

# UNITED THERAPEUTICS CORP

## FORM 10-K (Annual Report)

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

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Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**FORM 10-K**

(Mark One)

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

For the fiscal year ended December 31, 2005

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 0-26301

**United Therapeutics Corporation**

(Exact Name of Registrant as Specified in Its Charter)

**Delaware**

(State or Other Jurisdiction of  
Incorporation or Organization)

**52-1984749**

(I.R.S. Employer  
Identification No.)

**1110 Spring Street, Silver Spring, MD**

(Address of Principal Executive Offices)

**20910**

(Zip Code)

**(301) 608-9292**

Registrant's Telephone Number, Including Area Code

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

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

None

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

Common Stock, par value \$.01 per share  
and associated preferred stock purchase rights

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☒

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ 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 a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Securities Exchange Act. (Check one) Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

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

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

**DOCUMENTS INCORPORATED BY REFERENCE**

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

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## PART I

### ITEM 1. BUSINESS

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

- *Prostacyclin Analogs* , which are stable synthetic forms of prostacyclin, an important molecule produced by the body that has powerful effects on blood-vessel health and function. Our drug Remodulin<sup>®</sup> has been approved by the Food and Drug Administration (FDA) in the United States for the treatment of pulmonary arterial hypertension in patients with NYHA Class II-IV symptoms to diminish symptoms associated with exercise, and in other countries for similar use;
- *Immunotherapeutic Monoclonal Antibodies* , which are antibodies that activate patients' immune systems to treat cancer, including OvaRex<sup>®</sup> , which is being developed for the treatment of ovarian cancer;
- *Glycobiology Antiviral Agents* , which are a novel class of small molecules which may be effective as an oral therapy for hepatitis C and other infections;

Most of our resources are focused on our prostacyclin analogs for the treatment of cardiovascular disease and immunotherapeutic monoclonal antibodies for the treatment of cancer. Our other principal focus area is the development of glycobiology antiviral agents for the treatment of hepatitis and other diseases.

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

## United Therapeutics' Products

Our product portfolio includes the following:

<u>Product</u>	<u>Mode of Delivery</u>	<u>Indication/Market</u>	<u>Current Status</u>	<u>Our Territory</u>
Remodulin <sup>®</sup>	Continuous subcutaneous	Pulmonary arterial hypertension	Commercial in U.S., most of Europe**, Australia, Canada, Israel, Chile and Argentina	Worldwide
Remodulin <sup>®</sup>	Continuous intravenous	Pulmonary arterial hypertension	Commercial in U.S., Canada and Israel. European reviews are ongoing	Worldwide
Arginine Formulations	Oral dietary supplement	Vascular function	Commercial	Worldwide
CardioPAL <sup>®</sup> and Decipher <sup>®</sup> Recorders	Telemedicine	Arrhythmias and ischemic heart disease	Commercial	Worldwide
OvaRex	Intravenous	Ovarian cancer	Phase III	Worldwide *
Remodulin	Intermittent subcutaneous	Critical limb ischemia	Phase II	Worldwide
TRIUMPH	Inhaled	Pulmonary arterial hypertension	Phase II/III	Worldwide
UT-15C Sustained Release	Oral	Pulmonary arterial hypertension and peripheral vascular disease	Phase I/II	Worldwide
BrevaRex <sup>®</sup>	Intravenous	Pancreatic cancer	Phase I	Worldwide *
Beraprost <sup>®</sup> SR	Oral	Peripheral vascular disease and pulmonary arterial hypertension	Phase I	U.S./Canada
Glycobiology Antiviral Agents	Oral	Hepatitis B/C, dengue fever and Japanese encephalitis	Preclinical	Worldwide
OncoRex <sup>®</sup>	Intravenous	Various cancers	Preclinical	Worldwide *
ProstaRex <sup>®</sup>	Intravenous	Prostate cancer	Preclinical	Worldwide *
GivaRex <sup>®</sup>	Intravenous	Gastrointestinal cancer	Preclinical	Worldwide *

\* Including Germany, but excluding the rest of Europe and the Middle East.

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

### *Remodulin*

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

### *Pulmonary Arterial Hypertension*

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

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. However, due to the rareness of pulmonary arterial hypertension and the complexities of diagnosing it, only a fraction of these patients are being treated for pulmonary arterial hypertension.

Pulmonary arterial hypertension is associated with reduced production of the natural hormone prostacyclin in the pulmonary blood vessels. Prostacyclin appears to dilate blood vessels, 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 is approved for the treatment of patients with certain subsets of late-stage pulmonary arterial hypertension.

#### *Subcutaneous Remodulin*

In March 2000, we completed an international, randomized, placebo-controlled, double-blind study of subcutaneous Remodulin involving a total of 470 patients with pulmonary arterial hypertension. Half of the patients received Remodulin subcutaneously for 12 weeks, while the other half received a placebo. The study data showed 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, we filed a New Drug Application with the FDA in late 2000. On May 21, 2002, the FDA approved Remodulin (treprostinil sodium) Injection as a continuous subcutaneous infusion for the treatment of pulmonary arterial hypertension in patients with NYHA class II-III-IV (with class IV representing the most severely ill patients) symptoms to diminish symptoms associated with exercise. Remodulin may be prescribed for all forms of pulmonary arterial hypertension and is the only pulmonary arterial hypertension treatment approved anywhere for patients with NYHA class II (early-stage) symptoms.

We believe Remodulin provides patients with a less invasive alternative to Flolan. In contrast to Flolan, Remodulin is stable at room temperature and has a significantly longer duration inside the human body. These attributes allow for safer and more convenient delivery of Remodulin to patients. Unlike Flolan, Remodulin can be delivered by subcutaneous infusion with a pager-sized microinfusion device such as those 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 an intravenous catheter. Remodulin's extended life in the body may also reduce the risk of an abrupt recurrence of pulmonary hypertension and death if treatment is interrupted. The stability of Remodulin also allows it to be prepackaged, thus eliminating the need to reconstitute the drug one or more times daily under completely sterile conditions, as is required with Flolan. Lastly, Remodulin does not require the use of cooling packs or refrigeration as is required with Flolan, to keep it stable. When infused subcutaneously, Remodulin causes infusion site pain and infusion site reaction in most patients in varying degrees. Patients who cannot tolerate subcutaneous Remodulin may instead use it intravenously. Intravenous Remodulin is delivered continuously by an external pump through a surgically implanted intravenous catheter, similar to Flolan. When delivered intravenously, Remodulin bears a risk of infection, similar to that of Flolan, but it does not require cooling packs or refrigeration and can be continuously infused for up to 48 hours before refilling the infusion pump.

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

amend the due date of the final study report and make other changes to the trial design, including reducing the number of patients to 39. As amended, the Phase IV clinical trial was required to have been one-half enrolled by June 2004 and fully enrolled by June 2005, with a final study report due December 2005. These enrollment deadlines were not met, and a final study report was not submitted in December 2005.

Although the Phase IV clinical trial, as amended, established deadlines and required a final report by December 2005, the FDA permitted an interim assessment and opportunity to terminate the Phase IV study after only 21 patients completed the study. In July 2005, the first 21 patients completed the study and we chose to perform the interim assessment. The results of the interim assessment, as analyzed by an independent statistician were positive. The p value was 0.0006, meaning that the likelihood that the achieved result was incorrect is six out of ten thousand. Specifically, 13 of 14 patients (93%) in the Remodulin arm were able to successfully transition from Flolan and complete the study without the need to institute rescue therapy, compared to only 1 of 7 patients (14%) in the placebo arm. Based on this positive outcome, we submitted the interim study results to the FDA in July 2005, and requested permission to end the Phase IV clinical study in satisfaction of our Phase IV commitments. By agreement with the FDA, enrollment in the Phase IV clinical study has been suspended pending FDA review and acceptance of the interim study results.

If the FDA does not accept the interim study results or does not otherwise agree with our assessment of the interim results, the FDA could, among other things, grant an extension of time to continue to enroll the trial, or institute a public hearing to withdraw marketing approval for Remodulin. If a withdrawal hearing were instituted by the FDA, we would pursue the opportunity to participate in the hearing, as we believe that we have exercised good faith due diligence in pursuing enrollment of this trial.

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

<u>Country</u>	<u>Date</u>	<u>Approved Indication</u>
Canada	October 7, 2002	Pulmonary arterial hypertension in NYHA class III and IV patients who do not respond adequately to conventional therapy
Israel	October 31, 2002	Primary pulmonary arterial hypertension, pulmonary arterial hypertension associated with connective tissue disorders and pulmonary arterial hypertension associated with congenital systemic to pulmonary shunts
Australia	May 21, 2004	Pulmonary arterial hypertension in NYHA class III and IV to diminish symptoms associated with exercise
Switzerland	November 26, 2004	Primary pulmonary hypertension and pulmonary hypertension with connective tissue disease for NYHA class III and IV patients
France	March 8, 2005	Primary pulmonary hypertension in NYHA class III patients
Argentina	May 4, 2005	Pulmonary arterial hypertension in NYHA class II-IV patients
Austria, Belgium, Czech Republic, Cyprus, Denmark, Estonia, Finland, Germany, Greece, Hungary, Iceland, Italy, Latvia, Lithuania, Luxembourg, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia and Sweden	August 10, 2005	Primary pulmonary hypertension in NYHA class III patients
Chile	January 3, 2006	Pulmonary arterial hypertension in NYHA class II-IV patients

In most of Europe, the national governments must approve an official price for Remodulin before it can be marketed there by us or our distributors. Currently, France and Portugal are the only countries that have agreed to official prices for Remodulin and we are just now commencing our commercialization efforts in those countries. The receipt of official pricing approvals for the remainder of Europe may take up to one or two years or longer. In the meantime, we will continue to sell (but not market) Remodulin across Europe under the named-patient system, whereby these governments permit us to import and sell Remodulin to hospitals for use in specifically named patients.

We filed applications in Ireland, Spain and the United Kingdom were filed, and later withdrew them with plans to resubmit applications in those countries with data from the Phase IV clinical trial discussed above. Marketing authorization applications are currently under review in other countries for subcutaneous Remodulin.

#### *Intravenous Remodulin*

In July 2003, the FDA accepted our Investigational New Drug Application 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 was filed with the FDA to request approval for intravenous use of Remodulin for pulmonary arterial hypertension. On November 24, 2004, based on data establishing intravenous Remodulin's bioequivalence with the previously approved subcutaneous administration of Remodulin, the FDA approved the intravenous use of Remodulin for those not able to tolerate subcutaneous infusion. This approval was also conditioned upon the diligent and timely completion of the Phase IV trial described above, as well as its outcome.

In March 2005, we commenced a 12-week placebo-controlled trial of intravenous Remodulin in patients with pulmonary arterial hypertension to further assess the clinical benefits of Remodulin. The trial was conducted in India and was designed to enroll up to 126 patients. Interim results of this trial were to be analyzed after 33, 66 and 99 patients completed the 12-week trial. In August 2005, after enrolling 45 patients, we suspended enrollment of new patients, per the recommendation of the trial's independent Data Safety Monitoring Board, which is a panel of independent experts. Preliminary results from the 45 patients were positive ( $p=0.008$ ). Specifically, intravenous Remodulin produced an 83-meter median improvement in six-minute walk distance compared to placebo after twelve weeks.

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

Intravenous infusion of Remodulin was approved in Israel in 2006 and in Canada in 2005 for the treatment of pulmonary arterial hypertension. Marketing authorization applications are currently under review in other countries for intravenous Remodulin.



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

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

In the United States, it is estimated that 750,000 people suffer from critical limb ischemia. The disease is characterized by extreme pain, non-healing ulcers in the legs, reduced exercise capacity and severely reduced blood flow in the limbs. There are currently no drugs approved to treat critical limb ischemia in the United States. 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 temporary relief to patients, but do not address the underlying causes of peripheral vascular disease. Due to the lack of adequate treatments, approximately 200,000 limb amputations are performed each year on patients with critical limb ischemia.

In September 1998, we 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. We commenced a 30 patient placebo-controlled pre-pivotal clinical study of Remodulin for critical limb ischemia in 2002. Approximately 19 patients were enrolled. The study was ended before becoming fully enrolled due to difficulties in recruiting patients for the study. We believe that more convenient formulations of Remodulin, such as an oral form, may be more appropriate for patients with peripheral vascular disease.

### *UT-15C Sustained Release*

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

### *TRIUMPH*

During 2004 and 2005, independent clinical investigators in the United States and Europe performed small uncontrolled trials of inhaled treprostinil, the active ingredient in Remodulin. We are now conducting a 12-week placebo-controlled trial of inhaled treprostinil in at least 150 patients with pulmonary arterial hypertension who are also being treated with Tracleer<sup>®</sup>, which is another drug used to treat pulmonary arterial hypertension. The trial is known as TRIUMPH-1, **T**reprostinil **I**nhalation **U**sed in the **M**anagement of **P**ulmonary **H**ypertension, and is being conducted at approximately 15 centers in the U.S. and Europe. Additional centers are expected to be added during 2006. As of December 31, 2005, approximately 55 patients were enrolled in the study. At February 21, 2006, the trial is approximately one-half enrolled.

Our marketing strategy for Remodulin relies upon our own staff to educate the prescribing community. During 2002, we formed an internal marketing team to handle these educational efforts. The team consisted of approximately 20 employees as of December 2005 with further employee growth expected in 2006. Additionally, we rely on chronic care specialty pharmacy distributors to handle doctor and patient requests for Remodulin on a non-exclusive basis in the United States. See *Domestic Distribution Agreements* below. These specialty distributors are experienced in the sale, distribution and reimbursement from insurance companies and other payers of chronic therapies. Outside of the United States, we entered into six exclusive distributor agreements covering Canada, most of Europe, Australia, South America and Israel. We sell Remodulin to our distributors in the United States at a discount from an average wholesale price recommended by us, and to our international distributors at a transfer price set by us. We earned approximately \$109.2 million, \$66.1 million and \$45.1 million of revenues from the sales of Remodulin in 2005, 2004 and 2003, respectively.

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

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

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

In January 2003, we initiated two identical Phase III pivotal clinical trials of OvaRex in patients with stage III/IV advanced ovarian cancer, called IMPACT I and II. We are conducting these studies throughout the United States at approximately 60 centers. We are recruiting a total of 354 patients. As of December 31, 2005, approximately 330 patients were enrolled in the IMPACT I and II trials. Patients enrolled in these studies have successfully completed front-line therapy, consisting of surgery and chemotherapy. The primary endpoint for these trials is upon a patient's relapse, so that we can measure the time it takes for the disease to relapse. The study results will be analyzed once there have been at least 118 relapses in each study. Following relapse, patients will also be followed to assess survival rate.

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

In March 2000, we 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. These glycobiology antiviral agents are small molecules which may be effective as an oral therapy for the treatment of hepatitis C and B infections, as well as dengue fever, Japanese encephalitis virus and other infectious diseases. Currently, many of these agents are undergoing laboratory testing, and new agents are also being synthesized.

The most advanced agent identified to date is UT-231B. An Investigational New Drug Application was submitted for UT-231B in 2002 and accepted by the FDA. UT-231B completed acute and chronic Phase I dosing studies in early 2003. Phase II clinical studies in patients infected by hepatitis C were initiated in July 2003 and were completed in October 2004. In that trial, UT-231B did not demonstrate efficacy against hepatitis C in a population of patients that previously failed conventional treatments. We are now conducting preclinical testing of additional glycobiology drug candidates for the treatment of infectious diseases.

### ***Telemedicine Services***

We provide telemedicine services to detect cardiac arrhythmias and ischemic heart disease through our wholly owned subsidiary Medicomp, Inc. (Medicomp), which we acquired in December 2000. Cardiac arrhythmias and ischemic heart disease afflict an estimated 20 million Americans, and possibly ten times that number worldwide. If left undetected and untreated, these conditions can result in heart attacks and death. Medicomp provides cardiac Holter (a 24 hour continuous test of heart rhythms), event monitoring and analysis and pacemaker monitoring remotely via telephone lines and the Internet for hospitals, clinicians and other providers. Medicomp's services are delivered through its proprietary, miniaturized, digital Decipher Holter recorder/analyzer and its CardioPAL family of event monitors.

Holter, event and pacemaker services and systems are marketed to physicians, hospitals, and managed care providers directly by Medicomp's internal sales force. Revenues of approximately \$5.8 million, \$5.3 million and \$4.2 million from the sales of telemedicine products and services were earned in 2005, 2004 and 2003, respectively.

### ***Arginine***

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

The HeartBar and a related line of products were marketed directly to consumers by us, by independent distributors and through the Internet. In January 2006, we discontinued the sales of the HeartBar line of products, after evaluating recent clinical trial results and market potential, among other considerations. Sales of non-HeartBar arginine products and license royalties from third parties selling arginine based products are continuing. We are currently prosecuting patent enforcement lawsuits against other parties believed to have violated our arginine patents. We have entered into patent licenses with two infringers and are in negotiations with others. We believe that there are a substantial number of additional infringers and intend to vigorously enforce our patents requiring these infringers to pay royalties to us. Approximately \$293,000, \$531,000 and \$2.3 million of revenues were earned from the sales of HeartBar and related products in 2005, 2004 and 2003, respectively.

### ***Beraprost SR***

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

Beraprost is an oral form of prostacyclin that is chemically stable. Like natural prostacyclin and Remodulin, beraprost is believed to dilate blood vessels, prevent platelet aggregation and prevent proliferation of smooth muscle cells surrounding blood vessels. Intermittent oral doses of immediate release beraprost did not prove effective in Phase III studies that we conducted in 2000 and 2001. However, we believe 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 SR is presently in Phase I clinical testing being conducted by Toray Industries in Japan.

Toray is required to complete testing of beraprost SR through Phase I to adequately document its performance in humans and to transfer clinical trial materials for use in trials in the United States. If Toray is able to do so, we would be obligated to grant Toray an option to purchase 500,000 shares of our common stock at the then current fair value of that stock. The development of beraprost SR, however, has been significantly delayed. Discussions are ongoing with Toray about the status of beraprost SR and our license agreement.

