated financial statements.

### ***Financial Instruments***

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*. SFAS No. 150 establishes standards for the classification and measurement of certain financial instruments with characteristics of both liabilities and equity. SFAS No. 150 was adopted effective September 15, 2003 and did not have an impact on United Therapeutics' consolidated financial statements.

### ***Guarantees***

In November 2002, the FASB issued Interpretation No. 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others* (FIN 45). FIN 45 elaborates on the disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under certain guarantees that it has issued. It also clarifies that a guarantor is required to recognize, at the inception of a guarantee, a liability for the fair value of the obligation undertaken in issuing the guarantee. The initial recognition and initial measurement provisions of FIN 45 are applicable on a prospective basis to guarantees issued or modified after December 31, 2002. The disclosure requirements of FIN 45 are effective for financial statements of interim or annual periods ending after December 15, 2002. Adoption of FIN 45 did not have a significant effect on United Therapeutics' consolidated financial statements.

### **Item 7A. *Quantitative and Qualitative Disclosures About Market Risk***

At December 31, 2003, 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 instrument would be expected to decrease. The opposite is also true. To minimize such market risk, United Therapeutics holds such instruments to maturity at which time these instruments would be redeemed at their stated or face value. At December 31, 2003, United Therapeutics had approximately \$48.8 million in debt securities issued by federally sponsored agencies with a weighted average stated interest rate of approximately 3.1% maturing through December 2010 and callable annually. The fair market value of this portfolio at December 31, 2003 was approximately \$48.3 million. Included in this total are two Federal Home Loan Mortgage Corporation ("Freddie Mac") notes in the amounts of \$10.0 million and \$20.0 million at December 31, 2003. The Freddie Mac notes are callable annually, mature in 2009 and bear stated interest rates of 3% and 3.25% respectively, which automatically increase by 50 basis points each year.

**ITEM 8:    *Financial Statements and Supplementary Data***

**UNITED THERAPEUTICS CORPORATION**

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## INDEPENDENT AUDITORS' REPORT

The Board of Directors  
United Therapeutics Corporation:

We have audited the accompanying consolidated balance sheet of United Therapeutics Corporation as of December 31, 2003, and the related consolidated statements of operations, stockholders' equity, and cash flows for the year then ended. Our audit also included the financial statement schedules 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 auditing standards generally accepted in the 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 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 audit provides 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, 2003, and the consolidated results of its operations and its cash flows for the year ended December 31, 2003, in conformity with accounting principles generally accepted in the United States. Also, in our opinion, the related financial statement schedules taken as a whole, present fairly in all material respects the information set forth therein.

ERNST & YOUNG LLP

McLean, Virginia  
February 20, 2004

## INDEPENDENT AUDITORS' REPORT

The Board of Directors  
United Therapeutics Corporation:

We have audited the accompanying consolidated balance sheet of United Therapeutics Corporation and subsidiaries (the Company) as of December 31, 2002, 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, 2002. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. 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 audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of United Therapeutics Corporation and subsidiaries as of December 31, 2002, and the results of their operations and their cash flows for each of the years in the two-year period ended December 31, 2002, in conformity with accounting principles generally accepted in the United States of America.

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"*.

KPMG LLP

McLean, Virginia  
February 28, 2003

**UNITED THERAPEUTICS CORPORATION**  
**CONSOLIDATED BALANCE SHEETS**  
(In thousands, except share and per share data)

	December 31,	
	2003	2002
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 68,562	\$ 122,655
Accounts receivable, net of allowance of \$119 for 2003 and \$268 for 2002	10,151	9,649
Interest receivable	461	10
Prepaid expenses	1,874	1,234
Inventories	8,116	7,164
Due from affiliate	81	—
Other current assets	476	1,145
Total current assets	89,721	141,857
Marketable investments	48,775	10,000
Certificate of deposit	—	641
Goodwill, net	7,465	7,465
Other intangible assets, net	6,446	7,001
Property, plant, and equipment, net	15,225	9,120
Investments in affiliates	7,221	6,388
Note receivable from affiliates	433	433
Note receivable from employee and other assets	4,216	1,661
Total assets	\$ 179,502	\$ 184,566
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 4,324	\$ 2,988
Accounts payable to affiliates	2	—
Accrued expenses	5,459	4,451
Due to affiliates	1	1,706
Current portion of notes and leases payable	773	111
Other current liabilities	59	51
Total current liabilities	10,618	9,307
Notes and leases payable, excluding current portion	25	1,767
Due to affiliates	946	1,813
Other liabilities	148	21
Total liabilities	11,737	12,908
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, 21,836,342 and 21,449,470 shares issued at December 31, 2003 and 2002, respectively, and 21,309,742 and 20,922,870 outstanding at December 31, 2003 and 2002, respectively	218	215
Additional paid-in capital	368,537	364,130
Accumulated other comprehensive income	1,674	8
Treasury stock at cost, 526,600 shares	(6,874)	(6,874)
Accumulated deficit	(195,790)	(185,821)
Total stockholders' equity	167,765	171,658
Total liabilities and stockholders' equity	\$ 179,502	\$ 184,566

See accompanying notes to consolidated financial statements.





**UNITED THERAPEUTICS CORPORATION**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
(In thousands, except share and per share data)

**For Years Ended December 31,**

	<b>2003</b>	<b>2002</b>	<b>2001</b>
Revenues:			
Net product sales	\$ 49,715	\$ 26,677	\$ 2,565
Service sales	3,626	3,443	2,529
Service sales to affiliates	—	—	541
Grant revenue	—	—	96
Total revenue	<u>53,341</u>	<u>30,120</u>	<u>5,731</u>
Operating expenses:			
Research and development	35,417	26,778	32,590
Selling, general and administrative	22,667	15,889	16,943
Cost of product sales	4,994	3,757	1,458
Cost of service sales	1,789	1,699	1,679
Total operating expenses	<u>64,867</u>	<u>48,123</u>	<u>52,670</u>
Loss from operations	(11,526)	(18,003)	(46,939)
Other income (expense):			
Interest income	2,435	4,954	10,021
Interest expense	(112)	(117)	(173)
Equity loss in affiliate	(953)	(209)	(257)
Other, net	187	45	60
Write-down of investment	—	(2,893)	—
Loss on marketable investments	—	(7,428)	—
Total other income (expense)	<u>1,557</u>	<u>(5,648)</u>	<u>9,651</u>
Loss before income tax	(9,969)	(23,651)	(37,288)
Income tax	—	—	—
Net loss	<u>\$ (9,969)</u>	<u>\$ (23,651)</u>	<u>\$ (37,288)</u>
Net loss per common share — basic and diluted	<u>\$ (0.47)</u>	<u>\$ (1.15)</u>	<u>\$ (1.84)</u>
Weighted average number of common shares outstanding — basic and diluted	<u>21,134,607</u>	<u>20,644,308</u>	<u>20,285,732</u>

See accompanying notes to consolidated financial statements.

**UNITED THERAPEUTICS CORPORATION**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
(In thousands, except share data)

	<b>Common Stock</b>		<b>Additional Paid-in Capital</b>	<b>Accumulated Other Comprehensive Income</b>	<b>Treasury Stock</b>	<b>Accumulated Deficit</b>	<b>Total</b>
	<b>Shares</b>	<b>Amount</b>					
Balance, December 31, 2000	20,740,086	\$207	\$363,485	\$ —	\$(4,072)	\$(124,882)	\$234,738
Stock issued in exchange for services	9,868	1	750	—	—	—	751
Options issued in exchange for services	—	—	995	—	—	—	995
Exercise of stock options	1,866	—	5	—	—	—	5
Purchases of treasury stock	—	—	—	—	(2,802)	—	(2,802)
Net loss	—	—	—	—	—	(37,288)	(37,288)
Balance, December 31, 2001	20,751,820	208	365,235	—	(6,874)	(162,170)	196,399
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)
Foreign currency translation adjustments	—	—	—	8	—	—	8
Net loss	—	—	—	—	—	(23,651)	(23,651)
Balance, December 31, 2002	21,449,470	215	364,130	8	(6,874)	(185,821)	171,658
Options issued in exchange for services	—	—	325	—	—	—	325
Exercise of stock options	386,872	3	4,082	—	—	—	4,085
Foreign currency translation adjustments	—	—	—	13	—	—	13
Unrealized gain on available-for-sale securities	—	—	—	1,653	—	—	1,653
Net loss	—	—	—	—	—	(9,969)	(9,969)
Balance, December 31, 2003	21,836,342	\$218	\$368,537	\$1,674	\$(6,874)	\$(195,790)	\$167,765

See accompanying notes to consolidated financial statements.

**UNITED THERAPEUTICS CORPORATION**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(In thousands)

	<b>Years Ended December 31,</b>		
	<b>2003</b>	<b>2002</b>	<b>2001</b>
Cash flows from operating activities:			
Net loss	\$ (9,969)	\$ (23,651)	\$ (37,288)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	2,363	2,022	2,821
Loss on disposals of equipment	108	—	27
Provision for bad debt	425	68	280
Stock and options issued in exchange for services	325	323	996
Write-down of investment	—	2,893	—
Write-down of inventory	325	477	284
Write-down of intangibles	—	—	221
Amortization of premiums and discounts on marketable investments	(38)	1,113	694
Loss on sales of marketable investments	—	7,428	—
Equity loss in affiliate	953	209	257
Changes in operating assets and liabilities:			
Accounts receivable	(927)	(8,267)	(197)
Interest receivable	(451)	2,763	(2,772)
Inventories	(1,202)	(1,867)	(4,036)
Prepaid expenses	(639)	(318)	161
Other current assets	668	(1,023)	(595)
Other noncurrent assets	(2,556)	(1,506)	(38)
Due from affiliate	(81)	(433)	—
Accounts payable	1,338	(3,361)	1,826
Accrued expenses	1,007	997	(1,069)
Due to affiliate	(206)	(112)	(361)
Other liabilities	(5)	(13)	(110)
Net cash used in operating activities	(8,562)	(22,258)	(38,899)
Cash flows from investing activities:			
Purchases of property, plant and equipment	(7,004)	(3,581)	(687)
Proceeds from disposals of property, plant and equipment	336	1	40
Investment in Northern Therapeutics, Inc.	(2,500)	(500)	—
Investment in AltaRex Medical Corp.	—	(4,914)	—
Acquisition of patent rights	(300)	—	—
Purchases of marketable investments and certificates of deposit	(44,711)	(11,218)	(152,520)
Sales and maturities of marketable investments	6,641	140,567	18,386
Net cash provided by (used in) investing activities	(47,538)	120,355	(134,781)
Cash flows from financing activities:			
Purchases of common stock	—	—	(2,802)
Proceeds from exercise of stock options	4,085	245	6
Payments of principal on notes payable	(1,982)	(22)	(17)
Principal payments under capital lease obligations	(96)	(38)	(69)
Net cash provided by (used in) financing activities	2,007	185	(2,882)

Net increase (decrease) in cash and cash equivalents	(54,093)	98,282	(176,562)
Cash and cash equivalents, beginning of year	122,655	24,373	200,935
	<u>          </u>	<u>          </u>	<u>          </u>
Cash and cash equivalents, end of year	\$ 68,562	\$122,655	\$ 24,373
	<u>          </u>	<u>          </u>	<u>          </u>

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**UNITED THERAPEUTICS CORPORATION**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(In thousands)

	<b>Years Ended December 31,</b>		
	<b>2003</b>	<b>2002</b>	<b>2001</b>
Supplemental schedule of noncash investing and financing activities:			
Notes payable issued for building and land	\$974	\$ —	\$ —
Equipment acquired under a capital lease	\$ —	\$ —	\$117
Supplemental cash flow information — cash paid for interest	\$ 87	\$129	\$155

See accompanying notes to consolidated financial statements.

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## UNITED THERAPEUTICS CORPORATION

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### 1. Organization and Business Description

United Therapeutics Corporation (United Therapeutics) is a biotechnology company focused on the development and commercialization of unique therapeutic products to treat patients with chronic and life-threatening cardiovascular, infectious and oncological 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., Medcomp, 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 agreed with the FDA that it would perform a post-marketing Phase IV clinical study to further assess the clinical benefits of Remodulin. The Phase IV study commenced in late 2002 and the final study report must be submitted to the FDA by December 2005. Continued FDA approval is conditioned on the completion and outcome of the Phase IV study. 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 and Europe. 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 \$68.6 million and \$122.7 million at December 31, 2003 and 2002, respectively.

##### *Inventories*

United Therapeutics manufactures certain compounds and purchases medical supplies for use in its product sales and ongoing clinical trials. United Therapeutics purchases 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

# UNITED THERAPEUTICS CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

market. At December 31, 2003 and 2002, inventories consisted of the following net of reserves of approximately \$321,000 and \$421,000 at December 31, 2003 and 2002, respectively (in thousands):

	December 31,	
	2003	2002
Remodulin:		
Raw materials	\$ 172	\$ 216
Work in progress	4,971	2,924
Finished goods	921	1,161
Remodulin delivery pumps and medical supplies	1,544	2,208
Cardiac monitoring equipment components	211	369
HeartBar and related product lines	297	286
	<hr/>	<hr/>
Total inventories	\$8,116	\$7,164
	<hr/>	<hr/>

### *Property, Plant and Equipment*

Property, plant and equipment are stated at cost. Depreciation 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,	
	2003	2002
Land	\$ 1,375	\$ 647
Buildings, building improvements and leasehold improvements	8,790	4,544
Holter and event cardiac monitoring systems	2,836	2,356
Furniture, equipment and vehicle	6,004	4,065
	<hr/>	<hr/>
	19,005	11,612
Less — accumulated depreciation	(3,780)	(2,492)
	<hr/>	<hr/>
Property, plant and equipment, net	\$15,225	\$ 9,120
	<hr/>	<hr/>

### *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.





## UNITED THERAPEUTICS CORPORATION

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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.