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

In December 2000, we formed a new company in Canada, Northern Therapeutics, Inc. (Northern Therapeutics), with the inventor of a new form of autologous (meaning it is derived from the patient's own body and not from foreign material such as viruses) gene therapy for the treatment of pulmonary arterial hypertension and other diseases. Northern Therapeutics is currently conducting a Phase I trial with the gene therapy in Canada and, until February 2006, was distributing Remodulin there.

In February 2006, Northern Therapeutics agreed to grant us a license to develop and commercialize the gene therapy in the United States, which license is expected to be executed in early 2006. The license will require us to pay to Northern Therapeutics incremental milestone payments totalling \$1.5 million during and for completion of the Phase I trial. After successful completion of the Phase I trial, we will assume the development program and related costs for the United States. Northern Therapeutics will receive royalty payments following commercialization. As part of this agreement, we and Northern Therapeutics terminated the Remodulin distribution agreement for Canada. We now distribute Remodulin directly in Canada through our Canadian wholly owned subsidiary, Unither Biotech Inc.

We received approximately 59 percent of the initial outstanding common stock of Northern Therapeutics in exchange for \$5.0 million, and currently own approximately 68 percent of Northern Therapeutics. Although we own approximately 68 percent of Northern Therapeutics, minority shareholders possess substantive participating rights that preclude us from controlling Northern Therapeutics and consolidating Northern Therapeutics' financial statements.

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

Medtronic MiniMed partnered with us for the use of Medtronic MiniMed's pager-sized continuous microinfusion pump for delivery of Remodulin subcutaneously. We 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 us to purchase 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 will continue 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. We purchase Medtronic MiniMed products and resell those products to several of our distributors. In 2004, several distributors commenced purchasing supplies directly from Medtronic MiniMed. Approximately \$397,000, \$1.7 million and \$1.7 million of revenues were earned from the resale of MiniMed pumps and supplies in 2005, 2004 and 2003, respectively.

## **Domestic Distribution Agreements**

To provide for marketing, promotion and distribution of Remodulin in the United States, we entered into non-exclusive distribution agreements with CuraScript (a wholly owned subsidiary of Express Scripts, Inc. and formerly Priority Healthcare Corporation), Accredo Therapeutics, Inc. (a wholly owned subsidiary of Medco Health Solutions, Inc.), and Caremark, Inc. in February 2000, March 2000 and May 2003, respectively. Under these distribution agreements, we sell Remodulin at a discount from an average wholesale price recommended by us and sell 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 initial agreements commenced on signing and continued for two years following the May 2002 FDA approval of Remodulin for CuraScript (which has been extended through September 30, 2006) and three years following the May 2002 launch of Remodulin for Accredo. The terms of the Caremark agreement commenced on signing and continued for two years from signing. These agreements have been and will continue to be automatically renewed for additional two-year periods, in the case of CuraScript, and one-year periods in the case of Accredo and Caremark, unless any party provides notice of termination. All of the agreements continue to be active. If these distributor agreements expire or terminate, under certain conditions, we may be required to repurchase unsold Remodulin inventory held by the distributors.

## **Patents and Proprietary Rights**

Our success will depend in part on our ability to obtain and maintain patent protection for our products, preserve trade secrets, prevent third parties from infringing upon our 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 *Item 7—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 all rights to the use of the stable prostacyclin analog now known as Remodulin to us. The patent covering the use of Remodulin for pulmonary hypertension does not expire in the United States until October 2014 (as extended—see *Patent Term Extensions* below) and until various dates from September 2009 to August 2013 in nine other countries.

### ***Pharmacia License***

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

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

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

On December 10, 2004, AltaRex Medical Corp. was acquired by ViRexx Medical Corporation in an all stock for stock transaction. AltaRex Medical now operates as a wholly owned subsidiary of ViRexx. These transactions have not affected our licensing agreements.

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

In March 2000, we 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 various stages of preclinical testing or early clinical testing, and are the subject of a combination of issued patents and pending applications in the United States and around the world.

In November 2000, we and Synergy amended the exclusive license agreement to include the development of new analogs of the licensed compounds. As part of this amendment, we 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 us and Synergy. We received an exclusive license from the University of Oxford to all inventions arising from such research and entered into the first such license in November 2002 for the lead compound, UT-231B. A second exclusive license for different rights is pending.

In March 2003, we 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 all of its intellectual property rights in the glycobiology antiviral agents to us and exclusively sublicensed to us all of the intellectual property rights that had been licensed to Synergy by third parties, the prosecution and maintenance of which are now our responsibility. Synergy also released us 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, we 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). We will own all rights to any new products derived from these licenses.

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

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

### **Research & Development Expenditures**

We are engaged in research and development and have 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 2005, 2004 and 2003 totaled approximately \$36.1 million, \$30.7 million and \$35.4 million, respectively. (See *Item 7—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**

We make treprostinil, the active ingredient in Remodulin for all routes of administration, in Chicago, Illinois and are planning to move our laboratories to Silver Spring, Maryland. Baxter Healthcare Corporation (formerly Cook Imaging Corporation) formulates Remodulin for us. The agreement with Baxter had an initial term which ended in October 2004 and was renewed for an additional eighteen months. The contract is renewable for successive eighteen month terms. We rely on Cardinal Health, Inc. for stability studies on Remodulin, formulation of treprostinil for inhalation use and analyses of other products we are developing. Medtronic MiniMed provides the delivery device used to administer subcutaneous Remodulin to patients.

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

Although we believe that other manufacturers and suppliers could provide similar products, services and materials, there are a limited number of companies which could replace these manufacturers and suppliers. A change in supplier or manufacturer could cause a delay in the manufacture, distribution and research efforts associated with the respective product or result in increased costs. (For further discussion on this risk, see *Item 1A—Risk Factors—We have limited experience with manufacturing and depend on third parties, who may not perform, to synthesize and manufacture many of our products.*)

### **Competition**

Many drug companies engage in research and development to commercialize products to treat cardiovascular, cancer and infectious diseases. We are aware of four existing treatments already approved in the United States for pulmonary arterial hypertension with which Remodulin competes. They are: Flolan, an intravenously delivered prostacyclin marketed by GlaxoSmithKline, PLC; Tracleer, an oral endothelin antagonist marketed by Actelion, Ltd.; Revatio<sup>®</sup>, a PDE-5 inhibitor and a new formulation of the very successful drug Viagra<sup>®</sup>, marketed by Pfizer; and Ventavis<sup>®</sup>, an inhaled prostacyclin marketed by CoTherix, Inc. in the United States and by Schering A.G. in Europe. Two additional oral endothelin antagonists are being developed. One is Thelin<sup>™</sup>, being developed by Encysive Pharmaceuticals, Inc., and

the other is ambrisentan, being developed by Myogen, Inc. In addition, competitors may develop and commercialize other products that compete with our products and may do so more rapidly than us. (For further discussion on this risk, see *Item 1A—Risk Factors—We are aware of investigational products being developed for the treatment of PAH with which our products may have to compete*).

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

Many companies market or are developing products that will compete with our arginine products in the nutritional supplement market. However, we are the only company that owns the patent rights to claim the use of the key ingredient, arginine, for maintaining vascular function. Two competitors agreed to pay a royalty to us on their arginine products. We are pursuing other potential infringers and are 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.

We compete with all of these companies for customers, funding, access to licenses, personnel, third-party collaborators, product development and commercialization. Almost all of these companies have substantially greater financial, marketing, sales, distribution and technical resources, and more experience in research and development, product development and marketing, clinical trials and regulatory matters, than we do.

### **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;
- Clinical studies in healthy volunteers;
- 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 our 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, then 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, a New Drug Application is typically submitted. The FDA may request additional information before accepting a New Drug Application for filing, in which case the application must be resubmitted with the additional information. Once the submission has been accepted for filing, the FDA generally takes ten months to review the application and respond to the applicant. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the New Drug Application to an appropriate advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee. The FDA may also inspect the manufacturing facility before approving a New Drug Application.

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

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

Subcutaneous Remodulin was approved by the FDA for the treatment of pulmonary arterial hypertension in patients with NYHA Class II-IV symptoms to diminish symptoms associated with exercise, and intravenous Remodulin was approved for those patients not able to tolerate subcutaneous infusion. If regulatory approval of our other products is granted, such approvals will similarly be limited to certain disease states or conditions. The manufacturers of approved products and their manufacturing facilities will be subject to continual review and periodic inspections. In addition, identification of certain side

effects or the occurrence of manufacturing problems after a drug is on the market could cause subsequent withdrawal of approval, reformulation of the drug, additional preclinical testing or clinical trials, and changes in labeling of the product.

The Waxman-Hatch Act provides that patent terms may be extended to compensate for some of the patent life that is lost during the FDA regulatory review period for the product. This extension period would generally be one-half the time between the effective date of an Investigational New Drug Application and the submission date of a New Drug Application, plus all of the time between the submission date of a New Drug Application and the approval of that application, subject to a maximum extension of five years. Similar patent term extensions are available under European laws. We filed with the United States Patent and Trademark Office, a patent term extension application, for our patent covering the method of treating pulmonary arterial hypertension using Remodulin following FDA approval. The application was approved in February 2005 and the patent now expires on October 6, 2014.

Outside the United States, our ability to market our 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, the applicant is then required to engage in pricing discussions and negotiations with a separate prescription pricing authority in that country.

To secure European regulatory approvals for the use of Remodulin for pulmonary arterial hypertension we used the decentralized procedure and filed our first Marketing Authorization Application in France in February 2001. Review of our application was completed in 2005. As a result, Remodulin was approved in 23 countries of the EU under the mutual recognition process described above. We withdrew applications in Spain, the United Kingdom and Ireland with the intent of refiling them in the future with additional clinical data. Regulatory applications for the use of Remodulin for pulmonary arterial hypertension have also been approved in Canada, Israel, Australia, Switzerland, Argentina and Chile. Regulatory applications are pending in other countries.

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

In the United States, reimbursements are provided for Remodulin by many independent third-party payers, as well as the Medicare and Medicaid programs. Medicare is the federal program which provides health care benefits to certain senior citizens and disabled persons, and Medicaid is the federal program administered by states to provide health care benefits to certain financially disadvantaged persons. The Medicare contractors who administer the program provide reimbursement for Remodulin at a rate generally equal to 95 percent of the published average wholesale price, as recommended by us. The state Medicaid programs generally provide reimbursement for Remodulin at a price that is below the published average wholesale price. Beginning in 2007, the Medicare Modernization Act requires that we and the Centers for Medicare and Medicaid Services negotiate a new price for Remodulin. In return for agreeing to include Remodulin in the Medicare and Medicaid programs, we have agreed to pay a rebate to state Medicaid agencies that provide reimbursement for Remodulin. We have also agreed to sell Remodulin under contracts with the Veterans Administration, Department of Defense, Public Health Service and numerous other federal agencies as well as certain hospitals that are designated as 340B entities (which are entities designated by federal programs to receive discounted drug prices) at prices that are significantly below the price we charge to our distributors. These programs and contracts impose many regulations and restrictions on our business. Failure to comply with these regulations and restrictions could result in a loss of our ability to continue receiving reimbursement for Remodulin. We estimate that between 35-50 percent of Remodulin sales in the United States are reimbursed under the Medicare and Medicaid programs.

### **Employees**

We had approximately 210 employees as of February 21, 2006. We also maintain active independent contractor relationships with various individuals, most of whom are on month-to-month or annual consulting contracts. We believe our employee relations are excellent.

### **Industry Segments and Geographic Areas**

The information required by Item 101(b) and 101(d) of Regulation S-K relating to financial information about industry segments and geographical areas is contained in Notes 16 and 6, respectively, of the audited consolidated financial statements, which are included in this Annual Report on Form 10-K.

### **Corporate Website**

Our Internet website address is [www.unither.com](http://www.unither.com). Our 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.

## EXECUTIVE OFFICERS OF THE REGISTRANT

The following is a list, as of February 21, 2006, setting forth certain information regarding our executive officers. Each executive officer holds office until the first meeting of the Board of Directors after the annual meeting of stockholders, and until his or her successor is elected and qualified or until his or her earlier resignation or removal. Each executive officer's employment will end pursuant to the terms of his or her employment contract. Each of the employment contracts generally provide for an initial term of service of five years which may be renewed after each year for additional one-year periods.

<u>Name</u>	<u>Age</u>	<u>Position</u>
Martine A. Rothblatt, Ph.D., J.D., M.B.A.	51	Chairman, Chief Executive Officer and Director
Roger Jeffs, Ph.D.	44	President, Chief Operating Officer and Director
Paul A. Mahon, J.D.	42	Executive Vice President for Strategic Planning, General Counsel and Corporate Secretary
Fred T. Hadeed	41	Executive Vice President for Business Development and Chief Financial Officer

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

*Roger Jeffs, Ph.D.* , joined United Therapeutics in September 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 his own law firm specializing in technology and media law.

*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 last served as a senior manager in KPMG's life sciences practice.

## ITEM 1A. RISK FACTORS

### Forward-Looking Statements

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

- expectations of revenues and profitability;
- the timing and outcome of clinical studies and regulatory filings;
- the achievement and maintenance of regulatory approvals;
- the ability to find alternate sources of supply and manufacturing for our products;
- the existence and activities of competitors;
- the expectation not to pay dividends on common stock in the foreseeable future;
- the pricing of Remodulin;
- the dosing and rate of patient consumption of Remodulin;
- the impacts of price changes and changes in patient consumption of Remodulin on future revenues;
- the expectation of reimbursement by third-party payers for intravenous Remodulin;
- the timing, impact, materiality and outcome of under-reimbursement by third-party payers, such as Medicare;
- the timing and outcome of the Remodulin Phase IV clinical trial;
- acceptance by the FDA of the Remodulin Phase IV clinical trial interim study report following the 21-patient interim assessments;
- any actions that may or may not be taken by the FDA as a result of the timing and outcome of the Remodulin Phase IV clinical trial;
- the outcome of potential future warning letters from the FDA and any actions that may or may not be taken by the FDA as a result of any such warning letters;
- the rate of physician and patient acceptance of our products as safe and effective;
- the development and sale of products covered by licenses and assignments;
- the adequacy of our intellectual property protections;
- the outcome of any litigation in which we are or become involved;
- the ability of third parties to develop, market, distribute and sell our products;
- the composition of our management team;
- the adequacy of our insurance coverage;
- the ability to obtain financing in the future;
- the value of our common stock;
- the funding of operations from future revenues;

- the expectation of continued profits or losses;
- the expected impact of the discontinuance of the HeartBar line-of-products in January 2006;
- expectations concerning milestone and royalty payments in 2006 and beyond;
- expectations concerning payments of contractual obligations in all future years and their amounts;
- the use of net operating loss carryforwards and business tax credit carryforwards and the impact of Section 382 of the Internal Revenue Code on their use;
- income tax expenses and benefits in current and future periods;
- the completion of in-process research and development projects and their impact on our business;
- the pace and timing of enrollment in clinical trials;
- the expectation, outcome and timing of new and continuing regulatory approvals;
- the timing, resubmission, completion and outcome of the applications for approval of subcutaneous Remodulin in Ireland, Spain and the United Kingdom;
- the timing, completion and outcome of pricing approvals in European Union countries that approve subcutaneous Remodulin;
- the expected levels and timing of Remodulin sales;
- the adequacy of our resources to fund operations;
- the timing and level of spending to construct a laboratory production facility in Silver Spring, Maryland;
- the potential amount of the minimum residual value guarantee to Wachovia under the synthetic lease;
- events that could occur upon termination of the Wachovia synthetic lease and related agreements;
- the potential impacts of new accounting standards;
- the sale of common stock at favorable terms under the primary registration statement filed with the SEC in February 2005;
- our intent and ability to hold certain marketable investments until maturity;
- any statements preceded by, followed by or that include the words “believes,” “expects,” “predicts,” “anticipates,” “intends,” “estimates,” “should,” “may” or similar expressions; and
- other statements contained or incorporated by reference in this Annual Report on Form 10-K that are not historical facts.

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

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

*Actual consolidated revenues and net income may be different from published securities analyst projections. In addition, we have a history of losses and may not continue to be profitable.*

Many independent securities analysts have published quarterly and annual projections of our revenues and profits. These projections were made independently by the securities analysts based on their own analysis. Such estimates are inherently subject to a degree of uncertainty. As a result, the actual revenues and net income may be greater or less than projected by such securities analysts. Even small variations in reported revenues and profits as compared to securities analysts' expectations can lead to significant changes in our stock price.

Although we were profitable for every quarter ended after March 31, 2004, we lost money from the date of our inception in 1996 through March 31, 2004. At December 31, 2005, our accumulated deficit was approximately \$115.3 million.

Factors that could affect consolidated revenues and profitability and cause our quarterly and annual operating results to fluctuate include the following:

- Extent and timing of sales of Remodulin to distributors;
- Levels of Remodulin inventory held by our distributors and changes to those levels from quarter to quarter;
- Level of patient demand for Remodulin and other products;
- Changes in prescribers' opinions about Remodulin;
- Impact of medical and scientific opinion about our products;
- Levels of research and development, selling, general and administrative expenses;
- Timing of payments to licensors and corporate partners;
- Retention and growth of patients treated with Remodulin;
- Remodulin side effects, including impact of infusion site pain and reaction from subcutaneous use of Remodulin;
- Changes in the current pricing and dosing of Remodulin;
- Changes in the length of time that Remodulin vials may be used by patients;
- Changes in the pricing of other therapies approved for PAH, including possible generic formulations of other approved therapies, such as Flolan, which may be sold in generic form beginning in May 2007;
- Willingness of private insurance companies, Medicare and Medicaid to reimburse Remodulin at current pricing levels;
- Impacts of new legislation and regulations and changes to the Medicare and Medicaid programs;
- The outcome of the Remodulin Phase IV post-marketing study;
- Our ability to maintain regulatory approval of Remodulin in the United States and other countries;
- Additional regulatory approvals for Remodulin in countries other than where it is currently sold;
- Status and impact of other approved competitive products such as Ventavis, Revatio, Tracleer and Flolan and investigational competitive products such as ambrisentan, Thelin, Cialis<sup>®</sup>, Gleevec<sup>®</sup> and other potential investigational competitive products;

- Continued performance by current Remodulin distributors under existing agreements;
- Size, scope and outcome of development efforts for existing and additional products;
- Future milestone and royalty payments under license and other agreements;
- Cost, timing and outcomes of regulatory reviews;
- Rate of technological advances;
- Our ability to establish, defend and enforce 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;
- Impact of any regulatory restrictions on our marketing and promotional activities;
- Recovery of goodwill, intangible assets and investments in affiliates;
- Collection of accounts receivable and realization of inventories;
- Risks associated with acquisitions, including the ability to integrate acquired businesses;
- Unforeseen expenses;
- Actual growth in sales of telemedicine and arginine products;
- Actual expenses incurred in future periods; and
- Completion of additional acquisitions and execution of licensing agreements.

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

***We may not successfully compete with established drugs and the companies that develop and market them.***

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

We are aware of existing treatments that compete with our products, especially in the field of PAH. Patients and doctors may perceive these competing products to be safer, more effective, more convenient or less expensive than Remodulin. Accordingly, sales of Remodulin may not increase or may even decrease if doctors prescribe less Remodulin than they are prescribing at present.

For the treatment of PAH, we compete with many approved products in the United States and worldwide, including the following:

- Flolan was the first product approved by the FDA for treating PAH and has been marketed by GlaxoSmithKline PLC since 1996. Generic formulations of Flolan could be available for



commercial sale as early as 2007. Flolan is delivered by intravenous infusion and considered to be an effective treatment by most PAH experts;

- Ventavis was approved in December 2004 in the United States and in September 2003 in Europe. Ventavis is the only prostacyclin that has been approved for inhalation, whereas Remodulin is only currently approved to be delivered through intravenous or subcutaneous infusion. Ventavis is marketed by CoTherix, Inc. in the United States and Schering AG in Europe;
- Tracleer, the first oral drug to be approved for PAH, is also the first drug in its class, known as endothelin receptor antagonists. Tracleer was approved in December 2001 in the United States and May 2002 in Europe. Tracleer is marketed by Actelion, Ltd. worldwide. As an oral therapy, Tracleer is a very convenient therapy; and
- Revatio was approved in June 2005 in the United States. Revatio is also an oral therapy and is marketed by Pfizer. Revatio is a different formulation of the very successful drug Viagra and is the first drug in its class, known as PDE-5 inhibitors, to be approved for PAH.

Doctors may reduce the dose of Remodulin given to their patients if they prescribe our competitors' products in combination with Remodulin.

Many companies are marketing and developing products containing arginine that compete with our arginine product line. Many local and regional competitors and a few national competitors provide cardiac Holter and event monitoring services and systems that compete with our telemedicine products. A number of drug companies are pursuing treatments for ovarian and other cancers and hepatitis that will compete with any products we may develop from our immunotherapeutic monoclonal antibody platform and glycobiology antiviral agents platform.

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

Other companies may make discoveries or introduce new products that render all or some of our technologies and products obsolete or not commercially viable. Researchers are continually making new discoveries that may lead to new technologies to treat the diseases for which our products are intended. In addition, alternative approaches to treating chronic diseases, such as gene therapy, may make our products obsolete or noncompetitive. Other investigational therapies for PAH could be used in combination with Remodulin. If this happens, doctors may reduce the dose of Remodulin given to their patients. This could result in less Remodulin being used by such patients and, hence, reduced sales of Remodulin.

***We are aware of investigational products being developed for the treatment of PAH with which our products may have to compete.***

Our Remodulin-based products may have to compete with investigational products currently being developed by other companies, including:

- Sitaxentan (Thelin) is being developed by Encysive Pharmaceuticals, Inc. worldwide for the treatment of PAH. Encysive has completed testing of Thelin, an oral tablet, and, based on favorable results, has filed for approval with the Food and Drug Administration in the United States. This application is currently being reviewed. If approved, Thelin would become the second drug available in the class known as endothelin receptor antagonists;
- Ambrisentan is being developed by Myogen, Inc. for the treatment of PAH. Ambrisentan, an oral tablet, is still in clinical testing and is also an endothelin receptor antagonist;
- Cialis<sup>®</sup> is an approved oral treatment for erectile dysfunction and is currently marketed by Lilly ICOS LLC, a joint venture of Eli Lilly & Company and ICOS Corporation. Cialis is currently being studied in patients with PAH; and is in the same class of drugs as Revatio;

- Gleevec is an approved oral treatment for chronic myeloid leukemia (a cancer of the blood and bone marrow) and is currently marketed by Novartis Pharmaceuticals Corporation. Recently, researchers experienced in PAH have conducted studies of Gleevec and believe that it may be effective in treating PAH;
- PRX-08066, a serotonin receptor 5-HT<sub>2B</sub> antagonist, is being developed by Predix Pharmaceuticals Holdings, Inc., as an oral tablet for the treatment of PAH. Two Phase I clinical trials of PRX-08066 are being conducted in healthy volunteers;
- PulmoLAR™ is being developed by PR Pharmaceuticals, Inc. It is a once-a-month injectible which contains a metabolite of estradiol and has been shown in animal and cell models to address the key pathological processes associated with PAH; and
- Aviptadil, an inhaled formulation of vasoactive intestinal protein, is being developed by mondoBIOTECH Holding SA, for the treatment of PAH.

There may be additional drugs in development for PAH and there may also be currently approved drugs that may be effective in treating the disease. If any of these drugs in development or other currently approved drugs are used to treat PAH, sales of Remodulin may fall.

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

Our commercial success depends heavily on third-party payers, such as Medicare, Medicaid and private insurance companies, agreeing to reimburse patients for the costs of our pharmaceutical products. These third-party payers frequently challenge the pricing of new and expensive drugs, and it may be difficult for pharmacies selling Remodulin to convince these payers to reimburse patients for the cost of Remodulin. Remodulin and the associated infusion pump and supplies are very expensive. We believe our investigational products, if approved, will also be very expensive. Presently, most third-party payers, including Medicare and Medicaid, reimburse patients for the cost of Remodulin therapy. In the past, Medicare has not reimbursed the full cost of the therapy for some patients. Beginning on January 1, 2007, the Medicare Modernization Act requires that we and the Centers for Medicare and Medicaid Services negotiate a new price for Remodulin. Third-party payers may not approve our new products for reimbursement or continue to approve Remodulin for reimbursement, or may seek to reduce the amount of reimbursement for Remodulin based on changes in pricing of other therapies for PAH, including possible generic formulations of other approved therapies, such as Flolan, which may be sold in generic form beginning in May 2007. If third-party payers do not approve a product of ours for reimbursement or limit the amount of reimbursement, sales will suffer, as patients will opt for a competing product that is approved for reimbursement.

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

We are currently marketing products in three of our five therapeutic platforms: Remodulin in our prostacyclin analog platform, the products containing arginine in our arginine formulations platform, and CardioPAL cardiac event monitors and Holter monitors in our telemedicine platform. We do not have the ability to independently conduct clinical studies, obtain regulatory approvals, market, distribute or sell most of our products and intend to rely substantially on experienced third parties to perform all of those functions. We may not locate acceptable contractors or enter into favorable agreements with them. If third parties do not successfully carry out their contractual duties or meet expected deadlines, we might not be able to obtain marketing approvals and sell our products.

Medtronic MiniMed is our exclusive partner for the subcutaneous delivery of Remodulin using the MiniMed microinfusion device for PAH. We rely on Medtronic MiniMed's experience, expertise and performance. Any disruption in the supply to PAH patients of MiniMed's microinfusion device could delay or prevent patients from initiating or continuing Remodulin therapy, which could adversely affect our revenues. Similarly, we rely on Accredo Therapeutics, Inc. (a wholly owned subsidiary of Medco Health Solutions, Inc.), CuraScript (a wholly owned subsidiary of Express Scripts, Inc. and formerly Priority Healthcare Corporation) and Caremark, Inc. to market, distribute, and sell Remodulin in the United States. Accredo, CuraScript and Caremark are also responsible for convincing third-party payers to reimburse patients for the cost of Remodulin, which is very expensive. If our partners and contractors do not achieve acceptable profit margins, they may not continue to distribute our products. If our partners in the United States and internationally are unsuccessful in their efforts, our revenues will suffer.

During 2005, two of our Remodulin distributors in the United States were sold to larger companies. These distributors continue to purchase Remodulin from us and distribute it. Together, they account for most of the Remodulin sales we have made thus far. When these distributors were independently managed, distribution of Remodulin was more significant to the distributors, because they were much smaller. Now, Remodulin is much less significant to the distributors because they are divisions or subsidiaries of multi-billion dollar companies. It is possible, therefore, that these distributors may devote fewer resources to the distribution of Remodulin. If so, this may negatively impact our sales.

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

The process of obtaining and maintaining regulatory approvals for new drugs is lengthy, expensive and uncertain. The manufacture, distribution, advertising and marketing of these products are subject to extensive regulation. Any new product approvals we receive in the future could include significant restrictions on the use or marketing of the product. Product approvals, if granted, can be withdrawn for failure to comply with regulatory requirements (including those relating to misleading advertising and we already received one warning letter from the FDA related to advertising in 2005 which was resolved satisfactorily) or upon the occurrence of adverse events following commercial introduction of the products.

The FDA has approved Remodulin for the treatment of PAH in patients with Class II-IV symptoms to diminish symptoms associated with exercise. This approval is subject to the requirement that we perform a post-marketing Phase IV clinical study to further assess the clinical benefits of Remodulin. Continued FDA approval of Remodulin is subject to the diligent and timely completion of that trial, as well as its outcome. The 39-patient Phase IV clinical trial was required to have been one-half enrolled by June 2004 and to have been fully enrolled by June 2005. The final study report was required to have been submitted in December 2005. Twenty two patients were enrolled in the Phase IV trial. Enrolling patients in this study is difficult, in part because it involves randomizing some of the patients to placebo despite the fact that approved drugs were available for these patients. We did not enroll the Phase IV trial within the time frame specified by the FDA, and therefore are at risk of the FDA at any time instituting a public hearing to withdraw marketing approval for Remodulin.

The FDA permitted an interim assessment and opportunity to terminate the Phase IV study after only 21 patients completed the study. In July 2005, the first 21 patients completed the study and we performed the interim assessment. The results of the interim assessment, as analyzed by an independent statistician, were positive. The p value was 0.0006, meaning that the likelihood that the achieved result was incorrect is six out of ten thousand. Specifically, 13 of 14 patients (93%) in the Remodulin arm were able to successfully transition from Flolan and complete the study without the need to institute rescue therapy, compared to only 1 of 7 patients (14%) in the placebo arm. Based on this positive outcome, we have submitted the interim study results to the FDA and have requested permission to end the Phase IV clinical

study in satisfaction of our Phase IV commitments. By agreement with the FDA, enrollment in the Phase IV clinical study was suspended pending FDA review and acceptance of the interim study results.

We do not know how long the FDA will take to review the interim study results, and we cannot predict the outcome of the review. If the FDA does not accept the interim study results or does not agree with our assessment of the interim results, we would still be required to comply with the FDA-approved protocol for the Phase IV clinical study, including enrolling 39 patients in the study and submitting the final study report by December 2005. The FDA could, among other things, grant an extension of time to continue to enroll the trial, or institute a public hearing to withdraw marketing approval for Remodulin.

We rely heavily on sales of Remodulin. During the year ended December 31, 2005, our Remodulin sales accounted for 94 percent of our total revenues. If approvals are withdrawn for a product, we cannot sell that product and our revenues will suffer. In addition, if product approvals are withdrawn, governmental authorities could seize our products or force us to recall our products.

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

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

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

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

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

- The manufacturing processes for some of our products have not been tested in quantities needed for commercial sales;

- Delays in scale-up to commercial quantities could delay clinical studies, regulatory submissions and commercialization of our products;
- A long lead time is needed to manufacture Remodulin, and the manufacturing process is complex;
- We and the manufacturers of our products are subject to the FDA's good manufacturing practices regulations and similar foreign standards, and although we control compliance issues with respect to synthesis and manufacturing conducted internally, we do not have control over compliance with these regulations by our third-party manufacturers;
- Even if we and the manufacturers of our products comply with the FDA's good manufacturing practices regulations and similar foreign standards, the sterility and quality of the products being manufactured may be deficient. If this occurred, such products would not be available for sale or use;
- If we have to change to another manufacturing contractor or abandon our own manufacturing operations, the FDA and comparable foreign regulators would require new testing and compliance inspections, and the new manufacturer would have to be educated in the processes necessary for the production of the affected product;
- We may not be able to develop or commercialize our products, other than Remodulin, as planned or at all and will have to rely solely on internal manufacturing capacity;
- We intend to transfer all of our drug laboratory operations to the Silver Spring, Maryland facility currently being built, and such transfer could result in manufacturing inefficiencies or delays because the building, equipment and many of the employees being deployed there will be new to the process of making our products. Additionally, the FDA and comparable foreign regulators will require new testing and compliance inspections and this could result in delays;
- The supply of raw and advanced materials and components used in the manufacture of Remodulin and other products may be interrupted, which could delay the manufacture and subsequent sale of such products. Any proposed substitute materials and components are subject to approval by the FDA before any manufactured product can be sold. The timing of such FDA approvals is difficult to predict and approvals may not be timely obtained;
- Without substantial experience in operating a manufacturing facility, we may not be able to successfully manufacture Remodulin without a third-party manufacturer; and
- We may not have intellectual property rights, or may have to share intellectual property rights, to many of the improvements in the manufacturing processes or new manufacturing processes for our new products.

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

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

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

We recently conducted a Phase IV clinical study for Remodulin. For a description of the status of this Phase IV study, see our discussion above under “*Factors that may affect United Therapeutics—If we cannot maintain regulatory approvals for our products, we cannot sell those products and our revenues will suffer.*” We have initiated a Phase II/III clinical study of an inhaled formulation of treprostinil and Phase I studies of an oral formulation of Remodulin. Our lead glycobiology antiviral agent, UT-231B, recently completed a Phase II, proof-of-concept study. In that trial, UT-231B did not demonstrate efficacy against hepatitis C in a population of patients that previously failed conventional treatments. We are now conducting preclinical testing of additional glycobiology drug candidates. We are also currently conducting two Phase III pivotal studies of OvaRex for the treatment of ovarian cancer. We are still completing or planning pre-clinical studies for our other products.

In the past, several of our product candidates have failed or been discontinued at various stages in the product development process, including, but not limited to: beraprost, which failed in Phase III testing for early stage peripheral vascular disease; Ketotop, which failed in Phase III testing for osteoarthritis of the knee; and UT-77, which failed in Phase II testing for chronic obstructive pulmonary disease. Also, the length of time that it takes for us to complete clinical trials and obtain regulatory approval for product marketing has in the past varied by product and by the intended use of a product. We expect that this will likely be the case with future product candidates and we cannot predict the length of time to complete necessary clinical trials and obtain regulatory approval.

Our ongoing and planned clinical studies might be delayed or halted for various reasons, including:

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

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

***Our corporate compliance program cannot guarantee that we are in compliance with all potentially applicable federal, state and foreign regulations.***

The development, manufacture, distribution, pricing, sales, marketing, and reimbursement of our products, together with our general operations, are subject to extensive federal, state and foreign regulation. While we have developed and instituted corporate compliance programs, we cannot assure that we or our employees are or will be in compliance with all potentially applicable federal, state and foreign regulations. If we fail to comply with any of these regulations, a range of actions could result, including, but not limited to, the termination of clinical trials, the failure to approve a product candidate, restrictions on our products or manufacturing processes, including withdrawal of our products from the market, significant fines, exclusion from government healthcare programs, or other sanctions or litigation.

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

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

- We may not be able to obtain future licenses, assignments and agreements at a reasonable cost or at all;
- If any of our licenses or assignments are terminated, we will lose our rights to develop and market the products covered by such licenses or assignments;
- The licenses and assignments that we hold generally provide for termination by the licensor or assignor in the event we breach the license or assignment agreement, including failing to pay royalties and other fees on a timely basis;
- In the event that GlaxoSmithKline (formerly Glaxo Wellcome) terminates its assignment agreement or Pfizer (formerly Pharmacia) terminates its license agreement, we will have no further rights to utilize the assigned patents or trade secrets to develop and commercialize Remodulin. For the year ended December 31, 2005, sales of Remodulin accounted for approximately 94 percent of our total revenues. GlaxoSmithKline or Pfizer could seek to terminate the assignment or license, respectively, in the event that we fail to pay royalties based on sales of Remodulin; and
- If licensors fail to maintain the intellectual property licensed or assigned to us as required by most of our license and assignment agreements, we may lose our rights to develop and market some or all of our products and may be forced to incur substantial additional costs to maintain the intellectual property ourselves or force the licensor or assignor to do so.

***Certain license and assignment agreements relating to our products may restrict our ability to develop products in certain countries and/or for particular diseases and impose other restrictions on our freedom to develop and market our products.***

When we acquire, license or receive assignments of drugs and other products that have been discovered and initially developed by others, we may receive rights only to develop such drugs or products in certain territories and not throughout the world. For example, we do not have the right to develop OvaRex and all our other monoclonal antibody immunotherapies for sale in most of Europe and the Middle East, and we only have the rights to develop beraprost for sale in the United States and Canada.