In 2001, United Therapeutics had agreements with third parties in which United Therapeutics conducted synthesis and manufacturing of complex compounds for these third parties. These synthesis and manufacturing agreements required United Therapeutics to perform certain research and development activities related to developing synthesis and manufacturing methods. These agreements with third parties generally were short in duration (average of approximately five months) and required the customer to pay a fixed price which was usually paid over the period of the agreement. Any know-how or intellectual property created as a result of these agreements was owned by the customers. United Therapeutics was not entitled to receive any royalty payments under these agreements. In the case of early termination, the customer would generally be required to pay United Therapeutics an amount equal to cover costs incurred under these agreements. Service revenues under these agreements totaled approximately \$801,000 for the year ended December 31, 2001. Costs incurred under these agreements totaled approximately \$458,000 for the year ended December 31, 2001. There were no revenues or costs associated with these agreements in 2002 and 2003.

#### *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.

#### *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.

#### *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 on October 1st 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, 2003.

**UNITED THERAPEUTICS CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

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

	<b>As of December 31, 2003</b>			<b>As of December 31, 2002</b>		
	<b>Gross</b>	<b>Accumulated Amortization</b>	<b>Net</b>	<b>Gross</b>	<b>Accumulated Amortization</b>	<b>Net</b>
Goodwill	\$9,072	\$(1,607)	\$7,465	\$9,072	\$(1,607)	\$7,465
Intangible assets:						
Noncompete agreements	\$ 273	\$ (273)	\$ —	\$ 273	\$ (273)	\$ —
Trademarks	2,802	(738)	2,064	2,802	(492)	2,310
Technology and patents	6,164	(1,782)	4,382	5,864	(1,173)	4,691
Total intangible assets	\$9,239	\$(2,793)	\$6,446	\$8,939	\$(1,938)	\$7,001

Total amortization expense for the years ended December 31, 2003, 2002 and 2001 was approximately \$855,000, \$899,000, and \$2.0 million, respectively. As of December 31, 2003, the aggregate amortization expense related to these intangible assets for each of the five succeeding years is estimated as follows (in thousands):

<b>Year ending December 31,</b>	
2004	\$479,000
2005	479,000
2006	479,000
2007	432,000
2008	432,000

***Investments in Affiliates***

The investments in affiliates represent United Therapeutics' investments in Northern Therapeutics, Inc. and AltaRex Medical Corp. (formerly AltaRex 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 has 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 AltaRex is being accounted for as an available-for-sale security as AltaRex 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 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 17.6 percent of AltaRex.

During 2002, the quoted market price of AltaRex's 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, 2003 and 2002, the investment in AltaRex common stock was reported at its fair market value of approximately \$3.7 and \$2.0 million, respectively, and is classified with investments in affiliates.

## UNITED THERAPEUTICS CORPORATION

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### *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. 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.

#### *Loss per Common Share*

Basic loss per common share is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the respective periods. Options and warrants that could potentially dilute earnings per share in the future were not included in the computation of diluted loss per share because to do so would have been antidilutive for the periods presented. As of December 31, 2003, these options and warrants totaled approximately 998,000 shares. Accordingly, diluted loss per common share is the same as basic loss per common share.

#### *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 loss and net 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*.

In accordance with SFAS No. 148, *Accounting for Stock-Based Compensation — Transition and Disclosure*, the effect on net loss and net loss per share if United Therapeutics had applied the fair value

# UNITED THERAPEUTICS CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

recognition provisions of SFAS No. 123 to stock-based employee compensation is as follows (in thousands, except per share amounts):

	Years ended December 31,		
	2003	2002	2001
Net loss, as reported	\$ (9,969)	\$(23,651)	\$(37,288)
Less total stock-based employee compensation expense determined under fair value based method for all awards	(12,964)	(18,082)	(13,022)
Pro forma net loss	\$(22,933)	\$(41,733)	\$(50,310)
Basic and diluted loss per common share:			
As reported	\$ (0.47)	\$ (1.15)	\$ (1.84)
Pro forma	\$ (1.09)	\$ (2.02)	\$ (2.48)

The effect of applying SFAS No. 123 on 2003, 2002 and 2001 pro forma net loss and net loss per share as stated above, is not necessarily representative of the effects on reported net 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.

### 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 monitoring analysis services are recognized when the services are performed.

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

Product sales from the HeartBar and related product lines 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.

Service sales from the synthesis and manufacture of complex compounds by the United Therapeutics' manufacturing division were generally made under fixed price agreements. United Therapeutics recognizes revenue based on the percentage-of-completion method. Billings in excess of amounts recognized as revenues are reported as deferred revenues. Losses on these contracts, if any, are recognized as soon as they are anticipated. No such revenues were earned in 2003 and 2002.

Grant revenues are recognized on the percentage-of-completion basis. No such revenues were earned in 2003 and 2002.

## UNITED THERAPEUTICS CORPORATION

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### *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.

#### *Concentrations of Suppliers, Products and Customers*

United Therapeutics currently relies on a single supplier to test the purity of each batch of Remodulin and other products, and on a single supplier for the delivery device to administer 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 2003, Remodulin drug sales accounted for approximately 85% of total revenues. The majority of these Remodulin drug sales were made to United States distributors. In the United States, United Therapeutics has contracted with two distributors who purchase and market Remodulin. There are several other qualified distributors that could market Remodulin, if an existing distributor ceased to market Remodulin.

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 2003, 2002 and 2001, approximately 92 percent, 93 percent and 87 percent of United Therapeutics' revenues were earned from customers located in the United States. In 2003 and 2002, approximately \$39.7 million and \$22.6 million in pharmaceutical segment revenues were derived from two distributors in the United States, respectively.

United Therapeutics sells its lead product Remodulin to specialty pharmacy distributors. If these agreements expire or are terminated, under certain conditions, United Therapeutics may have to repurchase unsold Remodulin inventory held by the distributors. In 2004, United Therapeutics terminated one of its three distributor agreements in the United States. United Therapeutics does not believe that it will be required to repurchase any Remodulin inventory from this terminated distributor.

#### *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 of approximately \$1.1 million. United Therapeutics maintains a commercial insurance policy for claims liabilities exceeding these limits. Liabilities of approximately \$510,000 at December 31, 2003 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.

## UNITED THERAPEUTICS CORPORATION

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### *Advertising Costs*

Advertising costs are expensed when incurred. Advertising costs expensed during the years ended December 31, 2003, 2002 and 2001 were approximately \$526,000, \$92,000, and \$868,000, respectively.

#### *Reclassifications*

Certain amounts in the 2002 and 2001 consolidated financial statements were reclassified to conform to the 2003 presentation.

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

#### *Office Leases*

In December 2001, a subsidiary of United Therapeutics leased office space from Beacon Projects, Inc., a company owned by the Chairman and CEO of United Therapeutics. The property was sold in 2002 by Beacon and the United Therapeutics subsidiary leased the office space from the successor (unrelated) landlord until December 2003. During the year ended December 31, 2002, the total amount paid to Beacon Projects was approximately \$57,000 under this lease.

In March 1999 and December 2000, UTSC entered into lease agreements for office space from Beacon Projects, Inc. United Therapeutics incurred expenses under these leases of approximately \$44,000 during the year ended December 31, 2001. These leases were all terminated in June 2001.

#### *Legal Services*

During and prior to 2001, United Therapeutics obtained professional services from a law firm affiliated with the General Counsel and the Chairman and CEO of United Therapeutics. In June 2001, the General Counsel joined United Therapeutics as a full time employee and the arrangement with the law firm for professional services was terminated. The Chairman and CEO does not receive compensation from the law firm. United Therapeutics incurred expenses of approximately \$212,000 during the year ended December 31, 2001 for services rendered by the law firm.

#### *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 and \$205,000 for the years ended December 31, 2002 and 2001, respectively. This agreement was terminated in June 2002.

#### *Receivable from Employees*

At December 31, 2003 and 2002, United Therapeutics had interest and non-interest bearing advances totaling approximately \$1,137,000 and \$1,358,000, respectively, due from employees. The advances are classified as note receivable from employee and other assets 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 will accrue 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

## UNITED THERAPEUTICS CORPORATION

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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 year ended December 31, 2003, Dr. Jeffs paid approximately \$303,000 of outstanding interest and principal on the note. At December 31, 2003, the amount due from Dr. Jeffs was approximately \$1,137,000.

#### *Iminosugar Program*

United Therapeutics reported expenses of approximately none, \$200,000 and \$3.5 million to Synergy Pharmaceuticals, Inc. during the years ended December 31, 2003, 2002 and 2001, respectively, for contract research services. From March 2000 until March 2003, United Therapeutics owned approximately 15 percent of Synergy.

#### *Marketing and Consulting Agreements*

In February 2003, United Therapeutics entered into an agreement for the development, hosting and maintenance of its Remodulin.com website with a company controlled by Raymond Kurzweil who is one of four non-independent directors on United Therapeutics' ten-person Board of Directors. Pursuant to this Agreement, United Therapeutics will pay the company \$29,000 and a continuing payment of \$1,250 per month for posting new information and maintenance of the website. In 2003, United Therapeutics incurred approximately \$29,000 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 relating to Medicomp, Inc. 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, 2003 and 2002 United Therapeutics incurred approximately \$484,000 and \$190,000, respectively, of fees and expenses related to this agreement, of which approximately \$80,000 and \$190,000 were payable to KTI at December 31, 2003 and 2002, respectively.

In 2001, United Therapeutics entered into a marketing agreement with a company affiliated with Raymond Kurzweil. The value of the agreement is \$30,000 annually. United Therapeutics also entered into an agreement in 2001 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 another marketing agreement with a company affiliated with Raymond Kurzweil with a total value of \$15,000. United Therapeutics paid a total of \$30,000, \$25,000 and \$25,000 under these agreements during the years ended December 31, 2003, 2002 and 2001, 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



## UNITED THERAPEUTICS CORPORATION

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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 10 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.

#### *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 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. United Therapeutics and Medtronic MiniMed have established a Management Committee comprised of two representatives from each company to implement the agreement. The guidelines implementing the agreement provide that United Therapeutics will purchase 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 to purchase its 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.

## UNITED THERAPEUTICS CORPORATION

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### *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 requires 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 are in early development and have 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.

#### *AltaRex Medical Corp.*

In April 2002, UPI acquired an option to develop and commercialize a platform of five immunotherapeutic monoclonal antibodies from AltaRex Medical Corp. (formerly AltaRex 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. UPI's cumulative ownership in AltaRex at December 31, 2003 and 2002 was approximately 17.6 percent and 19.9 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

## UNITED THERAPEUTICS CORPORATION

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

sheets. Also in August 2002, UPI loaned to AltaRex approximately \$433,000 as a secured convertible debenture due at the end of three years with interest of six percent due quarterly. The note is convertible into AltaRex common stock at a price of \$0.50 per share at any time by UPI. At December 31, 2003 and 2002, the closing price of AltaRex common stock was approximately \$0.40 and \$0.22 per share, respectively. 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 \$900,000 over two years and had an initial term expiring in September 2002 which was renewed until September 2004. 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):

Year ending December 31,	
2004	\$ 20
2005	245
2006	70
2007	1,470
2008 and thereafter	6,040

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.

##### *Employment Agreement*

In April 1999, United Therapeutics executed an employment agreement with its Chief Executive Officer (CEO). As amended in December 2000, the agreement establishes minimum compensation and benefits for a renewing five year period, and requires United Therapeutics to issue options to the CEO at the end of each of the next five years to purchase a number of shares of common stock equal to one-eighteenth of one percent of the increase in United Therapeutics' market capitalization from its average in December of each year (commencing December 2000) to its average the following year. Prior to granting, the Compensation Committee of the Board may reduce the number of shares covered by these options. The exercise price of the options will be 110 percent of the fair market value of a share of common stock on the date of grant, or 100 percent of fair market value if the CEO owns less than 10 percent of United Therapeutics' outstanding

## UNITED THERAPEUTICS CORPORATION

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

common stock on the date of grant. If the CEO is terminated without cause or leaves with good reason, she will receive severance equal to three years of base salary and bonus plus the value of any vested options.

#### *Purchase of Land*

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 laboratory facility. Settlement is expected to occur in 2004. At December 31, 2003, approximately \$2.8 million was placed in an escrow account pending settlement and is included in non-current other assets in the accompanying consolidated balance sheets.

#### **6. Concentrations Of Credit Risk**

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, 2003, 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.

#### **7. Stockholders' Equity**

##### *Common Stock*

In February 2000, United Therapeutics agreed to fund, over two years, a United Therapeutics Chair in Pulmonary Hypertension at Columbia University with a grant of United Therapeutics' common stock. The grant was funded with the issuance of 9,868 shares of United Therapeutics' common stock in February 2000 and 9,868 shares of United Therapeutics' common stock in April 2001, all of which was valued at \$1.5 million based on the closing Nasdaq price on February 10, 2000. In February 2002, United Therapeutics and Columbia University agreed that the shares issued to Columbia University would be transferred instead to the University's pulmonary hypertension research gift account to further research the causes and cures for pulmonary hypertension.

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.

# UNITED THERAPEUTICS CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

### *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 2003, 2002 and 2001. 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:

	<b>Number of Options Granted</b>	<b>Range of Exercise Prices</b>
For the year ended December 31,:		
2003	21,001	\$16.17 to \$23.10
2002	44,334	\$ 9.95 to \$15.00
2001	78,253	\$ 8.97 to \$16.94

### *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:

	<b>Number of Options Granted</b>	<b>Range of Exercise Prices</b>
For the year ended December 31,:		
2003	552,816	\$15.39 to \$23.27
2002	595,950	\$ 9.20 to \$16.70
2001	495,454	\$ 9.20 to \$15.69

# UNITED THERAPEUTICS CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Prior to July 1, 2003, options were also granted outside of the Plan described above (non-plan awards). Such grants were 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. A total of 212,420 non-plan options were granted to employees during the year ended December 31, 2003 with exercise prices ranging from \$14.98 to \$21.86 and a term of ten years.