In addition, provisions in our license and assignment agreements impose other restrictions on our freedom to develop and market our products. For example, in assigning Remodulin to us, GlaxoSmithKline retained an exclusive option and right of first refusal to negotiate a license agreement with us if we ever decide to license any aspect of the commercialization of Remodulin anywhere in the world. Similarly, in connection with its licenses of beraprost to us, Toray Industries, Inc. obtained a right of first refusal from us to develop and sell in Japan up to two compounds that we develop. We also agreed to provisions giving Toray the conditional right to approve our North American distributor, a conditional

restricted non-competition clause, and to minimum annual sales in order to maintain our exclusive rights to beraprost. The restrictions that we have accepted in our license and assignment agreements restrict our freedom to develop and market our products in the future.

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

Our United States patent for the method of treating pulmonary hypertension with Remodulin is currently set to expire in October 2014. The patent for OvaRex and its method of use are the subject of a combination of issued patents and pending applications in the United States and around the world. The issued patents for OvaRex have expiration dates ranging from 2017 to 2020. We believe that some of the patents to which we have rights may be eligible for extensions of up to five years based upon patent term restoration procedures in Europe and in the United States under the Waxman-Hatch Act. Competitors may develop products based on the same active ingredients as our products, including Remodulin, and market those products after the patents expire, or may design around our existing patents. If this happens, our sales would suffer and our profits could be severely impacted.

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

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

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

Litigation, which is very expensive, may be necessary to enforce or defend our patents or proprietary rights and may not end favorably for us. We are currently a party to pending litigation against other parties believed to have violated our patents related to our arginine products line, and the validity and enforceability of the patents related to our arginine products is currently being challenged. We may also choose to initiate litigation against other parties who we come to believe are infringing these patents. If such litigation is unsuccessful or if the patents are invalidated or canceled, we may have to write off the related intangible assets and such an event could significantly reduce our earnings. Any of our licenses, patents or other intellectual property may be challenged, invalidated, canceled, infringed or circumvented and may not provide any competitive advantage to us.

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

We are dependent on our current management, particularly our founder and Chief Executive Officer, Martine Rothblatt, Ph.D., our President and Chief Operating Officer, Roger Jeffs, Ph.D., our Executive Vice President for Business Development and Chief Financial Officer, Fred Hadeed, our Executive Vice President for Strategic Planning, General Counsel and Corporate Secretary, Paul Mahon, our Executive Vice President and Chief Operating Officer for Production, David Walsh, our Senior Vice President for Pharmaceutical Development, David Zaccardelli, Pharm.D., and our Senior Vice President for Biologics Production, Development and Supply, James Levin, DVM. While these individuals are employed by us pursuant to multi-year employment agreements, employment agreements do not ensure the continued retention of employees. We do not maintain key person life insurance on these officers. Our success will



depend in part on retaining the services of our existing management and key personnel and attracting and retaining new highly qualified personnel. Expertise in the field of cardiovascular medicine, infectious disease and oncology is not generally available in the market, and competition for qualified management and personnel is intense.

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

The testing, manufacture, marketing, and sale of human drugs involve product liability risks. Although we currently have product liability insurance covering claims up to \$20 million per occurrence and in the aggregate for our pharmaceutical products and product liability insurance covering claims up to \$10 million per occurrence and in the aggregate for our telemedicine and arginine supplement products, we may not be able to maintain this product liability insurance at an acceptable cost, if at all. In addition, this insurance may not provide adequate coverage against potential losses. If claims or losses exceed our liability insurance coverage, we may go out of business.

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

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

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

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

***Our activities involve hazardous materials, and improper handling of these materials could expose us to significant liabilities.***

Our research and development and manufacturing activities involve the controlled use of chemicals and hazardous materials. As a consequence, we are subject to numerous federal, state, and local environmental and safety laws and regulations, including those governing the management, storage and disposal of hazardous materials. We may be required to incur significant costs to comply with current or future environmental laws and regulations, and substantial fines and penalties for failure to comply with these laws and regulations. While we believe that we are currently in substantial compliance with laws and regulations governing these materials, the risk of accidental contamination or injury from these materials cannot be eliminated. In the event of such an accident, we could be liable for civil damages that result or for the cleanup of any release of hazardous materials, the cost of which could be substantial. Any such liability could exceed our resources and could have a material adverse effect on our business, financial condition and results of operations.

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

The market prices for securities of drug and biotechnology companies are highly volatile, and there are significant price and volume fluctuations in the market that may be unrelated to particular companies'

operating performances. The table below sets forth the high and low closing prices for our common stock for the periods indicated:

	<u>High</u>	<u>Low</u>
January 1, 2003 – December 31, 2003	\$ 24.65	\$ 14.70
January 1, 2004 – December 31, 2004	\$ 46.73	\$ 20.51
January 1, 2005 – December 31, 2005	\$ 77.82	\$ 41.37

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

- Quarterly and annual financial and operating results;
- Failure to meet estimates or expectations of securities analysts or our projections;
- Public concern as to the safety of products developed by us or by others;
- Changes in or new legislation and regulations affecting reimbursement of Remodulin by Medicare or Medicaid;
- Announcements by us or others of technological innovations or new products or announcements regarding our existing products;
- Developments in patent or other proprietary rights;
- Future sales of substantial amounts of common stock by us or our existing stockholders;
- The pace of enrollment in and the results of clinical trials;
- Future sales of common stock by our directors and officers;
- Failure to maintain approvals to sell Remodulin;
- Timing and outcome of additional regulatory approvals; and
- General market conditions.

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

If we issue common stock to raise capital, or our stockholders transfer their ownership of our common stock or sell a substantial number of shares of common stock in the public market, or investors become concerned that substantial sales might occur, the market price of our common stock could decrease. In February 2005, we filed a shelf registration statement covering the potential sale of up to five million shares of our common stock. In addition, each of our four executive officers has announced their adoption of 10b5-1 prearranged trading plans. In accordance with these plans, twice each month these executives sell a specified number of our common stock either owned by them or acquired through the exercise of stock options. However, these executives and our directors may choose to sell additional shares outside of 10b5-1 trading plans and one executive and five directors have done so. In addition, Toray Industries, Inc. has an option to acquire 500,000 shares of our common stock and piggyback registration rights with respect to such shares that arise if and when this option becomes exercisable. A decrease in our common stock price could make it difficult for us to raise capital by selling stock or to pay for acquisitions using stock. To the extent outstanding options are exercised or additional shares of capital stock are issued, existing stockholders may incur additional dilution.

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

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

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

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

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

Our directors and named executive officers beneficially owned approximately 10.1 percent of our outstanding common stock as of December 31, 2005, including stock options that could be exercised by those directors and executive officers within 60 days of that date. Accordingly, these stockholders as a group might be able to influence the outcome of matters requiring approval by our stockholders, including the election of our directors. Such stockholder influence could delay or prevent a change of control with respect to us.

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

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

## **ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

## **ITEM 2. PROPERTIES**

We currently maintain leased and owned facilities. We own our corporate office in Silver Spring, Maryland and an office in Satellite Beach, Florida. We also own three buildings and land adjacent to our corporate headquarters in Silver Spring, Maryland and have commenced building a laboratory facility on the vacant land adjacent to our corporate headquarters. It is anticipated that this building will be completed in April 2006. In January 2006, we entered into a contract to purchase additional land and a building adjacent to our corporate headquarters. We acquired land and buildings adjacent to our Satellite Beach office in 2005. We lease our legal and governmental affairs office in Washington, D.C. We lease our clinical development office in Research Triangle Park, North Carolina. We lease 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. Our subsidiaries, Unither Pharma, Inc. and Lung Rx, Inc. occupy the office in Satellite Beach, Florida. Our subsidiary, Unither Pharmaceuticals, Inc., leases office space in Wellesley, Massachusetts. Our subsidiary, Medicomp, Inc., leases office space in Melbourne, Florida. Our subsidiary, Unither Nutraceuticals, Inc., leases office space in Burlington, Vermont. Our subsidiary, United Therapeutics Europe Ltd., leases office space near London, England. Our Canadian subsidiary, Unither Biotech Inc., leases office space in Magog, Canada. We believe these facilities are adequate for current operations and additional land and facilities for future expansion are reasonably available.

The office spaces in Melbourne, Florida and Washington, D.C. are used in our telemedicine segment. All other properties and leased facilities are used in our pharmaceutical segment.

## **ITEM 3. LEGAL PROCEEDINGS**

Currently, and from time to time, we are involved in litigation incidental to the conduct of our business. We are not a party to any lawsuit or proceedings that, in the opinion of our management based on consultation with legal counsel, is likely to have a material adverse effect on our financial position or results of 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, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

#### Market for Common Equity

Our 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:

	2005		2004	
	High	Low	High	Low
January 1 – March 31	\$ 45.82	\$ 41.37	\$ 24.25	\$ 20.51
April 1 – June 30	\$ 57.10	\$ 44.21	\$ 25.93	\$ 22.27
July 1 – September 30	\$ 73.90	\$ 48.06	\$ 34.93	\$ 23.15
October 1 – December 31	\$ 77.82	\$ 60.46	\$ 46.73	\$ 29.00

As of February 13, 2006, there were 82 holders of record of common stock. We estimate that included within the holders of record are approximately 4,300 beneficial owners of common stock. As of February 21, 2006, the closing price for the common stock was \$61.57.

#### Dividend Policy

We have never paid and have no present intention to pay dividends on our common stock in the foreseeable future and intend to retain any earnings for use in our business operations.

## ITEM 6. SELECTED FINANCIAL DATA

The following selected consolidated financial data should be read in conjunction with our consolidated financial statements and related notes and “Item 7—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,				
	2005	2004	2003	2002	2001
<b>Consolidated Statements of Operations Data:</b>					
Revenues	\$ 115,915	\$ 73,590	\$ 53,341	\$ 30,120	\$ 5,731
Operating expenses:					
Research and development	36,052	30,713	35,417	26,778	32,590
Selling, general and administrative	24,655	21,418	22,667	15,889	16,943
Cost of sales	12,315	8,250	6,783	5,456	3,137
Total operating expenses	73,022	60,381	64,867	48,123	52,670
Income (loss) from operations	42,893	13,209	(11,526)	(18,003)	(46,939)
Other income (expense):					
Interest income	5,359	2,986	2,435	4,954	10,021
Interest expense	(29)	(4)	(112)	(117)	(173)
Equity loss in affiliate	(754)	(785)	(953)	(209)	(257)
Write-down of investment	—	—	—	(2,893)	—
Loss on marketable investments	—	—	—	(7,428)	—
Other, net	53	43	187	45	60
Total other income (expense), net	4,629	2,240	1,557	(5,648)	9,651
Net income (loss) before income tax	47,522	15,449	(9,969)	(23,651)	(37,288)
Income tax benefit	17,494	—	—	—	—
Net income (loss)	<u>\$ 65,016</u>	<u>\$ 15,449</u>	<u>\$ (9,969)</u>	<u>\$ (23,651)</u>	<u>\$ (37,288)</u>
Net income per share:					
Basic(1)	<u>\$ 2.85</u>	<u>\$ 0.71</u>	<u>\$ (0.47)</u>	<u>\$ (1.15)</u>	<u>\$ (1.84)</u>
Diluted(1)	<u>\$ 2.58</u>	<u>\$ 0.66</u>	<u>\$ (0.47)</u>	<u>\$ (1.15)</u>	<u>\$ (1.84)</u>
Weighted average number of common shares outstanding:					
Basic	<u>22,825</u>	<u>21,726</u>	<u>21,135</u>	<u>20,644</u>	<u>20,286</u>
Diluted	<u>25,206</u>	<u>23,351</u>	<u>21,135</u>	<u>20,644</u>	<u>20,286</u>

	Years Ended December 31,				
	2005	2004	2003	2002	2001
<b>Consolidated Balance Sheet Data:</b>					
Cash, cash equivalents and marketable investments (3)	\$ 191,013	\$ 139,140	\$ 117,337	\$ 132,655	\$ 172,299
Total assets	291,413	207,158	179,502	184,566	212,121
Notes and leases payable(2)	23	26	798	1,878	1,938
Accumulated deficit	(115,325)	(180,341)	(195,790)	(185,821)	(162,170)
Total stockholders’ equity	275,102	191,636	167,765	171,658	196,399

- (1) See Note 2 of Notes to Consolidated Financial Statements for a description of the computation of basic and diluted net income (loss) per share.
- (2) Includes current portion of notes and leases payable.
- (3) Includes restricted marketable investments and cash.

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

The following discussion should be read in conjunction with the consolidated financial statements and related notes appearing in this Annual Report. The following discussion contains forward-looking statements made pursuant to the safe harbor provisions of Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995 including the statements listed under “*Item 1A—Risk Factors*”. These statements are based on our beliefs and expectations as to future outcomes and are subject to risks and uncertainties that could cause our results to differ materially from anticipated results. Factors that could cause or contribute to such differences include those discussed below and described in this Annual Report on Form 10-K under “*Item 1A—Risk Factors—Forward-Looking Statements*”, and the other cautionary statements, cautionary language and risk factors set forth in other reports and documents filed with the Securities and Exchange Commission. We undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise.

### Overview

We are a biotechnology company focused on the development and commercialization of innovative therapeutic products for patients with chronic and life-threatening cardiovascular, cancer and infectious diseases. We commenced operations in June 1996 and, since our inception, have devoted substantially all of our resources to acquisitions and research and development programs.

#### *United Therapeutics Products and Services*

Our lead product is Remodulin, which is a prostacyclin analog, or a stable synthetic form of prostacyclin, an important molecule produced by the body that has powerful effects on blood-vessel health and function. On May 21, 2002, the United States Food and Drug Administration (FDA) approved subcutaneous (injection under the skin) use of Remodulin (treprostinil sodium) Injection for the treatment of pulmonary arterial hypertension, or PAH, in patients with NYHA class II-IV symptoms to diminish symptoms associated with exercise. PAH is a life-threatening condition characterized by elevated blood pressures between the heart and lungs. We were required to perform a post-marketing Phase IV clinical study to confirm the clinical benefits of Remodulin. Continued FDA approval of Remodulin is subject to the diligent and timely completion of that Phase IV trial, as well as its outcome. The study was originally to have been completed by May 2004 and involve 100 patients. In mid-2003, the FDA agreed to amend the due date of the final study report and make other changes to the trial design including reducing the number of patients to 39.

The amended Phase IV clinical trial was required to have been one-half enrolled by June 2004 and to have been fully enrolled by June 2005, with a final study report due December 2005. These enrollment deadlines were not met, and a final study report was not submitted.

Although the Phase IV clinical trial, as amended, established deadlines and required a final report in December 2005. The FDA permitted an interim assessment and opportunity to terminate the Phase IV study after only 21 patients have completed the study. In July 2005, the first 21 patients completed the study and we performed an interim assessment. The results of the interim assessment, as analyzed by an independent statistician, were positive. The p value was 0.0006, meaning that the likelihood that the achieved result was incorrect is six out of ten thousand. Specifically, 13 of 14 patients (93%) in the Remodulin arm were able to successfully transition from Flolan, which they had previously been using to treat their condition, and complete the study without the need to institute rescue therapy, compared to only 1 of 7 patients (14%) in the placebo arm. Based on this positive outcome, we submitted the interim study results to the FDA in July 2005, and requested permission to end the Phase IV clinical study in

satisfaction of our Phase IV commitments. By agreement with the FDA, enrollment in the Phase IV clinical study was suspended pending FDA review and acceptance of the interim study results.

If the FDA does not accept the interim study results or does not otherwise agree with our assessment of the interim results, the FDA could, among other things, grant an extension of time to continue to enroll the trial, or institute a public hearing to withdraw marketing approval for Remodulin. If a withdrawal hearing were instituted by the FDA, we would pursue the opportunity to participate in the hearing, as we believe that we have exercised good faith due diligence in pursuing enrollment of this trial.

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

The mutual recognition process to obtain approvals from European Union member countries for subcutaneous use of Remodulin was completed in August 2005, with positive decisions received from most European Union countries. We withdrew applications in Ireland, Spain and the United Kingdom and are engaged in regulatory discussions concerning the timing of resubmission in these three countries. Although these decisions were made in August 2005, the approving European countries may not provide formal action letters and pricing approvals required for the commercial sales of Remodulin for as long as up to one to two years, or longer. We can give no assurances as to the timing and receipt of the formal action letters and pricing approvals from European countries, or the outcome of applications in other countries. To date, we have received formal action letters and pricing approvals from France and Portugal.

We have generated revenues from sales of Remodulin and arginine products (which deliver an amino acid that is necessary for maintaining cardiovascular function) in the United States and other countries. In addition, we have generated revenues from telemedicine products and services, primarily designed for patients with abnormal heart rhythms called cardiac arrhythmias and poor blood flow to the heart, a condition known as ischemic heart disease, in the United States. We have funded our operations from the proceeds of sales of our common stock and from revenues from the sales of our products and services.

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

Remodulin is currently marketed by our own staff of approximately 20 employees who market directly to physicians specialized in treating pulmonary arterial hypertension, comprised mainly of pulmonologists and cardiologists. We face stiff competition from several other companies that market and sell competing therapies and expect the competition to continue growing.

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



### ***Future Prospects***

While we were profitable in each quarter since April 1, 2004, we incurred net losses for all quarters from inception through March 31, 2004. At December 31, 2005, we had an accumulated deficit of approximately \$115.3 million. Future profitability will depend on many factors, including timely and successful completion of the Remodulin Phase IV study discussed above under *United Therapeutics Products and Services*, the price, level of sales, level of reimbursement by public and private insurance payers, the impacts of competitive products and the number of patients using Remodulin and other currently commercialized products and services, as well as the results and costs of research and development projects.

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

Our major research and development projects are focused on 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, such as hepatitis.

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

Subcutaneous use of Remodulin was approved by the FDA in May 2002 for the treatment of PAH in NYHA Class II-IV patients to diminish symptoms associated with exercise. A condition of continued FDA approval is that a Phase IV clinical study must be completed in a timely and diligent manner as discussed above under *United Therapeutics Products and Services*. Material net cash inflows from the sales of Remodulin for PAH commenced in May 2002 after FDA approval was received.