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 2003, 2002 and 2001:

	Years ended December 31,		
	2003	2002	2001
Dividend yield	0 percent	0 percent	0 percent
Expected volatility	36.16 – 95.99 percent	40.21 – 106.58 percent	71.25 – 112.47 percent
Risk free interest rate	1.34 – 2.97 percent	2.67 – 4.66 percent	3.53 – 4.95 percent
Expected lives	1 – 5 years	1 – 5 years	5 years

A summary of the status of United Therapeutics' employee stock options as of December 31, 2003, 2002 and 2001, and changes during the years then ended is presented below:

	2003		2002		2001	
	Shares	Weighted-Average Exercise Price	Shares	Weighted-Average Exercise Price	Shares	Weighted-Average Exercise Price
Outstanding at beginning of period	4,032,871	\$26.13	3,083,246	\$29.98	3,156,356	\$36.58
Granted	765,236	20.90	1,189,555	14.46	624,930	12.73
Exercised	(388,616)	10.60	(28,648)	8.54	(1,866)	3.00
Forfeited	(95,335)	17.08	(211,282)	18.35	(236,241)	21.32
Canceled	(934)	3.00	—	—	(459,933)	56.72
Outstanding at end of period	4,313,222	\$26.81	4,032,871	\$26.13	3,083,246	\$29.93
Options exercisable at end of period	3,033,647	\$30.09	2,598,873	\$31.19	1,680,263	\$40.37
Weighted-average fair value of options granted during the period	\$ 10.83		\$ 9.17		\$ 9.39	

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 cancelled with exercise prices ranging from \$27.50 to \$116.38. The cancelled 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*

# UNITED THERAPEUTICS CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

*Stock Compensation*, no compensation expense was required to be recognized upon the grant of the replacement awards.

The following table summarizes information about employee stock options outstanding at December 31, 2003:

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	57,537	7.0	\$ 8.21	42,412	\$ 7.75
10.01 – 20.00	2,780,097	7.1	14.98	2,071,525	14.88
20.01 – 30.00	760,061	8.8	23.41	237,638	26.53
30.01 – 40.00	5,000	5.9	35.75	4,200	35.75
40.01 – 50.00	149,755	6.2	43.40	136,942	43.15
50.01 – 60.00	31,378	6.2	57.03	22,613	56.99
60.01 – 70.00	7,525	6.3	63.93	5,650	63.55
70.01 – 80.00	9,502	6.1	71.74	300	77.13
80.01 – 90.00	509,167	6.5	89.91	509,167	89.91
90.01 – 116.38	3,200	6.2	99.68	3,200	99.68
<b>\$ 3.00 – \$116.38</b>	<b>4,313,222</b>	<b>7.3</b>	<b>\$26.81</b>	<b>3,033,647</b>	<b>\$30.09</b>

During the year ended December 31, 2003, options to purchase a total of 386,872 shares of common stock were exercised. The proceeds from these exercises totaled approximately \$4.1 million.

## 8. Income Taxes

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

	Years Ended December 31,		
	2003	2002	2001
Federal tax provision (benefit) computed at the statutory rate	\$(3,567)	\$(8,041)	\$(12,678)
State tax provision (benefit), net of federal tax provision (benefit)	(518)	(1,249)	(1,969)
Change in the valuation allowance for deferred tax assets allocated to tax expenses	7,679	9,865	23,722
General business credits generated	(1,462)	(4,590)	(7,124)
Deductions for stock option exercises and other	(2,067)	—	—
Nondeductible expenses and other	(65)	4,015	(1,951)
<b>Total income tax expense</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ —</b>

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





# UNITED THERAPEUTICS CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

amounts used for income tax purposes. Significant components of United Therapeutics' net deferred tax asset as of December 31, 2003 and 2002, respectively, are approximately as follows (in thousands):

	December 31,	
	2003	2002
Deferred tax assets:		
Net operating loss carryforwards	\$ 48,791	\$ 40,934
General business credits	29,255	27,793
Impairment losses on investments	3,018	3,018
Realized losses on marketable investments	2,918	2,918
License fees capitalized for tax purposes	8,652	9,388
In-process research and development capitalized for tax purposes	5,366	5,890
Other	1,387	1,619
Total deferred tax assets	99,387	91,560
Deferred tax liabilities:		
Furniture and equipment principally due to differences in depreciation	(271)	(123)
Total deferred tax liabilities	(271)	(123)
Net deferred tax asset before valuation allowance	99,116	91,437
Valuation allowance	(99,116)	(91,437)
Net deferred tax asset	\$ —	\$ —

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 timing of additional product approvals and the levels of future product sales and profitability.

The valuation allowance for deferred tax assets increased by approximately \$7.7 million and \$9.9 million for the years ended December 31, 2003 and 2002, respectively.

At December 31, 2003, United Therapeutics had net operating loss carryforwards of approximately \$124.2 million and business tax credit carryforwards of approximately \$29.3 million for federal income tax purposes which expire at various dates from 2012 through 2023. Business tax credits can offset future tax liabilities and arise from qualified research expenditures. The portions of these carryforward items that were generated prior to June 1999 are subject to certain limitations. United Therapeutics does not believe that the limitations will cause the net operating loss and general business credit carryforwards to expire unused.

### 9. Notes and Leases Payable

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.

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 accompanying consolidated balance sheets and was paid in January 2004.

United Therapeutics also leased certain equipment under capital leases with interest rates of approximately 10.6 percent and terms up to 5 years.



**UNITED THERAPEUTICS CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)**

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

	<b>Notes Payable</b>	<b>Capital Leases</b>
<b>Year ending December 31,</b>		
2004	\$ 750	\$ 25
2005	—	16
2006	—	10
2007	—	—
2008	—	—
2009 and thereafter	—	—
	<hr/>	<hr/>
	750	51
Less amounts representing interest	(1)	(2)
Less current portion	(749)	(24)
	<hr/>	<hr/>
	\$ —	\$ 25
	<hr/>	<hr/>

At December 31, 2003 and 2002, the carrying value of equipment under capital leases approximated \$99,000 and \$227,000, respectively, and accumulated depreciation approximated \$53,000 and \$98,000, respectively. Equipment under capital leases are amortized to depreciation expense.

**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, 2003, 2002 and 2001 (in thousands):

	<b>December 31,</b>		
	<b>2003</b>	<b>2002</b>	<b>2001</b>
Net loss	\$ (9,969)	\$ (23,651)	\$ (37,288)
Other comprehensive income:			
Foreign currency translation adjustments	13	8	—
Unrealized gain on available-for-sale securities	1,653	—	—
	<hr/>	<hr/>	<hr/>
Comprehensive loss	\$ (8,303)	\$ (23,643)	\$ (37,288)
	<hr/>	<hr/>	<hr/>

**11. Marketable Investments**

Investments at December 31, 2002 consisted of a federally sponsored debt security. At December 31, 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, 2003 and 2002.

# UNITED THERAPEUTICS CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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, 2003	\$48,775	\$ 22	\$(480)	\$48,317
Agency notes at December 31, 2002	\$10,000	\$ —	\$ (56)	\$ 9,944

The following table summarizes maturities of United Therapeutics' marketable investment securities at December 31, 2003 (in thousands):

	Amortized Cost	Fair Value
Less than one year	\$ —	\$ —
Due in one to two years	2,826	2,808
Due in three to five years	39,949	39,935
Due after five years	6,000	5,574
Total	\$48,775	\$48,317

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

	Year Ended December 31,		
	2003	2002	2001
Gross proceeds	\$6,000	\$128,329	\$18,480
Realized gains	\$ —	\$ 384	\$ 13
Realized losses	\$ —	\$ 7,273	\$ —

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. Operating Leases

United Therapeutics leases various office and production space generally under noncancelable agreements with terms expiring through 2010. 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	
2004	\$1,127
2005	1,077
2006	1,325
2007	861
2008	575

Total rent expense for the years ended December 31, 2003, 2002, and 2001 was approximately \$1.4 million, \$1.0 million and \$521,000, respectively.



## UNITED THERAPEUTICS CORPORATION

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

#### 13. 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 to be held until December 2003. These shares are still being held in escrow.

Under terms of the acquisition agreement, Medicomp will 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. It is expected that United Therapeutics will issue approximately 600,000 shares to the sellers in 2004 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 conditions. 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 of which \$4.0 million was paid as of December 2003. The remaining \$1.0 million will be paid in 2005. 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, 2003, Lung Rx's investment in the new company was reported at approximately \$3.5 million, which is comprised of \$4.0 million paid in cash and the present value of the remaining \$1.0 million due in 2005, net of Lung Rx's share of Northern Therapeutics' losses since its formation. The amounts due to Northern Therapeutics at December 31, 2003 totaled approximately \$946,000 and are reported as due to affiliate in the accompanying consolidated balance sheets. Lung Rx's equity in the underlying net assets was approximately \$2.5 million at December 31, 2003.

# UNITED THERAPEUTICS CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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

	As of and for the year ended December 31,		
	2003	2002	2001
Total assets	\$ 3,660	\$4,233	\$5,010
Total liabilities	\$ 75	\$ 52	\$ 218
Net loss	\$(1,394)	\$ (305)	\$ (436)

### *Preventis, Inc.*

In 2000, United Therapeutics entered into an agreement to form Preventis, Inc., a Delaware corporation, to create new vaccine technology and to develop and commercialize novel therapeutics for infectious disease. United Therapeutics received 30 percent of the initial outstanding common stock of Preventis. The agreement does not require United Therapeutics to contribute cash or other capital. A then current director of United Therapeutics purchased a 57 percent common stock shareholding in the new company when it was formed in 2000 upon consent by United Therapeutics' Board of Directors. At December 31, 2003, United Therapeutics' investment in Preventis had an original cost of zero and was reported at zero. United Therapeutics' equity in the underlying net assets was a deficit of approximately \$1.3 million at December 31, 2003. During 2003, Preventis substantially reduced its operations.

### 14. Employees' Retirement Plan

Effective January 1, 1999, United Therapeutics adopted the United Therapeutics Corporation Employees' Retirement Plan (the Plan), a salary reduction profit sharing 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. No employer contributions have been made to the Plan as of December 31, 2003. Beginning January 1, 2004, United Therapeutics began matching employee contributions at a rate of 20 percent, subject to certain limitations.

### 15. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31,	
	2003	2002
Professional fees	\$ 163	\$ 112
Research	524	1,701
Payroll related	1,638	980
Milestones and royalties	1,552	142
Contracted services	706	690
Other	876	826
Total	\$5,459	\$4,451

### 16. 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, manufacture, and

# UNITED THERAPEUTICS CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

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, 2003 was as follows (in thousands):

	Pharmaceutical	Telemedicine	Consolidated Totals
Revenues from external customers	\$ 49,180	\$ 4,161	\$ 53,341
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):

	Pharmaceutical	Telemedicine	Consolidated Totals
Revenues from external customers	\$ 26,234	\$ 3,886	\$ 30,120
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

Segment information as of and for the year ended December 31, 2001 was as follows (in thousands):

	Pharmaceutical	Telemedicine	Consolidated Totals
Revenues from external customers	\$ 2,981	\$ 2,750	\$ 5,731
Losses	(33,860)	(3,428)	(37,288)
Interest income	9,983	38	10,021
Interest expense	166	7	173
Depreciation and amortization	1,558	1,263	2,821
Equity loss in affiliate	257	—	257
Total investments in equity method investees	4,342	—	4,342
Expenditures for long-lived assets	317	370	687
Goodwill, net	1,287	6,178	7,465
Total assets	200,630	11,491	212,121



## 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.

#### 17. Recent Accounting Pronouncements

##### *Disposal Activities*

In June 2002, the Financial Accounting Standards Board (FASB) issued SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* (SFAS 146). SFAS 146 addresses the financial accounting and reporting for costs associated with exit or disposal activities and is effective for exit or disposal activities initiated after December 31, 2002. SFAS No. 146 was adopted effective January 1, 2003, and did not have a significant impact on United Therapeutics' financial statements.

##### *Variable Interest Entities*

In January 2003, FASB issued Interpretation No. 46 (FIN 46), *Consolidation of Variable Interest Entities*. FIN 46 requires that if an entity has a controlling financial interest in a variable interest entity, the assets, liabilities and results of activities of the variable interest entity should be included in the consolidated financial statements of the controlling entity. FIN 46 requires that its provisions are effective immediately for all arrangements entered into after January 31, 2003. For any arrangements entered into prior to January 31, 2003, the provisions of FIN 46 are required to be adopted at the beginning of the first interim or annual period beginning after December 15, 2003. The adoption of FIN 46 did not have a significant impact on United Therapeutics' consolidated financial statements.

##### *Derivative Instruments and Hedging Activities*

In April 2003, the FASB issued SFAS No. 149, *Amendment of Statement 133 on Derivative Instruments and Hedging Activities*. SFAS No. 149 amends and clarifies certain provisions of SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities* for contracts entered into after September 30, 2003. SFAS No. 149 did not have an impact on United Therapeutics' consolidated financial statements.

##### *Financial Instruments*

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*. SFAS No. 150 establishes standards for the classification and measurement of certain financial instruments with characteristics of both liabilities and equity. SFAS No. 150 was adopted effective June 30, 2003, and did not have an impact on United Therapeutics' consolidated financial statements.

##### *Guarantees*

In November 2002, FASB issued Interpretation No. 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others* (FIN 45). FIN 45 elaborates on the disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under certain guarantees that it has issued. It also clarifies that a guarantor is required to recognize, at the inception of a guarantee, a liability for the fair value of the obligation undertaken in issuing the guarantee. The initial recognition and initial measurement provisions of FIN 45 are applicable on a prospective basis to guarantees issued or modified after December 31, 2002. The disclosure requirements of FIN 45 are effective for financial statements of interim or annual periods ending after December 15, 2002.

# UNITED THERAPEUTICS CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Adoption of FIN 45 did not have a significant impact on United Therapeutics' consolidated financial statements.