Remodulin was also approved in most of Europe, Canada, Israel, Australia, Argentina and Chile for similar uses. Marketing authorization applications are currently under review in other countries.

On March 29, 2005, the manufacturer of the Medtronic 407C infusion pump, which is used for the subcutaneous administration of Remodulin, received FDA approval for intravenous use of the pump. It was previously approved for subcutaneous use only. We are currently completing an evaluation of the Medtronic 407C infusion pump for use with intravenous Remodulin in patients with PAH. Studies were done in adult and pediatric patients to explore logistics associated with use of this pump and to expand clinical information.

In March 2005, we commenced a 12-week placebo-controlled trial of intravenous Remodulin in patients with PAH to further assess the clinical benefits of Remodulin. The trial was conducted in India and was designed to enroll up to 126 patients. Interim results of this trial were to be analyzed after 33, 66 and 99 patients completed the 12-week trial. In August 2005, after enrolling approximately 45 patients, we suspended enrollment of new patients, per the recommendation of the trial's independent Data Safety Monitoring Board, which is a panel of independent experts. Preliminary results from the 45 patients were positive ( $p=0.008$ ). Specifically, intravenous Remodulin produced an 83-meter median improvement in six-minute walk distance compared to placebo after twelve weeks.

We are in an early stage of developing oral and a later state of developing inhaled formulations of treprostinil, which is the active pharmaceutical ingredient in Remodulin. During 2004, we completed dosage studies of oral formulations of treprostinil in healthy volunteers. We filed an Investigational New Drug Application on January 28, 2005 to perform an additional Phase I healthy volunteer study. On July 21, 2005, the European Medicines Agency announced that oral treprostinil had been granted orphan product status in the European Union. Presently, we are planning placebo-controlled multi-national trials of oral treprostinil in patients with pulmonary arterial hypertension.

During 2004 and 2005, independent clinical investigators in Europe and the United States performed small uncontrolled trials of inhaled formulations of treprostinil in patients with PAH. In June 2005, Lung Rx, Inc., a subsidiary of United Therapeutics, commenced a 12-week placebo-controlled trial of inhaled treprostinil in at least 150 patients with PAH who are also being treated with Tracleer®. The trial is known as TRIUMPH-1, **T**reprostinil **I**nhalation **U**sed in the **M**anagement of **P**ulmonary **H**ypertension, and is being conducted at approximately 15 centers in the United States and in Europe. Additional centers are expected to be added during 2006. As of December 31, 2005, approximately 55 patients have been enrolled in this trial. As of February 21, 2006, the trial is approximately one-half enrolled.

We incurred expenses of approximately \$20.1 million, \$16.2 million, and \$13.5 million during the years ended December 31, 2005, 2004 and 2003, respectively, on Remodulin development. Approximately \$160.9 million from inception to date has been incurred on Remodulin development.

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

Our 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 (Stage III and IV) patients. These studies, which commenced in January 2003, are being conducted at approximately 60 centers throughout the United States and will enroll at least 354 patients. As of December 31, 2005 approximately 330 patients have been enrolled in these trials. These studies could take up to two years to complete following full enrollment, depending on how long it takes for each study to reach at least 118 relapse events. We incurred expenses of approximately \$8.7 million, \$7.3 million and \$10.0 million during the years ended December 31, 2005, 2004 and 2003, respectively, on OvaRex development. Approximately \$32.4 million from inception to date has been incurred on OvaRex development.

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

Our infectious disease program includes glycobiology antiviral drug candidates in the preclinical and clinical stages of testing. The drugs in this program are being developed for hepatitis C, hepatitis B and other infectious diseases. We completed acute and chronic Phase I clinical dosing studies for our first candidate for the treatment of hepatitis C, UT-231B, to assess safety in healthy volunteers in early 2003. We initiated Phase II clinical studies in patients infected with hepatitis C in July 2003 and completed those studies in October 2004. In that trial, UT-231B did not demonstrate efficacy against hepatitis C in a population of patients that previously failed conventional treatments. We are now conducting preclinical testing of additional glycobiology drug candidates. We incurred expenses of approximately \$3.2 million, \$3.3 million, and \$7.1 million during the years ended December 31, 2005, 2004 and 2003, respectively, for our infectious disease programs. Approximately \$34.9 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 unapproved 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;
- Hospitals, physicians and patients may not properly adhere to clinical study procedures;
- The drugs may not be safe and effective or may not be perceived as safe and effective;
- Other approved or investigational therapies may be viewed as safer, more effective or more convenient;
- Patients may experience severe side effects during treatment;
- Patients may die during the clinical study because their disease is too advanced or because they experience medical problems that are not related to the drug being studied;
- Other ongoing or new clinical trials sponsored by other drug companies may reduce the number of patients available for our studies;
- Patients may not enroll in the studies at the rate we expect;
- The FDA and foreign regulatory authorities may delay or withhold approvals to commence clinical trials or to manufacture drugs;
- The FDA and foreign regulatory authorities may request that additional studies be performed;
- Higher than anticipated costs may be incurred due to the high cost of contractors for drug manufacture, research and clinical trials;
- Drug supplies may not be sufficient to treat the patients in the studies; and
- The results of preclinical testing may cause delays in clinical trials.

If these projects are not completed in a timely manner, regulatory approvals would be delayed and our operations, liquidity and financial position could suffer. Without regulatory approvals, we could not commercialize and sell these products and, therefore, potential revenues and profits from these products would be delayed or impossible to achieve.

### **Financial Position**

Cash, cash equivalents and marketable investments (including all unrestricted and restricted amounts) at December 31, 2005 were approximately \$191.0 million, as compared to approximately \$139.1 million at December 31, 2004. The increase of approximately \$51.9 million is due primarily to cash provided by operating activities and proceeds from the exercise of stock options. Restricted cash and marketable investments pledged to secure our obligations under the synthetic operating lease discussed below under *Off Balance Sheet Arrangement* at December 31, 2005 totaled approximately \$20.7 million, as compared with approximately \$10.1 million at December 31, 2004. The increase in restricted cash and marketable investments was due to additional funds placed in these accounts to provide adequate collateral under the lease.

Inventories, net of reserves for obsolescence, at December 31, 2005 were approximately \$11.3 million, as compared to approximately \$8.0 million at December 31, 2004. The increase was due primarily to increased levels of Remodulin finished goods and work-in-process, to meet anticipated needs for future sales and clinical trials.

Other receivables at December 31, 2005 were approximately \$4.2 million, as compared to approximately \$1.0 million at December 31, 2004. The increase was due primarily to an increase in recoverable import duties on shipments of Remodulin to foreign countries of approximately \$1.1 million and in construction draws receivable from Wachovia Development Corporation of approximately \$2.0 million.

Investments in affiliates at December 31, 2005 were approximately \$8.3 million, as compared to approximately \$7.4 million at December 31, 2004. The increase was due primarily to an increase in the fair value of our investment in ViRexx Medical Corp., based on quoted market prices.

Property, plant and equipment at December 31, 2005 were approximately \$21.8 million, as compared to \$17.8 million at December 31, 2004. The increase was due primarily to the purchase of building and land adjacent to the Lung Rx, Inc. office located in Satellite Beach, Florida for approximately \$2.8 million.

Accounts payable at December 31, 2005 were approximately \$4.0 million, as compared to approximately \$6.1 million at December 31, 2004. The decrease was due generally to the timing of payments to vendors.

Accrued expenses at December 31, 2005 were approximately \$10.4 million, as compared to approximately \$7.7 million at December 31, 2004. The increase was due primarily to accrued expenses for royalties and clinical trial related expenses and tax withholdings related to December 2005 payroll and stock option exercises.

Total stockholders' equity at December 31, 2005 was approximately \$275.1 million, as compared to \$191.6 million at December 31, 2004. The increase in stockholders' equity of approximately \$83.5 million was due primarily to net income earned and the proceeds collected from exercises of stock options during the twelve months ended December 30, 2005.

## Results Of Operations

### *Years ended December 31, 2005 and 2004*

Revenues for the year ended December 31, 2005 were approximately \$115.9 million, as compared to approximately \$73.6 million for the year ended December 31, 2004. The increase of approximately \$42.3 million was due primarily to growth in sales of Remodulin to our distributors.

The following sets forth our revenues by source for the periods presented (in thousands).

	Revenues for the Years Ended December 31,	
	2005	2004
Remodulin	\$ 109,191	\$ 66,050
Telemedicine services and products	5,773	5,346
Other products	689	2,194
License fees	262	—
Total revenues	<u>\$ 115,915</u>	<u>\$ 73,590</u>

For the years ended December 31, 2005 and 2004, approximately 90 percent and 87 percent of our revenues, respectively, were earned from three customers located in the United States.

Total revenues are reported net of estimated government rebates, prompt pay discounts and fees due to a distributor for services. We pay government rebates to state Medicaid agencies that pay for Remodulin. Historically, we estimated our liability for such rebates based on the volume of Remodulin dispensed to Medicaid patients as reported to us by our distributors and the expected rebate per unit of Remodulin as determined by us in accordance with federal guidelines. Since April 1, 2005, we have estimated our liability for such rebates based on the historical level of government rebates invoiced by state Medicaid agencies relative to U.S. sales of Remodulin. Prompt pay discounts are offered on sales of Remodulin if the related invoices are paid in full generally within 60 days from the date of sale. We estimated our liability for prompt pay discounts based on historical payment patterns. Fees paid to a distributor for services are estimated based on contractual rates for specific services applied to estimated units of service provided by the distributor for the period.

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

	Years Ended December 31,	
	2005	2004
Liability accounts, at beginning of period	\$ 2,121	\$ 936
Additions to liability	6,789	7,642
Payments	(7,320)	(6,457)
Liability accounts, at end of period	\$ 1,590	\$ 2,121
Net reductions to revenues	\$ 6,789	\$ 7,642

Our distributors endeavor to maintain levels of Remodulin inventories sufficient to satisfy existing and new demand for the product. Inventory levels held by United States-based distributors (as reported to us by our distributors) at December 31, 2005 and 2004 were approximately \$14.1 million and \$14.0 million, respectively, based on our gross selling price. As Remodulin was only recently approved by certain member countries of the European Union, inventory levels outside of the United States were not believed to be significant. In the future, we expect that international sales will increase as Remodulin is commercialized in more countries. Due to the inherent difficulties in tracking inventories held by our six international distributors and their numerous sub-distributors, inventory information will not be reported in our periodic reports in the future. Product returns were due to arginine products and totaled approximately \$3,000 and \$33,000 during the years ended December 31, 2005 and 2004, respectively.

Research and development expenses consist primarily of salaries and related expenses, costs to acquire pharmaceutical products and product rights for development and amounts paid to contract research organizations, hospitals and laboratories for the provision of services and materials for drug development and clinical trials. Research and development expenses were approximately \$36.1 million for the year ended December 31, 2005, as compared to approximately \$30.7 million for the year ended December 31, 2004. The increase was due primarily to increased expenses for the Remodulin-related programs and cancer disease programs of approximately \$3.2 million, and \$1.5 million, respectively, during the year ended December 31, 2005, as compared to the year ended December 31, 2004. See *Major Research and Development Projects* above, for additional information regarding our research programs.

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 \$24.7 million for the year ended December 31, 2005, as compared to approximately \$21.4 million for the year ended December 31, 2004. The increase in selling, general and administrative expenses was due primarily to the payment of one-time application fees of approximately \$1.1 million to European countries as part of the mutual recognition

process for Remodulin approval and a subsequent filing for approval of intravenous Remodulin in Europe and increases in salary and related expenses of approximately \$1.2 million, during the year ended December 31, 2005.

Cost of sales consists of the cost to manufacture or acquire products that are sold to customers. Cost of service sales consists of the salaries and related overhead necessary to provide services to customers. Cost of product sales was approximately 9% of product sales for each of the years ended December 31, 2005 and 2004. Cost of service sales was approximately 40% of service sales for the year ended December 31, 2005, as compared to approximately 47% for the year ended December 31, 2004. The improvement in the cost of service sales as a percentage of service revenues was due to the growth in service sales during 2005 with no corresponding increase in costs.

Interest income for the year ended December 31, 2005 was approximately \$5.4 million, as compared to interest income of approximately \$3.0 million for the year ended December 31, 2004. The increase was due primarily to an increase in cash available for investing during 2005 and increased market interest rates.

Equity loss in affiliate represents our share of Northern Therapeutics, Inc.'s losses. The equity loss in affiliate was approximately \$754,000 for the year ended December 31, 2005, as compared to approximately \$785,000 for the year ended December 31, 2004. Northern Therapeutics, Inc.'s loss was due primarily to expenditures for its autologous (non-viral vector) gene therapy research for pulmonary hypertension and sales and marketing activities for Remodulin in Canada.

An income tax benefit of approximately \$17.5 million was recognized for the year ended December 31, 2005, as compared to none for the year ended December 31, 2004. The benefit in 2005 was due to an approximately \$19.7 million reduction in the valuation allowance of our deferred tax assets as of December 31, 2005. The reduction of the valuation allowance is based on our review of both historical and projected taxable income which has shown that it is more likely than not that certain portions of our deferred tax assets will be realizable and that a reduction of the valuation allowance related to net operating loss carry forwards, business credits and intangible assets capitalized for tax purposes of approximately \$17.0 million, \$1.7 million, and \$1.0 million, respectively, was required. The benefit from the reduction of the valuation allowance was offset by state income tax expenses and federal alternative minimum income tax expense totalling approximately \$631,000 and the use of approximately \$1.6 million of state net operating loss carry forwards attributable to stock option deductions which is recognized as an expense with a corresponding increase to additional paid-in-capital. The deferred tax assets may be expensed in future periods as a component of tax expense as we incur additional taxable income. Prior to 2005, due to the company's long history of operating losses, we did not believe our deferred tax assets had a realizable value and they were fully reserved. As a result, we did not report tax benefits or deferred tax assets prior to 2005.

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

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

The following sets forth our revenues by source for the periods presented (in thousands).

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

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.

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

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

Inventory levels held by United States-based distributors (as reported to us by our distributors) at December 31, 2004 and 2003 were approximately \$14.0 million and \$13.6 million, respectively, based on our selling price. As Remodulin was only recently approved by certain member countries of the European Union, inventory levels outside of the United States were not significant. In the future, we expect that international sales will increase as Remodulin is commercialized in more countries. Due to the inherent difficulties in tracking inventories held by our six international distributors and their numerous sub-distributors, inventory information will not be reported in our periodic reports in the future. Product returns were due to arginine products and totaled approximately \$33,000 and \$192,000 during the years ended December 31, 2004 and 2003, respectively.

Research and development expenses were approximately \$30.7 million for the year ended December 31, 2004, as compared to approximately \$35.4 million for the year ended December 31, 2003. During the year ended December 31, 2004, expenses for Remodulin-related programs increased by approximately \$2.7 million while expenses for the infectious disease and cancer programs were reduced by approximately \$3.8 million and \$2.7 million, respectively, as compared to 2003. The remaining decrease in total research and development expenses of approximately \$1.0 million was related to reduced expenses in other programs. See *Major Research and Development Projects* above, for additional information.

Selling, general and administrative expenses were approximately \$21.4 million for the year ended December 31, 2004, as compared to approximately \$22.7 million for the year ended December 31, 2003. The decrease was due primarily to decreases of approximately \$1.2 million in sales and marketing expenses related mostly to arginine products and approximately \$871,000 in travel expenses. These decreases were offset by increases of approximately \$495,000 in professional fees expenses and \$526,000 in insurance expenses.

Cost of product sales was approximately 9% of product sales for the year ended December 31, 2004, which is consistent with approximately 10% for the year ended December 31, 2003. Cost of service sales was approximately 47% of service sales for the year ended December 31, 2004, which is consistent with the cost of service sales of approximately 49% for the year ended December 31, 2003.

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

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

### **Liquidity and Capital Resources**

Until June 1999, we financed our operations principally through private placements of common stock. On June 17, 1999, we completed our initial public offering. Our net proceeds 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, we issued common stock in two private placements and received aggregate net proceeds of approximately \$209.0 million. Until 2002, we funded the majority of our operations from such net proceeds of equity. Since 2004, we funded the majority of our operations from revenues, mainly Remodulin-related, and this is expected to continue.

In February 2005, we filed a primary shelf registration statement with the SEC to enable us to offer and sell up to five million shares of our common stock from time to time in one or more offerings. The shelf registration statement will provide us the flexibility to take advantage of future financing opportunities on terms that we consider advantageous, with terms that would be established at the time of any such offering. The SEC declared the shelf registration statement effective in February 2005.

Our working capital at December 31, 2005 was approximately \$152.2 million, as compared to approximately \$96.6 million at December 31, 2004. The increase is primarily due to a net increase in cash and current marketable investments of approximately \$42.7 million, and an increase in deferred tax assets of approximately \$19.7 million.

Restricted cash and marketable investments pledged to secure our obligations under the synthetic operating lease discussed below under *Off Balance Sheet Arrangement* at December 31, 2005 totaled approximately \$20.7 million, as compared with approximately \$10.1 million at December 31, 2004. The increase in restricted cash and marketable investments was due to additional funds placed in these accounts to provide adequate collateral under the lease.

Net cash provided by operating activities was approximately \$43.7 million for the twelve months ended December 31, 2005 as compared to approximately \$20.8 million for the twelve months ended December 31, 2004. The increase in cash provided by operating activities is due primarily to growth in sales and collections of Remodulin. For the twelve months ended December 31, 2005, we invested approximately \$6.1 million in cash for property, plant and equipment, as compared to approximately \$5.2 million in the twelve months ended December 31, 2004.

We made milestone payments totalling \$20,000 pursuant to existing license agreements during each of the twelve months ended December 31, 2005 and 2004. We are obligated to make royalty payments on sales of Remodulin which exceed annual net sales of \$25.0 million and on all arginine products. Royalties on sales of all products currently marketed range up to 10% of sales of those products.



We believe that our existing revenues, together with existing capital resources (comprised primarily of unrestricted cash, cash equivalents and marketable investments), will be adequate to fund our operations. However, any projections of future cash needs and cash flows are subject to substantial uncertainty. See *“Item 1A—Risk Factors—Actual consolidated revenues and net income may be different from published securities analyst projections. In addition, we have a history of losses and may not continue to be profitable”*.

We recognized an income tax expense benefit for the year ended December 31, 2005 due primarily to an approximately \$19.7 million reduction in the valuation allowance against our deferred tax assets at December 31, 2005 based on our determination that certain of these deferred tax assets are more likely than not realizable.

At December 31, 2005, we had for federal income tax purposes net operating loss carryforwards of approximately \$98.3 million and business tax credit carryforwards of approximately \$30.8 million which expire at various dates from 2012 through 2024. Approximately, \$50.0 million of the net operating loss carryforwards is attributable to exercised stock options, the benefit of which, when realized, directly increases additional paid-in-capital. Business tax credits can offset future tax liabilities and arise from qualified research expenditures. We have been and may continue to be subject to federal alternative minimum tax and state income taxes, even though we have significant net operating loss and credit carryforwards.

Section 382 of the Internal Revenue Code limits the utilization of net operating losses when ownership changes occur as defined by that section. We have reviewed our ownership change position pursuant to Section 382 and have determined that ownership changes occurred in December 1997, June 1999, and November 2004 and, as a result, the utilization of certain of our net operating loss carryforwards may be limited. However, we do not expect any significant portion of our net operating loss carry forwards or business tax credits will expire unused. A portion of the net operating loss carryforwards continues to be fully reserved through a valuation allowance as of December 31, 2005. Although we have net operating losses available to offset future taxable income, we may be subject to federal alternative minimum taxes and state income taxes.

### **Off Balance Sheet Arrangement**

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

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

In addition, we agreed to pledge, as collateral, a portion of our marketable investments to secure our lease obligations. At December 31, 2005, approximately \$20.7 million of marketable investments and cash

were pledged as collateral and are reported as restricted marketable investments and cash in our consolidated balance sheet.

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

We anticipate that rent payments will commence in early 2006, after completion of construction, and continue through termination of the lease in May 2011. Based on construction costs of up to approximately \$32.0 million and the current effective rate of approximately 4.9 percent (equivalent to the current 30-day LIBOR rate plus approximately 55 basis points at December 30, 2005), the rents to be paid could approximate \$1.6 million annually. In addition, Wachovia paid us ground rent in June 2004 totalling an aggregate of approximately \$307,000 that will be recognized as income ratably through May 2011.

We guaranteed a minimum residual value of the laboratory facility. This guaranteed residual is generally equal to 86 percent of the amount funded by Wachovia towards construction. If, at the end of the lease term, we do not renew the lease or purchase the improvements, then the building will be sold to a third party. In that event, we have guaranteed that Wachovia will receive at least this residual value amount. The maximum potential amount of this guarantee is approximately \$27.5 million, equivalent to 86 percent of expected total construction costs of \$32.0 million. We have estimated the fair value of this guarantee liability at approximately \$839,000 and this amount is classified as a non-current liability in our balance sheet at December 31, 2005.

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

In March 2005, we entered into a construction management agreement with Turner Construction Company (Turner). Turner will manage the construction of the new laboratory facility. Under the terms of the agreement, Turner will be responsible for the construction of the facility. The agreement has a guaranteed maximum price clause in which Turner agrees that the construction cost of the facility will not exceed approximately \$27.0 million, which amount is subject to change based on agreed-upon changes to the scope of work. Turner will be responsible for covering any costs in excess of the guaranteed maximum price guarantee. If the ultimate cost of the project is less than the guaranteed maximum price of \$27.0 million, then a portion of the cost savings will be shared with Turner. In addition, Turner must pay us penalties if the construction is not completed by April 2006, which date is subject to change based on agreed-upon changes to the scope of work.

## Contractual Obligations

At December 31, 2005, we had contractual obligations coming due approximately as follows (in thousands):

	Payment Due In				
	Total	2006	2007 to 2009	2010 to 2011	2012 and Later
Notes payable and capital lease obligations	\$ 23	\$ 15	\$ 8	\$ —	\$ —
Operating lease obligations(1)	12,797	2,685	7,517	2,595	—
Construction agreement(2)	13,677	13,677	—	—	—
Purchase obligations	334	334	—	—	—
Other long-term liabilities reflected in the statement of financial position(1)	839	—	—	839	—
Milestone payments(3)	9,765	20	6,185	1,540	2,020
	<u>\$ 37,435</u>	<u>\$ 16,731</u>	<u>\$ 13,710</u>	<u>\$ 4,974</u>	<u>\$ 2,020</u>

- (1) Operating lease obligations include the estimated lease payments on the laboratory facility being constructed in Silver Spring, Maryland. The lease is expected to commence in early 2006 and will expire in May 2011. The lease payments will generally be equal to applying the current 30-day LIBOR rate plus approximately 55 basis points (approximately 4.9 percent at December 31, 2005) to the cost of the construction of the laboratory. Upon termination of the lease, we will generally have the option of renewing the lease, purchasing the laboratory or selling it and repaying Wachovia the cost of its construction. We guaranteed that if the laboratory is sold, Wachovia will receive at least 86 percent of the amount it funded towards the construction. It is estimated that the laboratory will cost approximately \$32.0 million to construct and the guarantee is estimated at approximately \$27.5 million. The estimated fair value of the guarantee is included in other long-term liabilities reflected in the statement of financial position. See *Off Balance Sheet Arrangement* for additional information.
- (2) Wachovia is contractually obligated to reimburse these amounts to us under the synthetic operating lease agreement described above under *Off Balance Sheet Arrangement*.
- (3) We licensed certain products from other companies under certain license agreements. These agreements generally include milestone payments to be paid in cash by us 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

### Income Taxes

We account for income taxes in accordance with Statement of Financial Accounting Standards (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. A net deferred tax asset or liability is reported in the balance sheet.

At each reporting date, we consider whether it is more-likely-than-not that some portion or all of the net deferred tax asset is realizable. If the net deferred tax asset is not fully realizable, then a valuation allowance is established to reduce the amount of net deferred tax asset reported in the balance sheet.

Based on the weight of available evidence at December 31, 2005, it was determined that a partial valuation allowance totalling approximately \$64.5 million was necessary at December 31, 2005.

### ***Remodulin Revenue Recognition***

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

One of our Remodulin distribution agreements stipulated minimum quarterly purchases by the distributor for periods through June 30, 2005 and no minimum quarterly purchases after June 30, 2005. The distribution agreement, however, does not permit the distributor to return Remodulin product solely based on the distributor's ability or inability to resell the product. As a result, revenues from sales to this distributor are recognized in the period that the Remodulin product is delivered to the distributor. During the years ended December 31, 2005, 2004 and 2003, approximately \$5.3 million, \$3.1 million and \$2.0 million, of Remodulin products were sold to this distributor and recognized as revenue, respectively, and this distributor has made voluntary purchases since June 30, 2005.

### ***Intangible Assets***

We adopted the provisions of SFAS No. 142, *Goodwill and Other Intangible Assets*, on January 1, 2002, which eliminated the amortization of goodwill. Rather, goodwill is subject to at least an annual assessment for impairment by applying a fair value-based test that is performed on October 1<sup>st</sup> of each year. We continually evaluate whether events and circumstances have occurred that indicate that the remaining value of goodwill may not be recoverable. At December 31, 2005, we believed that goodwill was not impaired and therefore no impairment losses have been recorded. This conclusion is based on our 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.

On January 19, 2006, we decided to discontinue the sales, marketing and production of our HeartBar line of products, which are arginine-enriched dietary supplements. This discontinuance was effective immediately. The decision to discontinue HeartBar is not meant to impact other aspects of our arginine line of business, which include sales of non-HeartBar arginine products and license royalties from third parties selling arginine based products. This decision was made by us after evaluating recent clinical trial results and market potential, among other considerations.

In connection with this discontinuance, we concluded that we will recognize non-cash impairment charges totalling approximately \$2.0 million from the write-off of the HeartBar trademark intangible. These impairment charges will be recorded in the quarter ending March 31, 2006. The other intangible assets related to the arginine line of business, primarily patents, are not affected by this discontinuance.

### **Marketable Investments**

Currently, we invest portions of our cash in marketable debt securities issued primarily by federally-sponsored agencies. Due to our intent and ability to hold these marketable debt investments until their maturities, these investments are reported at their amortized cost. We believe that we are able to hold these investments to maturity, due to the significant level of cash and cash equivalents that we have. If we did not have the ability and intent to hold these investments to maturity, we would have reported them in the consolidated balance sheets at their fair market values. At December 31, 2005, the amortized cost of these debt securities was approximately \$72.8 million and their fair values were approximately \$70.6 million.

### **Earnings per Share**

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

### **Stock Options**

We apply the principles of Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, in accounting for our stock options issued to our employees. The following table details the pro forma results had we applied the fair value principles of SFAS No. 123, *Accounting for Stock-Based Compensation*, for our employee options (in thousands):

	Years Ended December 31,		
	2005	2004	2003
Net income (loss), as reported	\$ 65,016	\$ 15,449	\$ (9,969)
Less total stock-based employee compensation expense determined under fair value based method for all awards	(23,097 )	(8,072 )	(12,964 )
Pro forma net income (loss)	<u>\$ 41,919</u>	<u>\$ 7,377</u>	<u>\$ (22,933)</u>

### **Investments in Affiliates**

The equity method of accounting is used to account for some of our investments in affiliates, including Northern Therapeutics. The equity method of accounting generally requires that we report our share of our affiliates' net losses or profits in our financial statements, but does not require that assets, liabilities, revenues and expenses of the affiliates be consolidated with our 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 us. Although our investment in Northern Therapeutics exceeds 50 percent, minority shareholders possess substantive participating rights that preclude Northern Therapeutics' financial statements from being consolidated.

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

The investment in ViRexx Medical Corp. (formerly AltaRex Medical Corp.) is accounted for as an available-for-sale security because its stock is publicly traded. We own less than 10 percent of ViRexx. 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. The fair value of the investment was

approximately \$6.2 million, \$4.6 million, and \$3.7 million at December 31, 2005, 2004 and 2003, respectively, based on quoted market prices. These changes in fair market value were reported as other comprehensive income or loss.

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

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

### ***Lease of Laboratory Facility***

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

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

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

## **Recent Accounting Pronouncements**

### ***Stock-Based Compensation***

On December 16, 2004, the FASB issued a revision of SFAS No. 123 (revised 2004), *Share-Based Payment* (Statement 123(R)), which is a revision of FASB Statement No. 123, *Accounting for Stock-Based Compensation* (Statement 123). Statement 123(R) supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees* (Opinion 25), and amends FASB Statement No. 95, *Statement of Cash Flows*.

Generally, the approach in Statement 123(R) is similar to the approach described in Statement 123. Statement 123(R) was initially required to be implemented by July 1, 2005, but its effective date has been delayed until January 1, 2006 by the Securities and Exchange Commission. Accordingly, we anticipate that we will adopt Statement 123(R) on January 1, 2006.

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

The full impact of adoption of Statement 123(R) cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had we adopted Statement 123(R) in prior periods, the impact of that standard would have approximated the impact of Statement 123 as described in the disclosure of pro forma net income and earnings per share in Note 2 to the consolidated financial statements contained in this Annual Report on Form 10-K for the year ended December 31, 2005. Statement 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement could reduce net operating cash flows and increase net financing cash flows in periods after adoption. We are unable to estimate what those amounts will be in the future because they depend on, among other things, the timing and volume of the exercise of stock options.

### ***Inventory Costs***

In December 2004, the FASB issued SFAS Statement No. 151 *Inventory Cost*, which is an amendment to Accounting Research Bulletin No. 43, *Restatement and Revision of Accounting Research Bulletins*. SFAS No. 151 clarifies the accounting treatment of certain expenses for inventory costing. The new standard will be effective for the first fiscal year beginning after June 15, 2005. We do not expect the adoption of SFAS 151 to have a significant impact on our results of operations and financial condition.

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

At December 31, 2005, a substantial portion of our assets was comprised of debt securities issued by federally-sponsored agencies. The market value of these investments fluctuates with changes in current market interest rates. In general, as rates increase, the market value of a debt investment would be expected to decrease. Likewise, as rates decrease, the market value of a debt investment would be expected to increase. To minimize such market risk, we hold such instruments to maturity at which time these instruments will be redeemed at their stated or face value. At December 31, 2005, we had approximately \$72.8 million in debt securities issued by federally-sponsored agencies with a weighted average stated interest rate of approximately 3.7 percent maturing through March 2012 and callable annually. The fair market value of this held-to-maturity portfolio at December 31, 2005 was approximately \$70.6 million.

At December 31, 2005, a portion of our assets was comprised of auction rate debt securities issued by state-sponsored agencies. While these securities have long term maturities, their interest rates are reset approximately every 7-28 days through an auction process. As a result, the interest income from these securities is subject to market risk since the rate is adjusted to accommodate market conditions on each reset date. However, since the interest rates are reflective of current market conditions, the fair value of these securities typically does not fluctuate from par or cost. At December 31, 2005, we had approximately \$48.4 million in these debt securities with a weighted average stated interest rate of approximately 4.3 percent. The fair market value of these available-for-sale debt securities as of December 31, 2005 was approximately \$48.4 million.

In June 2004, we entered into a synthetic operating lease and related agreements with Wachovia Development Corporation and its affiliates (Wachovia) to fund the construction of a laboratory facility in Silver Spring, Maryland. Under these agreements, we will pay rents to Wachovia generally based on applying the 30-day LIBOR rate plus approximately 55 basis points to the amount funded by Wachovia towards the construction of the laboratory. The total amount of construction is estimated to be approximately \$32.0 million. At December 31, 2005, the total amount incurred related to the construction was approximately \$16.1 million. Rents will be paid monthly from the time that the laboratory construction is completed until the termination of the lease in May 2011. These rents, therefore, are subject to the risk that LIBOR will increase or decrease during the period until termination in May 2011. At December 31, 2005, the 30-day LIBOR was approximately 4.4 percent. For every movement of 100 basis points (1 percent) in the 30-day LIBOR rate, the rents under this lease could increase or decrease by approximately \$320,000 on an annualized basis.



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

**UNITED THERAPEUTICS CORPORATION  
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

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## Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders  
United Therapeutics Corporation

We have audited the accompanying consolidated balance sheets of United Therapeutics Corporation as of December 31, 2005 and 2004, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2005. Our audits also included the financial statement schedules listed in the Index at Item 15 (a)(2). These financial statements and schedules are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedules based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of United Therapeutics Corporation at December 31, 2005 and 2004, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2005, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedules, when considered in relation to the basic financial statements taken as a whole, present fairly in all material respects the information set forth therein.

We also have audited, in accordance with the Standards of the Public Company Accounting Oversight Board (United States), the effectiveness of United Therapeutics Corporation's internal control over financial reporting as of December 31, 2005, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 23, 2006 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

McLean, Virginia  
February 23, 2006

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

The Board of Directors and Shareholders  
United Therapeutics Corporation

We have audited management's assessment, included in the accompanying Management's Report on Internal Control Over Financial Reporting, that United Therapeutics Corporation maintained effective internal control over financial reporting as of December 31, 2005, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). United Therapeutics Corporation's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, management's assessment that United Therapeutics Corporation maintained effective internal control over financial reporting as of December 31, 2005, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, United Therapeutics Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2005 consolidated financial statements of United Therapeutics Corporation and our report dated February 23, 2006 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

McLean, Virginia  
February 23, 2006

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

	<b>December 31,</b>	
	<b>2005</b>	<b>2004</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 69,180	\$ 82,586
Marketable investments	56,304	200
Accounts receivable, net of allowance of \$15 for 2005 and \$23 for 2004	13,873	13,743
Other receivable	4,201	1,042
Interest receivable	733	499
Due from affiliate	179	524
Prepaid expenses	6,384	3,230
Inventories, net	11,263	8,014
Deferred tax assets	4,611	—
Other current assets	29	654
Total current assets	<u>166,757</u>	<u>110,492</u>
Marketable investments	44,863	46,233
Marketable investments and cash—restricted	20,666	10,121
Goodwill, net	7,465	7,465
Other intangible assets, net	5,487	5,967
Property, plant, and equipment, net	21,802	17,799
Investments in affiliates	8,259	7,444
Notes receivable from affiliate and employee	26	446
Deferred tax assets	15,100	—
Other assets	988	1,191
Total assets	<u>\$ 291,413</u>	<u>\$ 207,158</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 3,974	\$ 6,098
Accounts payable to affiliates and related parties	6	29
Accrued expenses	10,394	7,689
Due to affiliates and related parties	134	32
Current portion of notes and leases payable	15	16
Total current liabilities	<u>14,523</u>	<u>13,864</u>
Notes and leases payable, excluding current portion	8	10
Other liabilities	1,780	1,648
Total liabilities	<u>16,311</u>	<u>15,522</u>
<b>Commitments and contingencies</b>		
<b>Stockholders' equity:</b>		
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, 23,845,004 and 22,955,129 shares issued at December 31, 2005 and 2004, respectively, and 23,318,404 and 22,428,529 outstanding at December 31, 2005 and 2004, respectively	239	229
Additional paid-in capital	393,469	375,945
Accumulated other comprehensive income	3,593	2,677
Treasury stock at cost, 526,600 shares	(6,874 )	(6,874 )
Accumulated deficit	(115,325 )	(180,341 )
Total stockholders' equity	<u>275,102</u>	<u>191,636</u>
Total liabilities and stockholders' equity	<u>\$ 291,413</u>	<u>\$ 207,158</u>

See accompanying notes to consolidated financial statements.