### 18. Quarterly Financial Information (Unaudited)

The following presents certain quarterly financial information for each of the years ended December 31, 2003 and 2002 (in thousands, except per share amounts):

	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)

  

	Quarters Ending During 2002			
	December 31, 2002	September 30, 2002	June 30, 2002	March 31, 2002
Net sales	\$12,021	\$ 5,128	\$11,564	\$ 1,406
Gross profit	10,524	3,853	9,651	636
Net loss	(2,605)	(12,188)	(3,180)	(5,678)
Loss per share — basic and diluted	\$ (0.12)	\$ (0.58)	\$ (0.16)	\$ (0.28)

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**United Therapeutics Corporation**  
**Schedule II — Valuation and Qualifying Accounts**  
**Years Ended December 31, 2003, 2002, and 2001**  
(in thousands)

**Allowance for Doubtful Accounts Receivable**

	<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, 2003	\$268	\$228	\$(377)	\$119
Year ended December 31, 2002	\$198	\$110	\$ (40)	\$268
Year ended December 31, 2001	\$ 98	\$136	\$ (36)	\$198

**Reserve for Inventory Obsolescence**

	<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, 2003	\$421	\$ 93	\$(193)	\$321
Year ended December 31, 2002	\$ —	\$421	\$ —	\$421
Year ended December 31, 2001	\$ —	\$ —	\$ —	\$ —

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**Item 9.    *Changes in and Disagreements with Accountants on Accounting and Financial Disclosures***

On August 29, 2003, United Therapeutics dismissed its independent public accountants, KPMG LLP (“KPMG”), and on September 8, 2003 engaged Ernst & Young LLP (“E&Y”) to serve as the United Therapeutics’ independent public accountants to audit its financial statements for the fiscal year ended December 31, 2003. The decision to dismiss KPMG and engage E&Y was made by United Therapeutics’ Audit Committee. KPMG’s audit reports on United Therapeutics’ consolidated financial statements as of and for each of the fiscal years ended December 31, 2001 and 2002 did not contain an adverse opinion or a disclaimer of opinion, nor were such reports qualified or modified as to uncertainty, audit scope or accounting principles other than reference to a change in accounting principle in KPMG’s report on United Therapeutics’ 2002 consolidated financial statements which included an explanatory paragraph which referred to United Therapeutics’ adoption of SFAS No. 142, *Goodwill and Other Intangible Assets*, effective January 1, 2002. During United Therapeutics’ fiscal years ended December 31, 2001 and 2002, and the subsequent interim period through August 29, 2003, there were no disagreements between United Therapeutics and KPMG on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to KPMG’s satisfaction, would have caused KPMG to make reference to the subject matter of the disagreement in connection with its reports. During United Therapeutics’ fiscal years ended December 31, 2001, and 2002 respectively, and the subsequent interim period through September 8, 2003, none of the reportable events described under Item 304(a)(1)(v) of Securities and Exchange Commission’s Regulation S-K occurred. During United Therapeutics’ fiscal years ended December 31, 2001 and 2002, and the subsequent interim period through September 8, 2003, the date on which E&Y was engaged, United Therapeutics did not consult with E&Y regarding any of the matters or events described in Item 304(a)(2)(i) and (ii) of Securities and Exchange Commission’s Regulation S-K.

**Item 9A.    *Controls and Procedures***

Based on their evaluation, as of December 31, 2003, United Therapeutics’ Chief Executive Officer and Chief Financial Officer have concluded that United Therapeutics’ disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) are effective. There have been no changes in United Therapeutics’ internal control over financial reporting that occurred during the period covered by this report that have materially effected, or are reasonably likely to materially affect, such internal control over financial reporting.

### 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 2004 annual shareholders meeting (the “2004 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 2004 Proxy Statement is hereby incorporated herein by this reference.

Information appearing under “Section 16(a) Beneficial Ownership Reporting Compliance” in the 2004 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 Investor Relations Department. 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 2004 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 2004 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, 2003 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	2,988,615	\$31.04	7,432,593
Equity compensation plans not approved by security holders	1,547,769	\$18.01	none
Total	4,536,384	\$26.60	7,432,593

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 6 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 of Exhibit 10.30.

**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 2004 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 2004 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:

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 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	Registration Rights Agreement, dated as of October 30, 1998, by and among the Registrant, Merrill Lynch KECALP L.P. 1997, and Merrill Lynch KECALP International L.P. 1997, incorporated by reference to Exhibit 4.2 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
4.3	Form of Common Stock Purchase Agreement, executed as of March 1998, by and between the Registrant and each of Community Investment Partners III L.P., LLLP, Mary Ellen and Raul Evelio Perez, Trustees of the Mary Ellen Perez revocable trust dated October 28, 1993, Edward D. Jones & Co., Oakwood Investors I, L.L.C. and James L. Nouss, Jr., incorporated by reference to Exhibit 4.3 of the Registrant's Registration Statement on form S-1 (Registration No. 333-76409).
4.4	Warrant to purchase shares of United Therapeutics common stock, issued on November 2, 1998 to Cortech, Inc., incorporated by reference to Exhibit 4.4 of the Registrant's Registration Statement on form S-1 (Registration No. 333-76409).
4.5	Stock Option Grant to purchase shares of United Therapeutics' common stock, issued on September 16, 1998, to Toray Industries, Inc., incorporated by reference to Exhibit 4.5 of the Registrant's Registration Statement on form S-1 (Registration No. 333-76409).
4.6	Registration Rights Agreement, dated as of October 7, 1999, by and among the Registrant and Robert M. Moriarty, Ph.D., Raju Penmasta, Ph.D., Liang Guo, Ph.D., George W. Davis, Esq. and David Moriarty, incorporated by reference to Exhibit 10.2 of the Registrant's Form 10-Q for the period ended September 30, 1999.
4.7	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).
4.8	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).
4.9	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).
4.10	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.
4.11	Registration Rights Agreement, dated as of December 15, 2000 by and between the Registrant and Cooke Pharma, Inc., incorporated by reference to Exhibit 2.2 of the Registrant's Form 8-K/A dated December 15, 2000.

Exhibit No.	Description
4.12	Escrow Agreement, dated as of December 15, 2000 among Registrant, UP Subsidiary Corporation, Cooke Pharma, Inc., and Mahon, Patusky, Rothblatt & Fisher, Chartered, as escrow agent, incorporated by reference to Exhibit 2.3 of the Registrant's Form 8-K/A dated December 15, 2000.
4.13	Registration Rights Agreement, dated as of December 28, 2000 by and between the Registrant and Medicomp, Inc., incorporated by reference to Exhibit 2.2 of the Registrant's Form 8-K/A dated December 28, 2000.
4.14	Escrow Agreement, dated as of December 28, 2000 among Registrant, UTSC Sub Acquisition, Inc., Medicomp, Inc., Mahon, Patusky, Rothblatt & Fisher, Chartered, as escrow agent, and Chicago Title, as successor escrow agent, incorporated by reference to Exhibit 2.3 of the Registrant's Form 8-K/A dated December 28, 2000.
4.15	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	First Flight Venture Lease Agreement dated July 1, 1997, between North Carolina Technological Development Authority, Inc. and the Registrant, incorporated by reference to Exhibit 10.2 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
10.8*	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).
10.9*	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).
10.10*	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).
10.11*	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).
10.12**	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.
10.13**	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.



Exhibit No.	Description
10.14*	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).
10.15**	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.
10.16	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.
10.17	Lease dated as of March 1, 1999, between the Unither Telemedicine Services Corp. and Beacon Projects, Inc., incorporated by reference to Exhibit 10.17 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
10.18	UAI Technology, Inc. Office Lease dated as of July 1, 1998, between the Registrant and UAI Technology, Inc., incorporated by reference to Exhibit 10.18 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
10.19	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).
10.20	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).*
10.21	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.
10.22	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).
10.23	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.
10.24	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.
10.25	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.
10.26	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.
10.27**	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.
10.28**	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.

Exhibit No.	Description
10.29***	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.
10.30**	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.
10.31**	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.
10.32**	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.
10.33**	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.
10.34	Real Estate Purchase Agreement dated October 31, 2003 by and between Unither Pharmaceuticals, Inc. and Montgomery County.
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.
23.2	Consent of KPMG LLP.
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.

(b) Reports on Form 8-K

On November 6, 2003, the Registrant filed a Form 8-K dated November 6, 2003 reporting an Item 12 event and attaching a press release related thereto.

## 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

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Martine A. Rothblatt, Ph.D.  
*Chairman of the Board and  
Chief Executive Officer*

March 12, 2004

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
/s/ MARTINE A. ROTHBLATT	Chairman of the Board and Chief Executive Officer	March 12, 2004
Martine A Rothblatt		
/s/ ROGER A. JEFFS	President, Chief Operating Officer and Director	March 12, 2004
Roger A. Jeffs		
/s/ FRED T. HADEED	Executive Vice President for Business Development and Chief Financial Officer	March 12, 2004
Fred T. Hadeed		
/s/ RICARDO BALDA	Chief Executive Officer, Medicomp, Inc. and Director	March 12, 2004
Ricardo Balda		
/s/ RAYMOND DWEK	Director	March 12, 2004
Raymond Dwek		
/s/ R. PAUL GRAY	Director	March 12, 2004
R. Paul Gray		
/s/ H. BEECHER HICKS, III	Director	March 12, 2004
H. Beecher Hicks, III		
/s/ RAYMOND KURZWEIL	Director	March 12, 2004
Raymond Kurzweil		
/s/ CHRISTOPHER CAUSEY	Director	March 12, 2004
Christopher Causey		
/s/ CHRISTOPHER PATUSKY	Director	March 12, 2004
Christopher Patusky		
/s/ LOUIS W. SULLIVAN	Director	March 12, 2004



**REAL ESTATE PURCHASE AGREEMENT**

THIS REAL ESTATE PURCHASE AGREEMENT ("Agreement") is made and entered into this 31st day of October, 2003 (the "Effective Date"), by and between UNITHER PHARMACEUTICALS, INC., a Delaware corporation ("Purchaser"), and MONTGOMERY COUNTY, a political subdivision of the State of Maryland ("Seller") (Seller and Purchaser, collectively, the "Parties").

**1. DESCRIPTION OF PROPERTY.** Subject to the terms and conditions of this Agreement, Seller hereby agrees to sell, assign and convey, and Purchaser hereby agrees to purchase, that certain approximately 0.92-acre parcel of real property situate in Silver Spring, Montgomery County, Maryland, as more particularly described in Exhibit A attached hereto, together with the easements, rights, privileges and appurtenances thereto belonging (including without limitation all rights attributable to previous dedications of portion of the Property for use as public rights of way) (the "Property").

**2. PURCHASE PRICE.** The purchase price of the Property is TWO MILLION EIGHT HUNDRED EIGHTY THOUSAND AND NO/100 DOLLARS (\$2,880,000.00) (hereinafter referred to as the "Purchase Price").

**3. PURCHASE DEPOSIT.**

(a) Within three (3) business days after the execution and delivery of this Agreement by the Parties, Purchaser shall deposit with Arthur Konopka Law Offices, 4530 Wisconsin Avenue, N.W., Suite 300, Washington, D.C. 20016 Attn. Arthur Konopka, Esq. ("Escrow Agent"), agent for Lawyers Title Insurance Corporation (the "Title Company"), the sum of Eighty Thousand and No/100 Dollars (\$80,000.00) (the "Initial Deposit").

(b) Within three (3) business days after the expiration of the Inspection Period (as hereinafter defined), and provided Purchaser has not terminated this Agreement as set forth in paragraph 5 below, Purchaser shall deposit with Escrow Agent the sum of Two Million Seven Hundred Thousand and No/100 Dollars (\$2,700,000.00) (the "Second Deposit").

(c) The Initial Deposit and the Second Deposit are hereinafter collectively referred to as the "Purchase Deposit," which term shall include all interest accrued thereon. The Purchase Deposit shall be held by Escrow Agent in one or more interest-bearing federally insured accounts with a financial institution reasonably acceptable to Purchaser and Seller. Interest on the Purchase Deposit shall accrue for the benefit of Purchaser.

**4. PAYMENT OF PURCHASE PRICE.** Purchaser agrees to pay to Seller the Purchase Price at the Closing (hereinafter defined) of which the Purchase Deposit shall constitute a part. The Purchase Price shall be paid in cash, certified funds or by electronic wire transfer at the Closing.

**5. CONTINGENCIES.** This Agreement is contingent upon the following:

A. Inspection. Purchaser shall have until 5:00 PM (Eastern time) on December 15, 2003, to inspect the condition of the Property (the "Inspection Period"), and if the Property does not meet Purchaser's satisfaction in its sole and absolute discretion, Purchaser shall be permitted to terminate this Agreement, by written notice to Seller received no later than such date and, upon termination of this Agreement, the Initial Deposit shall be promptly refunded and paid over to Purchaser and neither Party shall have any further liability to the other under this Agreement, except as expressly provided for by the terms of this Agreement.

B. Environmental Inspection. Purchaser shall have until 5:00 PM (Eastern time) on December 15, 2003, to conduct an environmental inspection and/or audit of the Property. In the event the inspection or audit reveals certain conditions which require the expenditure of any sums to bring the Property into compliance with all existing Federal and State of Maryland environmental laws, statutes, regulations or ordinances, Purchaser shall be permitted to terminate this Agreement by written notice to Seller received no later than December 15, 2003, and, upon termination of this Agreement, the Initial Deposit shall be promptly refunded and paid over to Purchaser and neither Party shall have any further liability to the other under this Agreement, except as expressly provided for by the terms of this Agreement. Under no circumstances will the

Seller be obligated to the Purchaser to remediate or otherwise abate or correct any environmental condition at the Property. Subject to the right of Purchaser in paragraph 10 below to terminate this Agreement upon the occurrence of an Environmental Event (as hereinafter defined), Purchaser agrees that it will be responsible for any remediation, abatement or corrective action that is required on the Property after Closing, even if the condition existed prior to Closing.

C. Right of Entry. During the pendency of this Agreement, Purchaser and its representatives, consultants and contractors may enter upon the Property upon reasonable notice to make such inspections and tests regarding the Property as Purchaser deems necessary or desirable, including without limitation investigations of zoning and topographic suitability to Purchaser's intended use, soil boring studies, environmental inspections, audits or tests (including soil borings and such "Phase 2" testing as may be necessary), and the location of public facilities and utilities for the Property (including the relocation of the Public Facilities, as hereafter defined). Purchaser and Seller have executed the Right of Entry Agreement, a copy of which is attached hereto as Exhibit B attached hereto. The Right of Entry Agreement shall not be merged into this Agreement and termination of this Agreement shall not constitute a termination of the Right of Entry Agreement.

D. Relocation of Public Facilities.

(1) Certain stormwater management facilities (including stormwater drains, an oil/grit separator and related facilities) and related facilities (collectively, the "Public Facilities") are currently located on the Property. Development of the Property for the use desired by Purchaser will necessitate the relocation of the Public Facilities. During the Inspection Period, Purchaser shall have the right to determine in its sole discretion whether the Public Facilities can be re-located on the Property such that the Property may be developed as Purchaser desires. If Purchaser shall determine in its sole discretion that the Public Facilities cannot be relocated on the Property such that the Property may be developed as Purchaser desires, or if Seller shall fail to provide the Seller's Relocation Approval (as hereinafter defined) prior to the Closing Date, Purchaser shall be permitted to terminate this Agreement by written notice to Seller received prior to the Closing Date and, upon termination of this Agreement, the Purchase Deposit shall be promptly refunded and paid over to Purchaser and neither Party shall have any further liability to the other under this Agreement, except as expressly provided for by the terms of this Agreement. Seller (acting solely in its role as the owner/operator of the parking garage owned by Seller and located adjacent to the Property (the "Adjacent Garage")), shall have the right to approve the proposed location of the Public Facilities solely for the purposes of determining whether said location, in comparison with the Public Facilities in their current location, would adversely impact the costs to the Seller of operating, maintaining, repairing and/or replacing the Public Facilities or would impair the functionality and effectiveness of the Public Facilities (said approval, the "Seller's Relocation Approval"). Nothing herein shall limit Purchaser's obligation to obtain approvals from Seller acting in its governmental regulatory capacity (or in its capacity as owner of any land other the Property upon which the Public Facilities are proposed to be located) as to the relocation of the Public Facilities to the extent such approvals are required by applicable law.

(2) If Purchaser determines in its sole discretion that the Public Facilities can be relocated on the Property to the location approved by Seller's Relocation Approval such that the Property may be developed as Purchaser desires (i.e. Purchaser elects not to terminate this Agreement as provided in subparagraph (1) above) and if Seller provides the Seller's Relocation Approval, Purchaser shall be responsible for performing all work as may be necessary to relocate the Public Facilities. Purchaser shall also be responsible for obtaining permits and approvals, including any NPDES approvals requires for the relocation of the Public Facilities. The design and specifications of the relocated Public Facilities shall be subject to approval by Seller (said approval not to be unreasonably withheld, conditioned or delayed), but in no event, other than as may be necessary to maintain no less than the same water quality and quantity management function for the Adjacent Garage as the Public Facilities served prior to relocation, shall Seller have the right to require Purchaser to provide Public Facilities which exceed in design and specifications (including with respect to capacity and size) the Public Facilities as are in place prior to relocation. The work related to the relocation of the Public Facilities shall be performed by Purchaser in conjunction with Purchaser's development of the Property. At Closing, Seller shall deposit into an escrow account to be held by Escrow Agent the sum of Three Hundred Thousand and No/100 Dollars (\$300,000.00) (the "Relocation Escrow"). The terms and conditions of the Relocation Escrow and the conditions for disbursement therefrom are set forth in that certain Relocation Escrow Agreement (the form of which is attached hereto as Exhibit C) to be executed and delivered by Seller, Purchaser and Escrow Agent at Closing. The provisions of the Relocation Escrow Agreement which shall govern any conflict with the provisions of this subparagraph (2). Purchaser also have the right, at its expense, to relocate any sanitary sewer lines on the Property that interfere with Purchaser's desired development of the Property and, with respect to any sanitary sewer line that serves the Adjacent Garage, the proposed location of the relocated sanitary sewer line shall be subject to the Seller's approval, which approval will not be unreasonably withheld, delayed or conditioned; provided, however, that Seller shall approve to the proposed location if the relocated sanitary sewer line, upon relocation, shall have at least the same degree of functionality and accessibility as the sanitary sewer line had in its original location .

E. Waiver of Subdivision Regulations. On September 25, 2003, in accordance with the opinion dated October , 2003, the Montgomery County Planning Board of the Maryland-National Capital Park and Planning Commission (the "Planning Board") approved the request for a waiver of certain Subdivision Regulations (the "Subdivision Waiver Approval"), such request having been made by that certain letter dated August 28, 2003, from Seller to the Planning Board. If any appeal of the Subdivision Waiver Approval shall be filed within any applicable appeal period and said appeal shall not have been be

finally resolved prior to Closing such that on the Closing Date the original Subdivision Waiver Approval has not been affirmed without possibility of future appeal, Purchaser shall have the right to terminate this Agreement by providing written notice to Seller on or prior to Closing and, upon termination of this Agreement, the Purchase Deposit shall be promptly refunded and paid over to Purchaser and neither Party shall have any further liability to the other under this Agreement, except as expressly provided for by the terms of this Agreement.

**6. REPRESENTATIONS, WARRANTIES AND COVENANTS OF SELLER.** Seller hereby represents, warrants and covenants to Purchaser, all of which are true as of the date hereof and shall be deemed to be remade by Seller to Purchaser as of the Closing Date (hereinafter defined) and shall survive the Closing (hereinafter defined).

A. Seller's Authority. The Seller is a political subdivision of the State of Maryland and has the lawful power and authority to enter into and carry out the terms of this Agreement. The execution, delivery and performance of this Agreement and the consummation of the transactions contemplated hereby, have been duly authorized and approved, and this Agreement, the Deed, the Right of Entry Agreement, the Relocation Escrow Agreement, the Easement Agreement, the Restrictive Covenant and Repurchase Agreement, and the Parking License Agreement, in the forms as attached as exhibits to this Agreement, each will constitute a valid and binding agreement of the Seller, enforceable in accordance with its terms.

B. No Violation. Neither the execution and delivery of this Agreement by the Seller, nor the consummation by the Seller of the transactions contemplated hereby, will to the Seller's actual knowledge constitute a violation of any applicable judgment, decree or order or, to the Seller's actual knowledge, any applicable code, resolution, law, statute, regulation, ordinance or rule.

C. No Government Proceedings. There are no existing, pending, nor to Seller's actual knowledge any contemplated or threatened, condemnation, incorporation, annexation or moratorium proceedings affecting the Property (or any portion thereof).

D. No Other Agreements. Seller owns fee title to the Property and the Property is not subject to any liens or encumbrances other than as may be determined upon examination of the title to the property in the Land Records for Montgomery County. Seller has not entered into any other contracts for the sale of the Property, and no party has a right of first refusal or option to purchase all or a portion of the Property.

If Seller becomes aware of the fact that any representation or warranty contained in this Agreement should become materially untrue or incorrect at or before the Closing (hereinafter defined), Seller shall notify Purchaser of such condition and Purchaser may (i) waive such condition and close, or (ii) terminate this Agreement, whereupon the Purchase Deposit shall be refunded to Purchaser and no party hereto shall have any further rights, claims or liabilities hereunder, except as expressly provided for by the terms of this Agreement.

## **7. TITLE AND SETTLEMENT.**

A. Title. Within ten (10) business days after the Effective Date, Purchaser shall (i) order from the Escrow Agent a commitment for title insurance (the "Commitment") accompanied by copies of all recorded documents relating to liens, encumbrances, plats, easements, rights of way, restrictions, covenants, ground leases and conditions affecting the Property, in such form as may be required by Purchaser, and (ii) order an ALTA/ACSM land title survey of the Property (the "Survey"). Within twenty (20) days after receipt of the Commitment, copies of all special exceptions identified therein, and the Survey, Purchaser shall notify Seller in writing ("Purchaser's Objection Notice") specifying any title matter, exceptions or survey matter to which it objects (any exceptions or title or survey matter to which Purchaser does not object shall be "Permitted Exceptions"). Within ten (10) business days after receipt of Purchaser's Objection Notice, Seller shall provide Purchaser written notice ("Seller's Cure Notice") of which objections set forth in Purchaser's Objection Notice that Seller will cure prior to the Closing; provided, however, that Seller shall not be required to expend any sum of money to cure any such objections. In the event Seller states in its Seller's Cure Notice that Seller is unable or unwilling to eliminate or modify any objection raised in Purchaser's Objection Notice, Purchaser may (i) terminate this Agreement by written notice to Seller whereupon the Purchase Deposit shall be refunded to Purchaser and no party shall have any further rights, claims or liabilities hereunder, except as expressly provided for by the terms of this Agreement, or (ii) accept such title as Seller can deliver.

B. Date of Settlement. The closing shall occur on the earlier to occur of the following (the "Closing" or the "Closing Date"): (i) such date after the Effective Date that is set forth on a written notice by Purchaser to Seller stating that Purchaser is ready to proceed to Closing (Closing to occur no sooner than ten (10) days after the date of such notice), or (ii) December 15, 2004, or (iii) on such other date as the Parties may agree. Seller and Purchaser agree to make full settlement in accordance with the terms hereof on the Closing Date.

C. Place of Settlement. The Closing shall take place at the offices of the Escrow Agent. The Purchase Deposit shall be held by the Escrow Agent in escrow pursuant to the terms and conditions of this Agreement.

D. Payment of Settlement Costs. Purchaser agrees to pay at the Closing the settlement charges in connection with the examination of title, the Survey, the cost of the preparation and recordation of any mortgage instruments and any

document recording expenses. Seller shall pay the cost to satisfy any deeds of trust, mortgages, judgments or other monetary liens upon the Property that Seller has agreed to discharge prior to Closing and provide releases with respect thereto. Purchaser shall also pay recording costs and fees with respect to the Deed (as hereinafter defined), any recordation, transfer and other taxes imposed on the Deed by the State of Maryland and/or Montgomery County (including Agricultural Transfer Taxes, if any), and all other costs of Closing. Seller and Purchaser hereby covenant and agree with each other that no real estate commissions, finder's fees or broker's fees have been or will be incurred in connection with this Agreement or the transactions contemplated herein. Each party shall indemnify and hold harmless the other from and against any costs or liability arising from the claim of a broker or agent claiming through such party.

E. Taking Title. The Property is to be conveyed in the name of Purchaser or such other entity or individual as designated by Purchaser. Seller agrees to execute and deliver the Deed at the Closing; said Deed shall convey good, marketable and insurable title to the Property to Purchaser, subject to the Permitted Exceptions.

F. Adjustments. Taxes, water rents, and all utility and other operating expenses of the Property are to be adjusted as of the date of the Closing.

G. Closing.

(1) Seller's Deliveries. On the Closing Date, Seller shall deliver to Escrow Agent two (2) original counterparts of the following documents, fully executed and acknowledged where appropriate, and such other items as follows:

(a) Deed. A special warranty deed executed by Seller in the form attached hereto as Exhibit D conveying Seller's title to the Property to Purchaser, or any nominee or assignee of Purchaser, subject only to the Permitted Exceptions (the "Deed"); and

(b) Owner's Affidavit. An owner's affidavit as to mechanic's liens and parties in possession in form and substance reasonably acceptable to Seller and as may be reasonably required by the Title Company to issue the Title Policy (as hereinafter defined);

(c) Non-Foreign Certificate. If required of a political subdivision, as affidavit executed by Seller in form and substance reasonable acceptable to the Seller certifying that Seller is not a "foreign person" as defined in Section 1445 of the Internal Revenue Code or any related regulations, as amended;

(d) Relocation Escrow Agreement. A Relocation Escrow Agreement executed by Seller and in form attached hereto as Exhibit C (the "Relocation Escrow Agreement");

(e) Easement Agreement. An Easement Agreement executed by Seller in the form contemplated by paragraph 13F below (the "Easement Agreement");

(f) Restrictive Covenant and Repurchase Agreement. A Restrictive Covenant and Repurchase Agreement executed by Seller and in form attached hereto as Exhibit E (the "Restrictive Covenant and Repurchase Agreement"); and

(g) Release of Memorandum of Real Estate Purchase Agreement. A release of the Memorandum of Real Estate Purchase Agreement executed by Seller in recordable form and in substance effective to release the Memorandum of Contact (as hereinafter defined) of record (the "Release of Memorandum").

(2) Purchaser's Deliveries.

(a) Purchase Price. On or prior to the Closing Date, Purchaser shall deliver to Escrow Agent a certified check or wire transfer in an amount equal to the Purchase Price, less the Purchase Deposit and any prorations or other adjustments provided for herein;

(b) Relocation Escrow Agreement. The Relocation Escrow Agreement executed by Purchaser;

(c) Easement Agreement. The Easement Agreement executed by Purchaser;

(d) Restrictive Covenant and Repurchase Agreement. The Restrictive Covenant and Repurchase Agreement executed by Purchaser; and

(g) Release of Memorandum of Real Estate Purchase **Agreement**. The Release of the Memorandum executed by Purchaser.

## **8. REPRESENTATIONS, WARRANTIES AND CONDITIONS TO PURCHASER'S OBLIGATIONS.**

A. Representations and Warranties of Purchaser:



Due Organization and Good Standing. The Purchaser is a corporation duly organized and validly existing and in good standing under the laws of Delaware and is duly qualified to enter into this Agreement and undertake the obligations provided for herein.

Purchaser's Authority. The Purchaser has the full and unrestricted lawful power and authority to enter into and carry out the terms of this Agreement. The execution, delivery and performance of this Agreement and the consummation of the transactions contemplated hereby have been or will be as of the Closing Date, duly authorized and approved by all requisite action, as the case may be, and this Agreement, when duly executed and delivered, will constitute a valid and binding

agreement of the Purchaser, enforceable in accordance with its terms.

No Conflict. Neither the execution or delivery of this Agreement, nor the consummation of the transactions contemplated hereby, will: (i) conflict with, or result in a breach of, the terms, conditions or provisions of, or constitute a default under Purchaser's articles of incorporation or bylaws or any agreement or instrument to which Purchaser is a party or is subject; (ii) violate any agreement, restriction, easement, restrictive covenant, or instrument to which Purchaser is a party or to which Purchaser is subject; or, (iii) to Purchaser's knowledge, constitute a violation of any applicable code, resolution, law, statute, regulation, ordinance, rule, judgment, decree or order applicable to Purchaser.

No Violation. There are no actions, suits, proceedings or investigations pending or, to the knowledge of the Purchaser, threatened against or affecting the Purchaser which question the validity of this Agreement, at law or in equity, before or by any federal, state, municipal or other governmental department, commission, board, bureau, agency or instrumentality.

B. Conditions of Purchaser's Obligation to Close. The obligation of Purchaser to consummate the conveyance of the Property hereunder is subject to the satisfaction of each of the following conditions precedent (any of which may be waived in whole or in part by the Purchaser at or prior to the Closing):

(1) The representations and warranties of Seller contained in this Agreement shall be true, complete and accurate, and all covenants and other agreements of Seller shall have been performed or observed, on and as of the date hereof and the Closing Date as if the same were made on and as of such date.