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

	For Years Ended December 31,		
	2005	2004	2003
Revenues:			
Net product sales	\$ 110,412	\$ 69,539	\$ 49,715
Service sales	5,241	4,051	3,626
License fees	262	—	—
Total revenue	115,915	73,590	53,341
Operating expenses:			
Research and development	36,052	30,713	35,417
Selling, general and administrative	24,655	21,418	22,667
Cost of product sales	10,242	6,347	4,994
Cost of service sales	2,073	1,903	1,789
Total operating expenses	73,022	60,381	64,867
Income (loss) from operations	42,893	13,209	(11,526)
Other income (expense):			
Interest income	5,359	2,986	2,435
Interest expense	(29)	(4)	(112)
Equity loss in affiliate	(754)	(785)	(953)
Other, net	53	43	187
Total other income (expense)	4,629	2,240	1,557
Net income (loss) before income tax	47,522	15,449	(9,969)
Income tax benefit	17,494	—	—
Net income (loss)	<u>\$ 65,016</u>	<u>\$ 15,449</u>	<u>\$ (9,969)</u>
Net income per common share:			
Basic	<u>\$ 2.85</u>	<u>\$ 0.71</u>	<u>\$ (0.47)</u>
Diluted	<u>\$ 2.58</u>	<u>\$ 0.66</u>	<u>\$ (0.47)</u>
Weighted average number of common shares outstanding:			
Basic	<u>22,825</u>	<u>21,726</u>	<u>21,135</u>
Diluted	<u>25,206</u>	<u>23,351</u>	<u>21,135</u>

See accompanying notes to consolidated financial statements.

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

	Common Stock		Additional	Accumulated		Accumulated	
	Shares	Amount	Paid-in	Other	Treasury	Deficit	Total
			Capital	Comprehensive	Stock		
				Income			
Balance, December 31, 2002	21,449,470	\$ 215	\$ 364,130	\$ 8	\$ (6,874)	\$ (185,821)	\$ 171,658
Net loss	—	—	—	—	—	(9,969 )	(9,969 )
Foreign currency translation adjustments	—	—	—	13	—	—	13
Unrealized gain on available-for-sale securities	—	—	—	1,653	—	—	1,653
Total other comprehensive income (loss)	—	—	—	1,666	—	(9,969 )	(8,303 )
Options issued in exchange for services	—	—	325	—	—	—	325
Exercise of stock options	386,872	3	4,082	—	—	—	4,085
Balance, December 31, 2003	21,836,342	218	368,537	1,674	(6,874 )	(195,790 )	167,765
Net income	—	—	—	—	—	15,449	15,449
Foreign currency translation adjustments	—	—	—	48	—	—	48
Unrealized gain on available-for-sale securities	—	—	—	955	—	—	955
Total other comprehensive income	—	—	—	1,003	—	15,449	16,452
Options issued in exchange for services	—	—	329	—	—	—	329
Exercise of stock options	526,955	5	7,085	—	—	—	7,090
Settlement of shares due to sellers of Medicomp	591,832	6	(6 )	—	—	—	—
Balance, December 31, 2004	22,955,129	229	375,945	2,677	(6,874 )	(180,341 )	191,636
Net income	—	—	—	—	—	65,016	65,016
Foreign currency translation adjustments	—	—	—	(220 )	—	—	(220 )
Unrealized gain on available-for-sale securities	—	—	—	1,136	—	—	1,136
Total other comprehensive income	—	—	—	916	—	65,016	65,932
Tax benefit from exercises of non-qualified stock options	—	—	1,586	—	—	—	1,586
Options issued in exchange for services	—	—	983	—	—	—	983
Exercise of stock options	889,875	10	14,955	—	—	—	14,965
Balance, December 31, 2005	23,845,004	\$ 239	\$ 393,469	\$ 3,593	\$ (6,874)	\$ (115,325)	\$ 275,102

See accompanying notes to consolidated financial statements.

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

	<b>Years Ended December 31,</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
Cash flows from operating activities:			
Net income (loss)	\$ 65,016	\$ 15,449	\$ (9,969)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization	2,534	2,381	2,363
Loss on disposals of equipment	58	—	108
Provisions for bad debt and write downs	90	37	425
Stock and options issued in exchange for services	983	329	325
Deferred tax benefit	(18,125)	—	—
Provisions for inventory obsolescence and write downs	228	487	325
Amortization of premiums and discounts on marketable investments	(120)	(105)	(38)
Unrealized foreign translation gain	(220)	—	—
Equity loss in affiliate	754	785	953
Changes in operating assets and liabilities:			
Accounts receivable	(220)	(3,630)	(927)
Interest receivable	(234)	(38)	(451)
Inventories	(3,461)	(385)	(1,202)
Prepaid expenses	(2,377)	(1,356)	(639)
Other current assets	(2,534)	(1,221)	668
Other noncurrent assets	203	2,781	(2,556)
Due from affiliate	332	680	(81)
Accounts payable	(2,122)	1,854	1,338
Accrued expenses	2,705	2,230	1,007
Due to affiliate and related parties	79	(21)	(206)
Other liabilities	131	521	(5)
Net cash provided by (used in) operating activities	<u>43,700</u>	<u>20,778</u>	<u>(8,562)</u>
Cash flows from investing activities:			
Purchases of property, plant and equipment	(6,117)	(5,217)	(7,004)
Proceeds from disposals of property, plant and equipment	—	821	336
Investment in Northern Therapeutics, Inc.	—	(1,000)	(2,500)
Acquisition of patent rights	—	—	(300)
Purchases of held-to-maturity investments	(17,009)	(37,474)	(44,911)
Purchases of available-for-sale investments	(61,050)	—	—
Maturities of held-to-maturity investments	—	30,000	6,641
Sales of available-for-sale investments	12,900	—	—
Net cash (used in) investing activities	<u>(71,276)</u>	<u>(12,870)</u>	<u>(47,738)</u>
Cash flows from financing activities:			
Proceeds from exercise of stock options	14,965	7,090	4,085
Payments of principal on notes payable	(777)	(750)	(1,982)
Principal payments under capital lease obligations	(18)	(24)	(96)
Net cash provided by financing activities	<u>14,170</u>	<u>6,316</u>	<u>2,007</u>
Net increase (decrease) in cash and cash equivalents	(13,406)	14,224	(54,293)
Cash and cash equivalents, beginning of year	<u>82,586</u>	<u>68,362</u>	<u>122,655</u>
Cash and cash equivalents, end of year	<u>\$ 69,180</u>	<u>\$ 82,586</u>	<u>\$ 68,362</u>
Supplemental schedule of noncash investing and financing activities:			
Notes payable issued for building and land	\$ —	\$ —	\$ 974
Supplemental cash flow information—cash paid for interest	<u>\$ 29</u>	<u>\$ 2</u>	<u>\$ 87</u>
Cash paid for income taxes	<u>\$ 185</u>	<u>\$ —</u>	<u>\$ —</u>

See accompanying notes to consolidated financial statements.

# 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 innovative therapeutic products for patients with chronic and life-threatening cardiovascular, cancer and infectious diseases. United Therapeutics was incorporated on June 26, 1996 under the laws of the State of Delaware and has the following wholly owned subsidiaries: Lung Rx, Inc. (Lung Rx), Unither Pharmaceuticals, Inc. (UPI), Unither Telmed, Ltd. (Unither Telmed and formerly Unither Telemedicine Services Corporation), Unither.com, Inc., United Therapeutics Europe, Ltd., Unither Pharma, Inc., Medcomp, Inc., Unither Nutraceuticals, Inc., Lung Rx, Ltd. and Unither Biotech Inc.

United Therapeutics' lead product is Remodulin®. On May 21, 2002, the United States Food and Drug Administration (FDA) approved Remodulin (treprostinil sodium) Injection for the treatment of pulmonary arterial hypertension in patients with NYHA class II-IV symptoms to diminish symptoms associated with exercise. United Therapeutics was required by the FDA to perform a post-marketing Phase IV clinical study to further assess the clinical benefits of Remodulin. Continued FDA approval of Remodulin is subject to the diligent and timely completion of the Phase IV trial, as well as its outcome. On November 24, 2004, the FDA approved intravenous infusion of Remodulin, based on data establishing its bioequivalence with the subcutaneous administration of Remodulin, for patients who are not able to tolerate a subcutaneous infusion. This approval was also conditioned upon the diligent and timely completion of the Phase IV trial, as well as its outcome. Several international applications for the approval of Remodulin have been granted and others are pending.

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

### 2. Summary of Significant Accounting Policies

#### *Principles of Consolidation*

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

#### *Cash Equivalents*

Cash equivalents consist of highly liquid investments with original maturities of three months or less. Cash equivalents consist of money market funds, commercial paper, and certificates of deposit and amount to approximately \$69.2 million and \$82.6 million at December 31, 2005 and 2004, respectively. Approximately \$1.5 million at December 31, 2005 and 2004 was held by a bank as a compensating balance in order to reduce fees charged by the bank. However, the agreement with the bank does not restrict United Therapeutics' ability to withdraw such balances.

#### *Inventories*

United Therapeutics manufactures certain compounds, such as treprostinil and purchases medical supplies, such as external pumps, for use in its product sales and ongoing clinical trials. United Therapeutics subcontracts the manufacture of cardiac monitoring equipment. United Therapeutics



**UNITED THERAPEUTICS CORPORATION**  
**Notes to Consolidated Financial Statements (Continued)**

contracts with third-party manufacturers to make arginine based products. These inventories are accounted for under the first-in, first-out method and are carried at the lower of cost or market. Included as a component of inventory manufactured by United Therapeutics are a portion of the general and administrative (G&A) costs pertaining to its Chicago facility. These G&A costs, primarily rent, utilities and depreciation expenses, are allocated to production activities based on direct labor hours related to production activities. For the years ended December 31, 2005 and 2004, approximately \$847,000 and \$874,000, respectively, of G&A costs were capitalized into inventory. At December 31, 2005 and 2004, inventories consisted of the following, net of reserves of approximately \$570,000 and \$447,000 at December 31, 2005 and 2004, respectively (in thousands):

	<b>December 31,</b>	
	<b>2005</b>	<b>2004</b>
Remodulin:		
Raw materials	\$ 814	\$ 553
Work in progress	7,582	5,428
Finished goods	2,052	960
Remodulin delivery pumps and medical supplies	673	804
Cardiac monitoring equipment components	59	—
HeartBar and related product lines	83	269
Total inventories	<u>\$ 11,263</u>	<u>\$ 8,014</u>

***Property, Plant and Equipment***

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

Buildings	39 Years
Building improvements	15-39 Years
Furniture, equipment and vehicle	3-15 Years
Holter and event cardiac monitoring systems	3-7 Years
Leasehold improvements	Life of the lease or asset, whichever is shorter

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

	<b>December 31,</b>	
	<b>2005</b>	<b>2004</b>
Land	\$ 6,076	\$ 4,477
Buildings, building improvements and leasehold improvements	10,941	9,116
Buildings under construction	413	412
Holter and event cardiac monitoring systems	4,002	3,307
Furniture, equipment and vehicle	7,999	6,160
	29,431	23,472
Less—accumulated depreciation	(7,629)	(5,673)
Property, plant and equipment, net	<u>\$ 21,802</u>	<u>\$ 17,799</u>

**UNITED THERAPEUTICS CORPORATION**  
**Notes to Consolidated Financial Statements (Continued)**

Depreciation expense for the years ended December 31, 2005, 2004 and 2003 was approximately \$2.1 million, \$1.9 million and \$1.5 million, respectively.

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

In May 2005, United Therapeutics purchased land and buildings adjacent to its Satellite Beach offices for approximately \$2.8 million in cash. In January 2006, United Therapeutics entered into a contract to purchase additional land and a building adjacent to its Silver Spring offices for approximately \$1.8 million in cash with settlement expected to occur in early 2006.

***Research and Development***

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

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

***Income Taxes***

Income taxes are accounted for in accordance with SFAS No. 109, *Accounting for Income Taxes*. Under the asset and liability method of SFAS No. 109, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using the tax rates and laws that are expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect of a change in tax rates on deferred taxes is recognized as either a change in the valuation allowance or in income in the period that includes the enactment date. Valuation allowances are provided against deferred tax assets, including those arising from net operating loss carry forwards, if it is anticipated that some or the entire asset may not be realized through future taxable income. United Therapeutics assesses quarterly the likelihood that the deferred tax assets will be recovered from future taxable income and to the extent it believes that recovery is not likely, it establishes a valuation allowance. To the extent United Therapeutics establishes a valuation allowance or changes to the valuation allowance occur in a given period, an income tax expense or benefit (i.e. reduction of expense) may be recognized in the statement of operations. A significant portion of the remaining deferred tax asset valuation allowance related to net operating losses at December 31, 2005, if released, will be reflected as a direct increase to additional paid-in-capital. The remainder at December 31, 2005, if reduced, will be reflected as a benefit to the income tax provision.

***Marketable Investments***

Approximately \$72.8 million and \$56.6 million of United Therapeutics' marketable investments are considered held-to-maturity securities at December 31, 2005 and 2004, respectively. 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.

**UNITED THERAPEUTICS CORPORATION**  
**Notes to Consolidated Financial Statements (Continued)**

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.

Approximately \$48.4 million and none of our marketable investments are considered available-for-sale securities at December 31, 2005 and 2004, respectively. Available-for-sale securities are those securities which United Therapeutics neither intends to hold until maturity nor intends to sell in the near term. Available-for-sale securities are recorded at their fair values. Changes in fair values are excluded from earnings and reported in other comprehensive income. United Therapeutics' available-for-sale securities are auction rate debt securities which have long term maturities, however, their interest rates reset approximately every 7 – 28 days, through a re-auctioning process. Since the interest rates are generally reflective of current market conditions, the fair value of these securities typically approximates cost.

***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. 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 business acquired relate to covenants not to compete, employment agreements, technology, patents, and trade names and were determined on the basis of independent valuations. The other intangibles are being amortized over three to eighteen years, consistent with the terms of the underlying agreements.

Goodwill is tested for impairment in October of each year. Intangible assets subject to amortization are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The measurement of possible impairment is based primarily on the ability to recover the balance of the goodwill and other intangible assets from expected future operating cash flows on an undiscounted basis. Impairment losses for other intangible assets 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, 2005.

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

	<u>As of December 31, 2005</u>			<u>As of December 31, 2004</u>		
	<u>Accumulated</u>			<u>Accumulated</u>		
	<u>Gross</u>	<u>Amortization</u>	<u>Net</u>	<u>Gross</u>	<u>Amortization</u>	<u>Net</u>
Goodwill	<u>\$ 9,072</u>	<u>\$ (1,607)</u>	<u>\$ 7,465</u>	<u>\$ 9,072</u>	<u>\$ (1,607)</u>	<u>\$ 7,465</u>
Intangible assets:						
Noncompete agreements	\$ 273	\$ (273)	\$ —	\$ 273	\$ (273)	\$ —
Trademarks	2,802	(1,230)	1,572	2,802	(984)	1,818
Technology and patents	6,164	(2,249)	3,915	6,164	(2,015)	4,149
Total intangible assets	<u>\$ 9,239</u>	<u>\$ (3,752)</u>	<u>\$ 5,487</u>	<u>\$ 9,239</u>	<u>\$ (3,272)</u>	<u>\$ 5,967</u>

Total amortization expense for the years ended December 31, 2005, 2004 and 2003 was approximately \$479,000, \$479,000, and \$855,000, respectively. The weighted average amortization period for the non-fully amortized trademark and technology and patents intangibles is approximately 6 and 17 years, respectively.

**UNITED THERAPEUTICS CORPORATION**  
**Notes to Consolidated Financial Statements (Continued)**

As of December 31, 2005, the aggregate amortization expense related to these intangible assets for each of the five succeeding years is estimated as follows (in thousands):

<u>Years ending December 31,</u>	
2006	\$479
2007	432
2008	432
2009	432
2010	432

On January 19, 2006, United Therapeutics' management determined to discontinue the sales, marketing and production of its HeartBar line of products, which are arginine-enriched dietary supplements. This discontinuance was effective immediately. The decision to discontinue HeartBar is not meant to impact other aspects of United Therapeutics' arginine line of business, which include sales of non-HeartBar arginine products and license royalties from third parties selling arginine based products.

In connection with this discontinuance, on January 19, 2006, United Therapeutics' management concluded that it will recognize non-cash impairment charges totalling approximately \$2.0 million from the write-off of the HeartBar trademarks. These impairment charges will be recorded in the quarter ending March 31, 2006. The other intangible assets related to the arginine line of business, primarily patents, are not affected by this discontinuance of HeartBar.

***Investments in Affiliates***

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

The investment in ViRexx is being accounted for as an available-for-sale security as ViRexx is a publicly traded company. Available-for-sale securities are reported at their fair values in the balance sheet. Changes in their fair values are reported as other comprehensive income or loss. Declines in values that are considered other-than-temporary are reported as losses in the statement of operations. United Therapeutics owns approximately 8.6 percent of ViRexx.

**UNITED THERAPEUTICS CORPORATION**  
**Notes to Consolidated Financial Statements (Continued)**

At December 31, 2005 and 2004, the investment in ViRexx's common stock was reported at its fair market value of approximately \$6.2 million and \$4.6 million, respectively, and is classified with investments in affiliates. The unrealized gain at December 31, 2005 and 2004 was approximately \$3.7 million and \$2.6 million, respectively.