(2) The Title Company shall be irrevocably committed to insure Purchaser on the Closing Date as the fee owner of the Property in the amount of the Purchase Price by issuance of an ALTA owner's title insurance policy (the "Title Policy") and in the standard form issued by the Title Company in the State of Maryland, subject only to the Permitted Exceptions.

(3) No Environmental Event (as hereinafter defined) shall have occurred at the Property.

(4) This Agreement shall not have been terminated as expressly provided by this Agreement.

## **9. REMEDIES.**

A. Seller's Default. In the event Seller shall fail to sell, transfer and assign the Property to Purchaser for any reason and/or perform any other obligation of Seller hereunder, except upon a material default of Purchaser or termination of this Agreement by Seller or Purchaser pursuant to the provisions hereof, Purchaser shall be entitled to its choice of the following remedies: (i) Purchaser may seek specific performance of this Agreement, or (ii) Purchaser may declare this Agreement to be null and void and demand return of the Purchase Deposit.

B. Purchaser's Default. In the event that Purchaser shall fail to consummate this Agreement for any reason, except upon a default of Seller or termination of this Agreement by Seller or Purchaser pursuant to the terms and provisions hereof, Seller shall be entitled as its sole and exclusive remedy to receive the Initial Deposit (and not the Second Deposit, which shall be promptly returned to Purchaser), as full and agreed upon liquidated damages and each of the Parties shall be released from any further liability hereunder.

## **10. DESTRUCTION, DAMAGE OR ENVIRONMENTAL EVENT PRIOR TO THE CLOSING DATE.**

(a) Except as otherwise provided herein or in the Right of Entry Agreement, Seller assumes all risk of loss or damage to the Property by fire or other casualty until the executed Deed is delivered to Purchaser at the Closing. If at any time on or prior to the Closing Date any portion of the Property is destroyed or damaged as a result of fire or any other cause whatsoever, or if an Environmental Event (as hereinafter defined) shall occur, Seller shall promptly give written notice thereof to Purchaser. In the event of such destruction, damage or Environmental Event, Purchaser shall have the right to terminate this Agreement by written notice to Seller within ten (10) days following the date upon which Purchaser receives written notice and, upon termination of this Agreement, the Purchase Deposit shall be promptly refunded and paid over to Purchaser and neither Party shall have any further liability to the other under this Agreement, except as expressly provided for by the terms of this Agreement. If Purchaser does not elect to so terminate this Agreement within said ten (10) day period, this Agreement shall remain in full force and effect and the parties shall proceed to the Closing without any reduction or adjustment in the Purchase Price and Purchaser shall assume all responsibility, legal and financial, for the Property in its "as is" condition at the time of Closing.

(b) For the purposes of this paragraph 10, the term "Environmental Event" shall mean the release, discharge or disposal of any Hazardous Material on, onto, in (or within), under, over or from the Property, or the violation of any Environmental Law because of the condition of, or activity on, the Property. The term "Hazardous Material" means any hazardous or toxic material, substance, contaminant or waste, or similar terms, defined by or regulated as such under any Environmental Laws, including, but not limited to, petroleum and petroleum products (other than petroleum products or other automotive fluids contained in the automobiles which are parked on the Property in connection with Seller's public parking operations at the Property or any de minimis amount of petroleum products or other automotive fluids that in the normal operations of a public parking operation would be expected to leak from the automobiles parked on the Property).



The term “Environmental Law(s)” means any federal, state or local law, ordinance, regulation, rule, court order or decree, or administrative order or any administrative policy or guideline concerning action levels of a governmental authority relating to the environment, public health, any Hazardous Material or any Environmental Event on, under or about the Property, in effect from time to time, including, but not limited to (i) the Federal Water Pollution Control Act, as amended (33 U.S.C. §1251 et seq.); (ii) the Resource Conservation and Recovery Act, as amended (42 U.S.C. §6901 et seq.); (iii) the Comprehensive Environmental Response, Compensation and Liability Act, as amended (42 U.S.C. §9601 et seq.); (iv) the Federal Clean Air Act, as amended (42 U.S.C. §7401 et seq.); (v) the Toxic Substances Control Act, as amended (15 U.S.C. §2601 et seq.); and (ix) all regulations or guidelines promulgated pursuant to all of the foregoing, as same may be amended from time to time.

## **11. CONDEMNATION.**

In the event, at any time prior to the Closing Date, any action or proceeding is filed, under which the Property, or any portion thereof, may be taken pursuant to any law, ordinance or regulation or by condemnation or the right of eminent domain, Seller shall promptly give written notice thereof to Purchaser. Purchaser shall have the right to terminate this Agreement by written notice to Seller within ten (10) days following the date upon which Purchaser receives notice of such action or proceeding from Seller and a description of the Property (or portion thereof) proposed to be taken thereunder, and, upon termination of this Agreement, the Purchase Deposit shall be promptly refunded and paid over to Purchaser and neither Party shall have any further liability to the other under this Agreement, except as expressly provided for by the terms of this Agreement. If Purchaser does not elect to so terminate this Agreement within said ten (10) day period, this Agreement shall remain in full force and effect and the Parties shall proceed to the Closing without any reduction or adjustment in the Purchase Price.

## **12. DISPOSITION OF DEPOSIT.**

The Purchase Deposit shall be held by Escrow Agent in accordance with this Agreement until the Closing, or until disposition thereof is made pursuant to the terms of this Agreement. Escrow Agent shall have the right to disburse the Purchase Deposit to Purchaser or Seller (a) at the Closing with respect to the Purchase Deposit and/or (b) otherwise, as provided in this Agreement upon ten (10) days written notice to the Parties; provided, however, that Escrow Agent shall not have received any written objections to such disbursements within ten (10) days after receipt by Purchaser and Seller of said notice. The Parties acknowledge that Escrow Agent shall have no liability to any party on account of Escrow Agent’s failure to disburse the Purchase Deposit if a dispute shall have arisen between the Parties with respect to the propriety of such disbursement; and there is an unresolved dispute as to who is entitled to receive the amount(s) escrowed, Escrow Agent shall have the right to retain the funds and disburse them in accordance with the final order of a Court of competent jurisdiction located in Montgomery County, Maryland, or to deposit such funds with said Court pending a final decision of such controversy. The Parties further agree that Escrow Agent shall not be liable for failure of any *bona fide*, federally-insured depository and shall not be otherwise liable except in the event of Escrow Agent is guilty of negligence or misconduct.

## **13. DEVELOPMENT.**

### **A. Definitions.**

(1) “Applicable Law” means any federal, state or local law or regulation, or bond covenants for Federal, County Government, or State bonds, applicable to the parties, the Property and/or this Agreement. Applicable Law includes orders of court or administrative agencies having jurisdiction over any of the parties hereto with respect to or affecting the Purchaser or the Property, including without limitation regulations of and requirements imposed by the United States Food and Drug Administration (the “FDA”).

(2) “Development Approvals” means, as contemplated by Applicable Law, and as may be necessary, any subdivision approval (including without limitation the Subdivision Waiver Approval), preliminary plan of subdivision approval, project plan approval, site plan approval, record plat approval and recordation, site plan enforcement agreements, building permits, storm water management approvals, sediment control permits, utility connections and any other permit or governmental or quasi-governmental approval (including without limitation from the FDA) which is necessary to commence and duly and diligently construct to completion, reconstruct, operate, repair and maintain the Project.

(4) “Force Majeure” means the following events or circumstances, to the extent that they cause the delay of performance of any obligation hereunder incurred by Purchaser and such delay is beyond the reasonable control of and could not be reasonably anticipated or accommodated by Purchaser:

Strikes or lockouts (excluding the general contractor’s workforce) or inability to procure materials or suitable substitute materials or failure of utilities necessary for performance;

Changes in law (including without limitation any Applicable Law) applicable to the development, construction and/or operation of the Project, including changes in law that would reduce or restrict the density, height or use



of the Project as contemplated by Purchaser;

Delays in obtaining Development Approvals for the development, construction and/or operation of the Project, including the imposition of conditions to Development Approvals that materially and adversely affect Purchaser's ability to construct the Project as contemplated by Purchaser;

Acts of God, tornadoes, hurricanes, floods, sinkholes, fires and other casualties, landslides, earthquakes, and abnormally inclement weather for the area;

Acts of war, terrorism, blockades, insurrection, riots, civil disturbances, or national calamities; and

Other acts or circumstances to the extent they would otherwise customarily constitute a Force Majeure event.

Force Majeure shall not include matters which increase cost but do not cause delay.

(3) "Permitted Uses" means the utilization of the Project for the Silver Spring Ovarian Cancer Laboratory Project, other biotechnology or laboratory purposes, and/or other uses supporting the primary use, including without limitation administrative offices and storage.

(4) "Project" means all improvements now or hereafter constructed on the Property from time to time. The initial phase of the Project shall include construction of approximately 37,000 square feet (and containing approximately 30,000 square feet of FAR) of laboratory space, related administrative laboratory space, and related administrative and ancillary uses.

#### B. Construction of Improvements.

(1) Commencement of Construction. Purchaser agrees to commence construction of the initial phase of the Project on the Property within ninety (90) days after the later to occur of (i) the Closing Date or (ii) the issuance of the Development Approvals (the "Construction Commencement Date"), and thereafter to proceed with reasonable dispatch to complete construction of the Project. Notwithstanding the foregoing, the Construction Commencement Date shall be extended one (1) day for each day that the construction of the initial phase of the Project cannot be undertaken due to events of Force Majeure up to a total of 18 months after the Construction Commencement Date.

(2) Completion of Construction. The initial phase of the Project shall be "Substantially Completed" by the date (the "Substantial Completion Date") which is no later than the later to occur of (i) October 1, 2007, or (ii) the date which is two (2) years after the issuance of the Development Approvals. Notwithstanding the foregoing, the Substantial Completion Date shall be extended one (1) day for each day that the construction of the initial phase of the Project cannot be undertaken or Substantially Completed due to events of Force Majeure. For purposes of this subparagraph (2), the initial phase of the Project shall be deemed to be "Substantially Completed" on the date that Purchaser's architect shall execute a certificate of substantial completion certifying, in part, that construction of the initial phase of the Project has been substantially completed and is available for occupancy (subject to issuance of a certificate of use and occupancy by the Montgomery County Department of Permitting Services) for one or more of the Permitted Uses. The terms, provisions and conditions of the above covenant are set forth in the Restrictive Covenant and Repurchase Agreement, which Restrictive Covenant and Repurchase Agreement shall control over any conflict with the terms, provisions and/or conditions of this subparagraph (2).

C. Cooperation in Obtaining Development Approvals. At all times after the Effective Date and prior to the date of Closing, Seller shall cooperate with Purchaser in assisting Purchaser to obtain Development Approvals. To this end, Seller has executed and delivered to Purchase the Agency Authorization in the form attached hereto as Exhibit F. The foregoing notwithstanding, any instruments or agreements required of Seller hereunder shall be in form reasonably acceptable to Seller and shall not impose any expense or liability on Seller except as Seller may otherwise agree.

D. Use of the Property. For a period of seven (7) years following issuance of a certificate of use and occupancy for the initial phase of the Project, the primary uses of the improvements constructed on the Property shall be restricted to one or more of the Permitted Uses unless otherwise approved by Seller (such approval not to be unreasonably withheld, conditioned or delayed). The terms, provisions and conditions of the above covenant are set forth in the Restrictive Covenant and Repurchase Agreement, which Restrictive Covenant and Repurchase Agreement shall control over any conflict with the terms, provisions and/or conditions of this subparagraph D.

E. Access Easement. The Property shall be developed in such manner as to preserve pedestrian and vehicular access to the Adjacent Garage from Cameron Street to a degree that is at least as good as that which currently exists. The Parties shall execute and deliver at Closing an Easement Agreement, in a form to be agreed upon by the Parties prior to Closing covering both the pedestrian and vehicular access and the Public Facilities.

**14. OPERATION OF THE PROPERTY PENDING CLOSING.** Until the Closing Date, Seller may continue to use the Property as a surface public parking lot in substantially the same manner as Seller operated the public parking lot immediately prior to the Effective Date and

consistent with the operation of other similar facilities operated by

Seller. Any material change in the use of the Property shall require the prior written approval of Purchaser, which may be granted or denied at Purchaser's sole discretion. Seller shall not construct on the Property improvements of any kind (other than pavement repair work for the existing surface lot or repairs needed in connection with the Public Facilities or other utilities serving the Adjacent Garage) without the prior written approval of Purchaser, which may be granted or denied at Purchaser's sole discretion. Other than in connection with the public parking on the Property or servicing the Adjacent Garage, Seller shall not store any vehicles, supplies or materials (including without limitation any Hazardous Materials) on the Property. Prior to the Closing Date, Seller shall remove at its sole cost and expense all parking meters and other personal property of Seller affixed to or located on the Property (excluding the Public Facilities). Any such property remaining on the Property after the Closing Date shall become the property of Purchaser and may be disposed of by Purchaser as it sees fit without obligation to Seller. Prior to Closing, Seller shall not encumber the Property or allow any judgment to attach to the Property or grant, convey or assign any easement or other property right or interest in the Property or any portion thereof

**15. CHOICE OF LAW .** This Agreement, the rights and obligations of the Parties hereto, and any claims or disputes relating thereto shall be governed by and construed in accordance with the laws of the State of Maryland. In the event of any dispute arising with respect to this Agreement, the Parties agree that venue shall be in the Circuit Court for Montgomery County, Maryland.

**16. TIME OF ESSENCE .** Purchaser and Seller agree that time is of the essence of this Agreement.

**17. ACCEPTANCE; DATE OF AGREEMENT .** The "Effective Date" shall be the date this Agreement is executed by the Seller. This Agreement must be ratified and accepted by Seller within thirty (30) business days after the date this Agreement is executed by Purchaser in order to be effectual and binding; otherwise, the obligations of Purchaser hereunder shall cease and terminate and the Purchase Deposit shall be refunded.

**18. BINDING EFFECT; ENTIRE AGREEMENT .** Purchaser and Seller mutually agree that this Agreement shall be binding upon them, and their respective heirs, executors, administrators, successors and assigns; that this Agreement contains the final and entire Agreement between the Parties, and that they shall not be bound by any terms, conditions, statements, warranties, or representations, oral or written, express or implied, not expressly contained herein. The language of this Agreement shall in all cases be construed as a whole and according to its fair meaning and not strictly for or against any party hereto, whether or not all or any portion of this Agreement was drafted by or on behalf of any party hereto.

**19. PRONOUNS.** The words "Seller," "Purchaser," all pronouns and any variations thereof shall be deemed to refer to the masculine, feminine, neuter, singular or plural, as the identity of the person or entity and the context may require.

**20. NOTICES.** Any notices, consents or other communications required or permitted to be given pursuant to this Agreement must be in writing and shall be deemed to have been delivered (a) if delivered in person or via courier, when received at the address of the person to whom notice is given, (b) if sent by a nationally recognized overnight delivery service (e.g., Federal Express, UPS, Airborne Courier), on the first (1st) business day after receipt by such delivery service for overnight delivery, or (c) if sent by certified United States Mail (except where actual receipt is specified in this Agreement), on the earlier of the date actually received or two (2) business days after deposited in a receptacle provided by the United States Post Office, addressed to the intended Parties at the following respective addresses:

If to Seller:  
Office of the County Executive  
101 Monroe Street, Second Floor  
Rockville, Maryland 20850  
Attention: Chief Administrative Officer

Montgomery County Government

With a copy that does not constitute notice to:

Montgomery County Government  
Department of Economic Development  
101 Monroe Street  
Rockville, Maryland 20850  
Attention: Director



With a copy that does not constitute notice to:

County Attorney for Montgomery County, Maryland  
101 Monroe Street, 3rd Floor  
Rockville, Maryland 20850  
Attn.: County Attorney

With a copy that does not constitute notice to:

Montgomery County Department of Public  
Works and Transportation, Division of Parking Services  
101 Orchard Ridge Drive, Suite 200  
Gaithersburg, Maryland 20878

If to Purchaser: Unither Pharmaceuticals, Inc.  
1110 Spring Street  
Silver Spring, Maryland 20910  
Attn: General Counsel

With a copy to: Holland & Knight LLP  
3 Bethesda Metro Center, Suite 800  
Bethesda, Maryland 20814  
Attn. Jerald S. Cohn, Esq.

If to Escrow Agent: Arthur Konopka Law Offices  
4530 Wisconsin Avenue, N.W., Suite 300  
Washington, D.C. 20016  
Attn. Arthur Konopka, Esq.

or to such other substitute address and/or addressee as any party hereto shall designate by written notice to the other party in accordance with the terms of this paragraph; provided, however, that no such notice of change of address and/or addressee shall be effective unless and until actually received by the party to whom such notice is sent.

**21. MEMORANDUM OF CONTRACT.** Upon execution of this Agreement, Seller and Purchaser shall execute and deliver a Memorandum of Real Estate Purchase Agreement (the "Memorandum of Contract") in the form attached hereto as Exhibit G. Purchaser shall thereupon cause the Memorandum of Contract to be recorded against the Property to provide notice of the existence of this Agreement.

## **22. MONTGOMERY COUNTY PROVISIONS.**

### **A. Master Plan Disclosures.**

(i) Seller has offered the Purchaser the opportunity to review the applicable master plan and municipal land use plan for the area in which the Property is located and any adopted amendment.

(ii) Seller has informed Purchaser that amendments affecting the plan may be pending before the County Planning Board or the County Council or a municipal planning body.

(iii) Purchaser has waived the right to review each plan and adopted amendment.

(iv) Purchaser understands, that to stay informed of future changes in county or municipal land use plans, Purchaser should consult the County Planning Board and the appropriate municipal planning body.

### **B. Water and Sewer Disclosures.**

(i) Seller has provided to Purchaser the all information required by §40-10A(a) of the

Montgomery Code (or Seller has informed Purchaser that Seller does not know the information required by said §40-10A(a)), including the following: (i) whether the Property is connected to, or has been approved for connection to, a public water and sewer system, (ii) the source, if any, of potable water for the Property, (iii) whether an individual sewage disposal system has been constructed on the Property or approved or disapproved for construction, (iv) the water and sewer service area category or categories that currently apply to the Property, and a brief explanation of how each category affects the availability of water and sewer service to the Property, (v) any recommendations in the applicable master plan regarding water and sewer service to the Property, and (vi) the status of any pending water and sewer comprehensive plan amendments or service area category changes that would apply to the Property.

(ii) Purchaser understands that, to stay informed of future changes in County or municipal water and sewer changes, Purchaser should consult the County Planning Board, the Washington Suburban Sanitary Commission, the Department of Permitting Services, or the Department of Environmental Protection, or any appropriate municipal planning board or water and sewer body.

C. Subdivision Plat. Purchaser acknowledges that, due to the pending subdivision process, Purchaser will not receive a copy of any plat of subdivision in which the Property is located and no plat of subdivision will exist on the date of Closing.

D. Airports, Heliports Disclosures. Purchaser hereby acknowledges that Seller has disclosed to Purchaser the relative location of an airport or heliport, as defined in the Montgomery County Zoning Ordinance, existing within a five-mile radius of the Property.

E. Special Protection Area Disclosures. Seller has disclosed to Purchaser whether the Property is located in an area designated as a special protection area under §19-62 of the Montgomery County Code. If the Property is located in a “special protection area,” Purchaser understands that special water quality measures and certain restrictions on land uses and impervious surfaces may apply to the Property.

[ Signatures Commence on Next Page ]

IN WITNESS WHEREOF, the Parties hereto hereby ratify, accept and agree to the above and acknowledge it to be our Agreement, all as of the day and year first hereinabove written.

PURCHASER:

UNITHER PHARMACEUTICALS, INC., a Delaware corporation

By: /s/ Martine Rothblatt, Ph.D.

Name: Martine Rothblatt, Ph.D.

Title: CEO

Date: October 31, 2003

SELLER:

MONTGOMERY COUNTY, MARYLAND

By: /s/ William Money

William Mooney  
Assistant Chief Administrative Officer

Date: November 20, 2003

APPROVED AS TO FORM AND LEGALITY

By: /s/ Diane R. A. Jones

Diane R. A. Jones

Date: November 14, 2003

## EXHIBIT E

After recording, return to:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

### RESTRICTIVE COVENANT AND REPURCHASE AGREEMENT

THIS RESTRICTIVE COVENANT AND REPURCHASE AGREEMENT (this “Agreement”) is made as of this \_\_\_\_ day of \_\_\_\_, 200\_\_\_\_, by and between MONTGOMERY COUNTY, MARYLAND, a political subdivision of the State of Maryland (the “County”), and UNITHER PHARMACEUTICALS, INC., a Delaware corporation (“Unither,” which term shall include the successors and assigns of Unither).

### RECITALS

A. Pursuant to that certain Special Warranty Deed of even date herewith, the County conveyed to Unither all the County’s right, title and interest in and to that certain parcel of real property located in Montgomery County, Maryland, more particularly described by Exhibit A attached hereto (the “Property”).

B. Unither has proposed to construct certain improvements on the Property.

C. The County and Unither agreed to enter into this Agreement in order to ensure that the Construction Covenant and the Permitted Uses Covenant (as hereinafter defined) as set forth in this Agreement (i) will, during the Effective Period (as hereafter defined), run with, encumber and burden the Property, and be binding, during the Effective Period, upon Unither and all others who may hereafter obtain any interest in or to all or any portion of the Property, and (ii) will, during the Effective Period, run to the benefit of the County and be enforceable, in accordance with the terms of this Agreement, by the County.

NOW, THEREFORE, in consideration of the foregoing recitals and of other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the County and Unither do hereby covenant and agree as follows:

#### 1. Definitions.

(a) “Additional Investment Costs” mean all actual out-of-pocket costs paid by Unither to third parties and which are incurred through the date of the closing of the repurchase for construction, architectural and engineering services and materials in connection with the development and construction of the improvements which comprise the Project.

(b) “Applicable Law” means any federal, state or local law or regulation, or bond covenants for Federal, County Government, or State bonds, applicable to the parties, the Property and/or this Agreement. Applicable Law includes orders of court or administrative agencies having jurisdiction over any of the parties hereto with respect to or affecting Unither or the Property, including without limitation regulations of and requirements imposed by the United States Food and Drug Administration (the “FDA”).

(c) “Changes in Law” means changes in law (including without limitation any Applicable Law) applicable to the development, construction and/or operation of the Project, including changes in law that would reduce or restrict the density, height or use of the Project as contemplated by Unither;

(d) “Development Approvals” means, as contemplated by Applicable Law, and as may be necessary, any subdivision approval (including without limitation approval beyond any applicable appeal period of the waiver of certain Subdivision Regulations as requested by Unither by letter dated August 28, 2003, to the Montgomery County Planning Board of the Maryland-National Capital Park and Planning Commission), preliminary plan of subdivision approval, project plan approval, site plan approval, record plat approval and recordation, site plan enforcement agreements, building permits, storm water management approvals, sediment control permits, utility connections and any other permit or governmental or quasi-governmental approval (including without limitation from the FDA) which is necessary to commence and duly and diligently construct to completion, reconstruct, operate, repair and maintain the Project.

(e) “Force Majeure” means the following events or circumstances, to the extent that they cause the delay of performance of any obligation hereunder incurred by Unither and such delay is beyond the reasonable control of and could not be reasonably anticipated or accommodated by Unither:

- Strikes or lockouts (excluding the general contractor’s workforce) or inability to procure materials or suitable substitute materials or failure of utilities necessary for performance;
- Changes in Law;
- Delays in obtaining Development Approvals for the development, construction and/or operation of the Project, including the imposition of conditions to Development Approvals that materially and adversely affect Unither’s ability to construct the Project as contemplated by Unither;
- Acts of God, tornadoes, hurricanes, floods, sinkholes, fires and other casualties, landslides, earthquakes, and abnormally inclement weather for the area;
- Acts of war, terrorism, blockades, insurrection, riots, civil disturbances, or national calamities; and
- Other acts or circumstances to the extent they would otherwise customarily constitute a Force Majeure event.
- Force Majeure shall not include matters which increase cost but do not cause delay.

(f) “Permitted Uses” means the utilization of the Project for the Silver Spring Ovarian Cancer Laboratory, other biotechnology or laboratory purposes, and/or other uses supporting the primary use, including without limitation administrative offices and storage.

(g) “Project” means all improvements now or hereafter constructed on the Property from time to time. The initial phase of the Project shall include construction of approximately 37,000 square feet (and containing approximately 30,000 square feet of FAR) of laboratory space, related administrative laboratory space, and related administrative and ancillary uses.

(h) “Repurchase Price” means the amount equal to the sum of (i) one hundred percent (100%) of the Purchase Price paid by Unither to the County for the Property, which is an amount equal to [ TWO MILLION EIGHT HUNDRED EIGHTY THOUSAND AND NO/100 DOLLARS (\$2,880,000.00) ], plus (ii) Additional Investment Costs.

## 2. Construction Covenant.

(a) Unither hereby covenants and agrees that the initial phase of the Project shall be “Substantially Completed” by the date (the “Substantial Completion Date”) which is no later than the later to occur of (i) October 1, 2007, or (ii) the date which is two (2) years after the issuance of the Development Approvals. Notwithstanding the foregoing, the Substantial Completion Date shall be extended one (1) day for each day that the construction of the initial phase of the Project cannot be undertaken or Substantially Completed due to events of Force Majeure.

(b) For purposes of paragraph 2(a) above, the initial phase of the Project shall be deemed to be “Substantially Completed” on the date that Unither’s architect shall execute a certificate of substantial completion certifying, in part, that construction of the initial phase of the Project has been substantially completed and is available for occupancy (subject to issuance of a certificate of use and occupancy by the Montgomery County Department of Permitting Services) for one or more of the Permitted Uses.

(c) Promptly after the initial phase of the Project has been Substantially Completed, upon request made by Unither to the County, the County shall execute a written release of the Construction Covenant to be recorded among the Land Records of Montgomery County, Maryland.

## 3. Permitted Uses Covenant.

(a) Unither hereby covenants and agrees that, commencing on the date of issuance of a certificate of use and occupancy for the initial phase of the Project and continuing through the last day of the Effective Period (as hereinafter defined), the primary use of the Project shall be restricted to one or more of the Permitted Uses unless otherwise approved by the County, such approval not to be unreasonably withheld, conditioned or delayed (the aforesaid covenant is hereinafter referred to as the “Permitted Uses Covenant”). Nothing herein shall be deemed to prohibit Unither from leasing or

licensing all or a portion of the Property (or to consent to any sublease) to related or third party tenants, subtenants or licensees so long as each said tenant, subtenant or licensee, as the case may be, is obligated by the term of its lease, sublease or license to use its premises solely for one or more of the Permitted Uses.

(b) Notwithstanding anything to the contrary set forth in this Agreement, in the event that a Change in Law shall occur which prohibits or materially limits any of the Permitted Uses, and said Change in Law was not initiated by Unither or acquiesced by Unither, then this Agreement shall thereupon automatically terminate (including without limitation the Construction Covenant and the Permitted Use Covenant) and be of no further force or effect. Upon request made by Unither to the County after the effective date of such a Change on Law, the County shall promptly execute a written release of this Agreement to be recorded among the Land Records of Montgomery County, Maryland.

#### 4. Default under Construction Covenant; Remedy.

(a) A “Construction Covenant Event of Default” shall be deemed to have occurred under this Agreement after the occurrence of all of the following:

- (i) A violation of the covenant set forth paragraph 2(a) above shall have occurred; *and*
- (ii) the County shall have provided to Unither a written notice of default describing the alleged violation in reasonable detail (the “Notice of Construction Covenant Default”); *and*
- (iii) Unither has failed to cure said violation within ninety (90) days after Unither’s receipt of the Notice of Construction Covenant Default (or, if the cure of the violation cannot reasonably be cured within said 90-day period and if Unither has commenced action to cure said violation within said 90-day period and continues diligently to pursue said cure, such longer time as may be reasonably necessary to cure such violation) (said cure period, the “Cure Period”).

(b) The County’s sole and exclusive remedy in the event of an occurrence of a Construction Covenant Event of Default shall be to elect to repurchase the entire Property (including the then-existing improvements), strictly in accordance with the provisions set forth in subparagraphs 4(b)(i) through (iv) below (the “Repurchase Right”).

(i) The County shall exercise the Repurchase Right by providing written notice to Unither (the “Exercise Notice”) no more than thirty (30) days after the expiration of the Cure Period. If the County shall fail to provide the Exercise Notice within said thirty (30) day period, the County shall be deemed to have waived its right to exercise its Repurchase Right with respect to said Construction Covenant Event of Default.

(ii) Upon exercise of the Repurchase Right, the County shall repurchase the Property (including without limitation any improvements constructed thereon) but excluding all personal property located thereon or therein) at the Repurchase Price. The County’s repurchase right shall exclude all of Unither’s personal property located on the Property (other than such fixtures and other items of personal property which are included as part of the Additional Investment Costs), which personal property shall be removed by Unither prior to the closing of the repurchase and shall all times remain the property of Unither unencumbered by this Agreement. Unither shall exercise due care in the removal of its personal property from the Property and Unither shall be responsible for the costs of repairing any damage caused to the improvements as a result of such removal. In the event that the Repurchase Price includes payment for documents, warranties, plans and/or specifications related to the Project and stored or maintained at a location other than the Property, Unither will, to the extent of its ownership rights therein, deliver or cause copies of such construction documents, warranties, plans and/or specifications to be delivered to the County at one or more locations to be prescribed by the County.

(iii) The closing on the repurchase shall occur on a date after the date of the Exercise Notice that is mutually satisfactory to Unither and the County, but in no event shall such closing occur more than one hundred eighty (180) days after the date of the Exercise Notice. At the closing of the repurchase (i) Unither will, by special warranty deed, convey to County all of Unither’s right, title, and interest in the Property and all improvements thereon, free and clear of all liens and encumbrances except the title exceptions listed as “Permitted Exceptions” in the deed to Unither from the County and any other easements, covenants and restrictions encumbering the Property that Unither accepted after said closing; and (ii) the County shall pay to Unither the Repurchase Price by wire transfer of funds pursuant to wire instructions to be provided to the County prior to the closing of the repurchase. If the County provides the Exercise Notice but fails, for any reason other than a breach or default by Unither, to close on the repurchase as aforesaid, the County shall waive all of its rights to repurchase the Property and this Agreement (including the Construction Covenant, the Permitted Uses Covenant, and the

Repurchase Right) shall be deemed terminated without further action by any party, and Unither may thereafter sell, use or lease the Property free and clear thereof.

(iv) Upon closing on the repurchase and the payment by the County to Unither of the Repurchase Price, the County and Unither agree that each shall be released of any and all liability to the County with respect to the Property, including without limitation arising by virtue of this Agreement.

5. Default under Permitted Uses Covenant; Remedy.

(a) A "Use Covenant Event of Default" shall be deemed to have occurred under this Agreement after the occurrence of all of the following:

- (i) A violation of the covenant set forth paragraph 3(a) above shall have occurred; *and*
- (ii) the County shall have provided to Unither a written notice of default describing the alleged violation in reasonable detail (the "Notice of Default"); *and*
- (iii) Unither has failed to cure said violation within ninety (90) days after Unither's receipt of the Notice of Default (or, if the cure of the violation cannot reasonably be cured within said 90-day period and if Unither has commenced action to cure said violation within said 90-day period and continues diligently to pursue said cure, such longer time as may be reasonably necessary to cure such violation).

(b) The County's sole and exclusive remedy in the event of an occurrence of a Use Covenant Event of Default shall be to enforce the Permitted Use Covenant by seeking from the Circuit Court for Montgomery County, Maryland, an appropriate injunction to enjoin the violation of the Permitted Uses Covenant. Unither acknowledges that, upon a violation of the Permitted Uses Covenant, the County would suffer damages that would not be compensated adequately by the award of money damages or other remedy at law alone. Accordingly, Unither agrees that the issuance of an injunction enjoining the violation of Permitted Uses Covenant would be appropriate. Unither shall raise no defense to any petition for an injunction sought by the County under this subparagraph except to argue, if appropriate, that the use in question is, in fact, one of the Permitted Uses. In the event of an occurrence of a Use Covenant Event of Default, (i) the County shall have no right to seek monetary damages and the County hereby waives any such right, and (ii) the County would have no right to repurchase the Property (or any portion thereof).

6. Effective Period. This Agreement shall be valid commencing on the date of this Agreement and shall terminate automatically (and without the need for any further documentation to be executed or recorded by any party) on the date that is seven (7) years after the initial use and occupancy certificate for the initial phase of the Project is issued by Montgomery County, Maryland (the "Effective Period"). Upon request made by Unither to the County after the Effective Period has expired, the County shall promptly execute a written release of this Agreement to be recorded among the Land Records of Montgomery County, Maryland.

7. Benefit and Burden. Each provision of this Agreement is, during the Effective Period, (i) an equitable servitude upon and a covenant running with, encumbering and burdening, during the Effective Period, the Property and (ii) binding upon Unither and all others who may hereafter obtain any interest in or to all or any portion of the Property. Each provision of this Agreement is, during the Effective Period, enforceable (only as permitted by paragraphs 4 and 5 of this Agreement, as applicable) by the County.

8. Governing Law. This Agreement, the rights and obligations of the parties hereto, and any claims or disputes relating thereto shall be governed by and construed in accordance with the laws of the State of Maryland. In the event of any dispute arising with respect to this Agreement, the parties agree that venue shall be in the Circuit Court for Montgomery County, Maryland.

9. Notices. Any notices, consents or other communications required or permitted to be given pursuant to this Agreement must be in writing and shall be deemed to have been delivered (a) if delivered in person or via courier, when received at the address of the person to whom notice is given, (b) if sent by a nationally recognized overnight delivery service (e.g., Federal Express, UPS, Airborne Courier), on the first (1st) business day after receipt by such delivery service for overnight delivery, or (c) if sent by certified United States Mail (except where actual receipt is specified in this Agreement), on the earlier of the date actually received or two (2) business days after deposited in a receptacle provided by the United States Post Office, addressed to the intended Parties at the following respective addresses:

If to the County:

Montgomery County Government  
Chief Administrative Officer  
101 Monroe Street, Second Floor  
Rockville, Maryland 20850

With a copy that does not constitute notice to:

Montgomery County Government  
Department of Public Works and Transportation  
101 Monroe Street, 10<sup>th</sup> Floor  
Rockville, Maryland 20850  
Attention: Director

With a copy that does not constitute notice to:

Montgomery County Government  
Department of Economic Development  
101 Monroe Street, 15<sup>th</sup> Floor  
Rockville, Maryland 20850  
Attention: Director

With a copy that does not constitute notice to:

County Attorney for Montgomery County, Maryland  
101 Monroe Street, 3<sup>rd</sup> Floor  
Rockville, Maryland 20850  
Attn.: County Attorney

If to Unither:

Unither Pharmaceuticals, Inc.  
1110 Spring Street  
Silver Spring, Maryland 20910  
Attn: General Counsel

With a copy that does not constitute notice to:

Holland & Knight LLP  
3 Bethesda Metro Center, Suite 800  
Bethesda, Maryland 20814  
Attn. Jerald S. Cohn, Esq.

or to such other substitute address and/or addressee as any party hereto shall designate by written notice to the other party in accordance with the terms of this paragraph; provided, however, that no such notice of change of address and/or addressee shall be effective unless and until actually received by the party to whom such notice is sent.

10. Binding Effect; Survival. This Agreement shall be binding, during the Effective Period, upon Unither and all others who may hereafter obtain any interest in or to all or any portion of the Property.

11. Partial Invalidity. If any provision of this Agreement or the application of any such provision to any person or circumstance shall be invalid or unenforceable, the remainder of this Agreement, and the application of that provision to persons or circumstances other than those as to which it is held invalid or unenforceable, shall not be affected, and each provision of this Agreement shall be valid and enforceable to the fullest extent permitted by law.

12. Interpretation. The article and section headings used in this Agreement are for convenience only and shall not enter into the interpretation of this Agreement. If any date upon which action is required under this Agreement shall be a Saturday, Sunday, or legal holiday, the date for such action shall be extended to the first regular business day after such date which is not a Saturday, Sunday or legal holiday. The Recitals set forth in this Agreement are incorporated into and made a part of this Agreement.

13. No Third-Party Beneficiaries. No party other than the County shall have any rights under this Agreement, as third-party beneficiaries or otherwise.





14. Entire Declaration. This Agreement contains the entire agreement between the parties regarding the subject matter of this Agreement. There are no promises, agreements, conditions, undertakings, warranties, or representations, oral or written, express or implied, between the parties relating to the subject matter hereof, other than as set forth in this Agreement. This Agreement is intended by the parties to be an integration of all prior or contemporaneous promises, agreements, conditions, negotiations, and undertakings between them. This Agreement shall not be construed more strictly against one party than against the other party merely because its may have been prepared by counsel for one of the parties, it being recognized and agreed that all parties are thoroughly familiar with the terms and provisions of this Agreement and, together with their respective counsel, have actively participated in the preparation of this Agreement.

15. Modifications, Waivers, and Consents. Modifications, waivers, and consents respecting this Agreement shall only be binding if in writing and signed by Unither (or its successor or assigns) and the County. In addition, no modification of this Agreement shall be effective unless and until duly recorded among the Land Records of Montgomery County, Maryland.

16. No Partnership. This Agreement is not intended to, and does not, create a joint venture, partnership, or any other similar relationship between the parties.

17. No Waiver. Except as otherwise expressly provided in this Agreement, (i) no delay or omission by the County in exercising any right or power accruing upon Unither's non-compliance with or failure to perform any of the provisions of this Agreement shall impair or be construed to be a waiver of any such right or power, and (ii) a waiver by the County of any of the obligations of Unither under this Agreement in one instance shall not be construed to be a waiver of any subsequent breach of that obligation or a waiver of any other term, covenant, or condition of this Agreement.

18. Estoppel Certificates. The County shall, without charge, at any time and from time to time hereafter, within twenty (20) days after written request of Unither, certify by written instrument, duly executed and acknowledged, to any mortgagee, proposed mortgagee, proposed purchaser or proposed tenant (collectively, the "Addressee"): (i) whether this Agreement has been supplemented or amended, and, if so, the substance and manner of the supplement or amendment; (ii) whether any default exists under this Agreement, and, if so, a description of each such default; (iii) whether any offsets, counterclaims or defenses exist on the part of the responding party with respect to its obligations under this Agreement, and, if so, the nature and amount of such offsets, counterclaims or defenses; and (iv) such other matters as maybe reasonably requested. Subject to the foregoing, any such certification shall be in form and substance acceptable to the County and shall provide that the certificate is for the sole benefit of the Addressee and may not be relied upon by any other person or entity. The certificate shall estop the County from asserting a defense or claim against the Addressee that is inconsistent with the facts contained in the certificate, but only to the extent the Addressee relied upon the statement of fact and had no actual knowledge of any facts that were inconsistent with the facts contained in the certificate. Regardless of any inaccuracy or misstatement contained therein, said certificate shall create no liability on the part of the County to the Addressee.

19. Recordation. Unither shall pay all costs of recording this Agreement, including, without limitation, the costs of tax certificates, notary fees, documentary stamps, all transfer and recordation taxes, and recording charges.

20. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be an original but all of which shall constitute one and the same instrument.

[ SIGNATURES COMMENCE ON NEXT PAGE ]

IN WITNESS WHEREOF, the parties have caused this Restrictive Covenant and Repurchase Agreement to be executed as of the above written date.

UNITHER:

UNITHER PHARMACEUTICALS, INC., a Delaware corporation

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

COUNTY:

MONTGOMERY COUNTY, MARYLAND

By: \_\_\_\_\_

Douglas M. Duncan,  
County Executive

APPROVED AS TO FORM AND LEGALITY

By: \_\_\_\_\_

Date: \_\_\_\_\_, 2003

STATE OF MARYLAND )

COUNTY OF MONTGOMERY )

) : ss

On this \_\_\_\_ day of \_\_\_\_\_, 2003, before me, personally appeared Douglas M. Duncan, who acknowledged himself to be the County Executive of Montgomery County, Maryland, a political subdivision of the State of Maryland, and that he, as said as County Executive, executed the foregoing Restrictive Covenant and Repurchase Agreement for the purposes therein contained.

IN WITNESS WHEREOF, I hereunto set my hand and official seal.

\_\_\_\_\_  
Notary Public

My Commission Expires: \_\_\_\_\_

THIS IS TO CERTIFY that the within instrument has been prepared by or under the supervision of the undersigned Maryland attorney.

---

Jerald S. Cohn

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 Ernst & Young LLP, Independent Auditors**

The Board of Directors  
United Therapeutics Corporation:

We consent to the incorporation by reference in the Registration Statements (Form S-8 Nos. 333-108169, 333-56922 and 333-95419) of United Therapeutics Corporation of our report dated February 20, 2004, with respect to the consolidated financial statements and schedules of United Therapeutics Corporation listed in Item 15(a) included in the Annual Report (Form 10-K) for the year ended December 31, 2003.

/s/ Ernst & Young LLP

McLean, Virginia  
March 8, 2004

Independent Auditors' Report and Consent

The Board of Directors  
United Therapeutics Corporation:

The audits referred to in our report dated February 28, 2003, included the related financial statement schedule for each of the years in the two-year period ended December 31, 2002, included in this annual report on Form 10-K of United Therapeutics Corporation. This financial statement schedule is the responsibility of the Company's management. Our responsibility is to express an opinion on this financial statement schedule based on our audits. In our opinion, such financial statement schedule, 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.

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 of United Therapeutics Corporation of our reports dated February 28, 2003, with respect to the consolidated balance sheet of United Therapeutics Corporation and subsidiaries as of December 31, 2002, 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, 2002, and the related financial statement schedule, which reports appear in the December 31, 2003 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  
March 9, 2004

**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) 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) 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
  - c) 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: March 12, 2004

/s/ Martine A. Rothblatt

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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) 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) 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
  - c) 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: March 12, 2004

/s/ Fred T. Hadeed

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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 ending December 31, 2003 as filed with the Securities and Exchange Commission on or about March 12, 2004 (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 compiles 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

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Martine A. Rothblatt  
Chairman and Chief Executive Officer  
United Therapeutics Corporation  
March 12, 2004

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 ending December 31, 2003 as filed with the Securities and Exchange Commission on or about March 12, 2004 (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 compiles 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  
March 12, 2004

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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