***Fair Value of Financial Instruments***

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

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

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

	<b>Years ended December 31,</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
Net income (loss) (Numerator)	\$ 65,016	\$ 15,449	\$ (9,969)
Shares (Denominator):			
Weighted average outstanding shares for basic EPS	22,825	21,726	21,135
Dilutive effect of stock options	2,381	1,625	—
Adjusted weighted average shares for diluted EPS	<u>25,206</u>	<u>23,351</u>	<u>21,135</u>
Earnings (loss) per share			
Basic	\$ <u>2.85</u>	\$ <u>0.71</u>	\$ <u>(0.47)</u>
Diluted	\$ <u>2.58</u>	\$ <u>0.66</u>	\$ <u>(0.47)</u>

***Use of Estimates***

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

**UNITED THERAPEUTICS CORPORATION**  
**Notes to Consolidated Financial Statements (Continued)**

**Stock Option Plan**

United Therapeutics accounts for its stock-based compensation under the intrinsic value method in accordance with the provisions of Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, and has provided the pro forma disclosures of net income and net income 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 EITF 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 income and net income per share if United Therapeutics had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation is as follows (in thousands, except per share amounts):

	Years ended December 31,		
	2005	2004	2003
Net income (loss), as reported	\$ 65,016	\$ 15,449	\$ (9,969)
Less total stock-based employee compensation expense determined under fair value based method for all awards	(23,097)	(8,072)	(12,964)
Pro forma net income (loss)	<u>\$ 41,919</u>	<u>\$ 7,377</u>	<u>\$ (22,933)</u>
Basic net income (loss) per common share:			
As reported	<u>\$ 2.85</u>	<u>\$ 0.71</u>	<u>\$ (0.47)</u>
Pro forma	<u>\$ 1.84</u>	<u>\$ 0.34</u>	<u>\$ (1.09)</u>
Diluted net income (loss) per common share:			
As reported	<u>\$ 2.58</u>	<u>\$ 0.66</u>	<u>\$ (0.47)</u>
Pro forma	<u>\$ 1.66</u>	<u>\$ 0.32</u>	<u>\$ (1.09)</u>

The effect of applying SFAS No. 123 on 2005, 2004 and 2003 pro forma net income (loss) and net income (loss) per share as stated above, is not necessarily representative of the effects on reported net income (loss) for future years due to, among other things, the vesting period of the stock options and the fair value of additional stock options that may be granted in future years.

As discussed in Note 17, The Financial Accounting Standards Board has issued a revision to SFAS No. 123 (SFAS 123(R)).

**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,

**UNITED THERAPEUTICS CORPORATION**  
**Notes to Consolidated Financial Statements (Continued)**

*Reporting Revenue Gross as a Principal versus Net as an Agent* . Title to these products passes upon delivery. Prompt payment discounts and government rebates are estimated and recognized as reductions of revenue in the same period that revenues are recognized. Return policies provide that product that has expired or become damaged in shipment may be replaced, but not returned.

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

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

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

License fees, derived from an agreement with a third party, are recognized when received. The agreement provides the third party with a one-year exclusivity period in which to perform due diligence with respect to certain property rights controlled by United Therapeutics. During this period, the third party may terminate the agreement at any time and subsequent installments would no longer be due. United Therapeutics has no substantial performance obligations during the period of the agreement except to agree not to license the rights to other parties. In January 2006, the third party terminated the agreement.

***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.

***Other Receivables***

Other receivables consists primarily of recoverable import duties on shipments of Remodulin to other countries and construction costs that will be reimbursed by Wachovia as discussed in Note 9.

***Treasury Stock***

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

***Employee Health Insurance***

On July 1, 2003, United Therapeutics became self-insured for health insurance claims up to \$60,000 annually per individual and an annual aggregate amount which approximated \$1.6 million at December 31, 2005. United Therapeutics maintains a commercial insurance policy for claims liabilities exceeding these limits. Liabilities of approximately \$638,000 and \$591,000 at December 31, 2005 and 2004, respectively, have been established for known claims and an estimated amount for claims incurred but not yet reported. These amounts are reported as accrued expenses in the accompanying consolidated balance sheets.

***Advertising Costs***

Advertising costs are expensed when incurred. Advertising costs expensed during the years ended December 31, 2005, 2004 and 2003 were approximately \$31,000, \$174,000, and \$526,000, respectively.

**UNITED THERAPEUTICS CORPORATION**  
**Notes to Consolidated Financial Statements (Continued)**

***Reclassifications***

Certain amounts in the 2004 consolidated financial statements were reclassified to conform to the 2005 presentation.

**3. Related Party Transactions**

***Receivable from Employees***

At December 31, 2005 and 2004, United Therapeutics had approximately \$26,000 and \$446,000, respectively, in interest and non-interest bearing advances due from employees. The advances are classified as notes receivable from affiliate and employee in the accompanying consolidated balance sheets.

In April 2002, United Therapeutics agreed to loan \$1.3 million to Dr. Roger Jeffs, its President and Chief Operating Officer, to purchase his primary residence, the principal and interest of which were fully repaid in May 2005. The loan and accrued interest were due at the end of five years or earlier, in part or in full, if Dr. Jeffs obtained a mortgage on the property, exercised and sold any United Therapeutics stock options, sold any United Therapeutics stock, or sold the property. Interest of 6.5 percent per year accrued on the note. The loan was secured by the property and all United Therapeutics stock that Dr. Jeffs owned or later acquired. The Audit Committee and the Compensation Committee of the Board of Directors, as well as the full Board of Directors, approved this transaction. In June 2002, Dr. Jeffs was elected to the Board of Directors by United Therapeutics' shareholders. During the years ended December 31, 2005 and 2004, Dr. Jeffs paid approximately \$451,000 and \$749,000 of outstanding interest and principal on the note, respectively. At December 31, 2005 and 2004, the amount due from Dr. Jeffs was none and approximately \$445,000, respectively. The note receivable and accrued interest are classified as noncurrent assets in the accompanying balance sheets.

***Marketing and Consulting Agreements***

In February 2003, United Therapeutics entered into an agreement for the development, hosting and maintenance of its website [www.Remodulin.com](http://www.Remodulin.com) with The Medical Learning Company, Inc., a company controlled by Raymond Kurzweil, who is one of three non-independent directors on United Therapeutics' eight-person Board of Directors. The Medical Learning Company, Inc., is a joint venture with the American Board of Family Practice, the second largest medical specialty board in the United States, and has extensive experience in the design, development and maintenance of Internet-based information resources for physicians. Pursuant to this Agreement, United Therapeutics paid The Medical Learning Company an initial payment of \$29,000 and agreed to pay a continuing payment of \$2,000 per month for posting new information to and maintenance of the website. In May 2005, this agreement was terminated. In 2005, 2004 and 2003, United Therapeutics incurred approximately \$16,000, \$22,000 and \$29,000, respectively under this agreement.

In September 2002, United Therapeutics entered into a technical services agreement with Kurzweil Technologies, Inc. (KTI), a company controlled by Raymond Kurzweil. Pursuant to this agreement, United Therapeutics will pay KTI \$40,000 monthly for consulting fees, additional sums for preapproved patent work, and up to \$1,000 monthly for reimbursement of expenses for certain telemedicine technology development services. In addition, United Therapeutics will pay KTI a five percent royalty on certain sales of products reasonably attributed to and dependent upon technology developed by KTI under the technical services agreement and which are covered by claims of an issued and unexpired United States patent(s). The agreement may be terminated by United Therapeutics upon 30 days advance notice to KTI.



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**Notes to Consolidated Financial Statements (Continued)**

and by KTI upon 180 days advance notice to United Therapeutics. During the years ended December 31, 2005, 2004 and 2003 United Therapeutics incurred approximately \$541,000, and \$520,000 and \$484,000, respectively, of fees and expenses related to this agreement, of which approximately \$134,000 and \$30,000 were payable to KTI at December 31, 2005 and 2004, respectively.

United Therapeutics entered into an agreement in 2002 with Raymond Kurzweil to provide strategic consulting services in the field of telemedicine. The value of the agreement is \$10,000 annually. In 2002, United Therapeutics entered into an agreement with a company affiliated with Raymond Kurzweil with a total value of \$15,000. United Therapeutics paid a total of \$15,000, \$15,000 and \$30,000 under these agreements during the years ended December 31, 2005, 2004 and 2003, 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<sup>®</sup>) for the treatment of pulmonary hypertension and congestive heart failure. Glaxo Wellcome has a right to negotiate a license from United Therapeutics if United Therapeutics decides to license any part of the marketing rights to a third party. Glaxo Wellcome waived this right with respect to the agreement with MiniMed described below. Under the agreement, Glaxo Wellcome is entitled to certain royalties on sales exceeding a specified threshold from United Therapeutics for a period of ten years from the date of the first commercial sale of any product containing Remodulin. If United Therapeutics grants to a third party any license to Remodulin, Glaxo Wellcome is also entitled to a percentage of all consideration payable to United Therapeutics by such licensee. United Therapeutics is responsible for all patent prosecution and maintenance for Remodulin.

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

In December 1996, the Pharmacia & Upjohn Company (now Pfizer, Inc.) exclusively licensed to United Therapeutics patents and a patent application for the composition and production of a prostacyclin analog. The Pharmacia agreement required milestone payments of up to \$325,000 for orphan indications of a prostacyclin analog manufactured utilizing technology licensed from Pharmacia and royalties between 2.5 percent (in the United States) and 5 percent (in certain other countries) of all net sales, subject to certain offsets, until the later of the expiration of the applicable patent or ten years after the date of the first commercial sale of a product in a country defined as a milestone country under the agreement. In October 2002, United Therapeutics and Pharmacia amended the license agreement to change the royalties to Pharmacia to 4 percent on annual net sales of Remodulin in excess of \$25.0 million. This 4 percent royalty is subject to a 50 percent 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 Medtronic MiniMed (MiniMed) in September 1997 to collaborate in the design, development, and implementation of therapies to treat pulmonary hypertension and peripheral vascular disease utilizing MiniMed products with subcutaneous Remodulin. The term of the agreement is for seven years following the May 2002 FDA approval for

**UNITED THERAPEUTICS CORPORATION**  
**Notes to Consolidated Financial Statements (Continued)**

Remodulin and will be automatically extended for additional 12-month periods unless otherwise terminated. The agreement is subject to early termination in the event of a material breach or bankruptcy of either party. The guidelines implementing the agreement provide that United Therapeutics will purchase subcutaneous infusion pumps and supplies from MiniMed at a discount off of MiniMed's list prices from time to time. In the event that there are any discoveries or improvements arising out of work performed under the agreement, the parties will have joint ownership of those discoveries or improvements. The guidelines require United Therapeutics and its distributors to purchase its subcutaneous Remodulin infusion pumps exclusively from MiniMed unless 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. United Therapeutics also agreed to pay Toray milestone payments of up to \$750,000.

***Synergy Pharmaceuticals, Inc.***

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

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

**UNITED THERAPEUTICS CORPORATION**  
**Notes to Consolidated Financial Statements (Continued)**

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

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

***ViRexx Medical Corp.***

In April 2002, UPI acquired an option to develop and commercialize a platform of five immunotherapeutic monoclonal antibodies from AltaRex Corp. (now known as AltaRex Medical Corp. and currently a wholly owned subsidiary of ViRexx Medical Corp.) through an agreement to exclusively license certain intellectual property from AltaRex. These products were being developed by AltaRex for use in ovarian, prostate, lung, breast, multiple myeloma and other forms of cancer. UPI will bear the cost of the necessary research and development and has full commercialization rights in all countries other than those in Europe and most of the Middle East. UPI has agreed to pay AltaRex and one of its licensors certain amounts based upon the achievement of specified milestones together with royalties based upon sales of products utilizing or incorporating the licensed technology.

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

As part of the April 2002 transactions, UPI acquired approximately 9.95 percent of the outstanding stock of AltaRex for \$2.5 million and an additional approximately 9.95 percent of the outstanding stock of AltaRex in August 2002 for approximately \$2.1 million. On December 13, 2004, AltaRex was acquired by ViRexx Medical Corp. in an all stock transaction which resulted in AltaRex operating as a wholly owned subsidiary of ViRexx. For every two shares of AltaRex stock, one share of ViRexx stock was received. UPI's ownership in ViRexx at December 31, 2005 and its ownership in AltaRex at December 31, 2004 was approximately 8.6 percent and 8.6 percent, respectively. This investment is being accounted for as an available-for-sale security and is classified with investments in affiliates in the accompanying balance sheets.

In August 2002, UPI loaned approximately \$433,000 to AltaRex (now ViRexx). The related note receivable was a secured debenture due in August 2005 with interest of six percent due quarterly and was convertible into common stock. In October 2005, ViRexx and UPI agreed to convert the note into 485,300 shares of ViRexx common stock, which were valued at approximately \$433,000 based on quoted market prices as of the maturity date in August 2005. At December 31, 2005, the closing price of ViRexx' common stock was approximately \$1.23 per share. At December 31, 2004, the closing price of AltaRex' common stock was approximately \$1.01 per share.

**UNITED THERAPEUTICS CORPORATION**  
**Notes to Consolidated Financial Statements (Continued)**

***Third-Party License***

In March 2005, United Therapeutics entered into an agreement providing a third party with a one-year exclusivity period in which to perform due diligence with respect to certain glycobiology intellectual property rights controlled by United Therapeutics, in exchange for approximately \$325,000. The fee was payable in installments over the one-year period. Amounts paid to United Therapeutics by the licensee during the twelve months ended December 31, 2005 are nonrefundable and were recognized as revenues in the periods in which they were received. At any time during the one-year period, the third party had the right to enter into negotiations with United Therapeutics to acquire an exclusive license to commercialize products under such intellectual property rights for a field of use outside of United Therapeutics' core therapeutic areas. In January 2006, the third party terminated the agreement.

**5. Commitments**

***Oxford University***

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

***Milestone and Royalty Payments***

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

Total milestone payments under these license agreements are expected based on estimates of the timing and success of the development and commercialization of products covered by these agreements to come due approximately as follows (in thousands):

<u>Years ending December 31,</u>	
2006	\$ 20
2007	1,420
2008	3,020
2009	1,745
2010 and thereafter	3,560

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 12.0 percent of net product revenues as defined in the respective agreements.

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**Notes to Consolidated Financial Statements (Continued)**

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

Financial instruments, which potentially subject United Therapeutics to credit risk, consist primarily of cash, money market funds, commercial paper, marketable investments, and trade receivables. United Therapeutics maintains its cash and money market funds with major financial institutions. The amounts deposited with these institutions exceed the Federal Deposit Insurance Corporation insurance limits. United Therapeutics has not experienced any losses on such bank accounts. United Therapeutics' commercial paper and marketable investments have been issued by state and local government agencies with high credit ratings and by federally sponsored agencies.

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

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

During the year ended December 31, 2005, Remodulin drug sales accounted for approximately 94 percent of total revenues. Upon FDA approval in 2002, United Therapeutics was required by the FDA to perform a post-marketing Phase IV clinical study to confirm the clinical benefits of Remodulin. Continued FDA approval of Remodulin is subject to the diligent and timely completion of the Phase IV trial, as well as its outcome.

The 39-patient Phase IV clinical trial was required to have been one-half enrolled by June 2004 and to have been fully enrolled by June 2005, with a final study report due December 2005. These enrollment deadlines were not met, and a final study report was not submitted in December 2005.

Although the Phase IV clinical trial established deadlines and required a final report by December 2005. The FDA permitted an interim assessment and opportunity to terminate the Phase IV study after only 21 patients completed the study. In July 2005, the first 21 patients completed the study and United Therapeutics chose to perform the interim assessment. The results of the interim assessment from these first 21 patients, as analyzed by an independent statistician were positive ( $p=0.0006$ ). Specifically, 13 of 14 patients (93%) in the Remodulin arm were able to successfully transition from Flolan<sup>®</sup> and complete the study without the need to institute rescue therapy, compared to only 1 of 7 patients (14%) in the placebo arm. Based on this positive outcome, United Therapeutics has submitted the interim study results to the FDA and has requested permission to end the Phase IV clinical study in satisfaction of its Phase IV commitments. By agreement with the FDA, enrollment in the Phase IV clinical study was suspended pending FDA review and acceptance of the interim study results.

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**Notes to Consolidated Financial Statements (Continued)**

If the FDA does not accept the interim study results or does not otherwise agree with United Therapeutics' assessment of the interim results, the FDA could, among other things, grant an extension of time to continue to enroll the trial, or institute a public hearing to withdraw marketing approval for Remodulin. If a withdrawal hearing were instituted by the FDA, United Therapeutics would pursue the opportunity to participate in the hearing, as it believes that it has exercised good faith due diligence in pursuing enrollment of this trial.

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

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

In 2005, 2004 and 2003, approximately 90 percent, 87 percent and 92 percent of United Therapeutics' revenues were earned from customers located in the United States. Foreign revenues were derived from several countries mainly located in Europe. All of United Therapeutics' long-lived assets are located in the United States. At December 31, 2005 and 2004, trade receivables are due primarily from two customers in the pharmaceutical segment.

United Therapeutics earned over 90 percent of its consolidated revenues from two customers in the pharmaceutical segment. Gross revenues from such customers totaled as follows (in thousands):

	Years Ended December 31,		
	2005	2004	2003
Accredo Therapeutics	\$ 75,317	\$ 41,777	\$ 23,887
CuraScripts	\$ 24,008	\$ 17,696	\$ 17,606

## **7. Stockholders' Equity**

### ***Common Stock***

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

### ***Preferred Stock***

A total of 10,000,000 shares of preferred stock with a par value of \$0.01 were authorized in 1997. No preferred stock has been issued.

### ***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

**UNITED THERAPEUTICS CORPORATION**  
**Notes to Consolidated Financial Statements (Continued)**

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 2005, 2004 and 2003. 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>Weighted Average Grant Price</b>
For the years ended December 31,		
2005	31,417	\$ 48.02
2004	14,334	\$ 29.77
2003	21,001	\$ 19.03

***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>Weighted Average Grant Price</b>
For the years ended December 31,		
2005	2,564,303	\$ 55.35
2004	654,692	\$ 34.82
2003	552,816	\$ 20.58

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**Notes to Consolidated Financial Statements (Continued)**

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

Non-Plan options were awarded as follows:

	<b>Number of Options Granted</b>	<b>Weighted Average Grant Price</b>
During the years ended December 31,		
2005	—	—
2004	17,500	\$ 23.89
2003	212,420	\$ 21.72

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 2005, 2004 and 2003:

	<b>Years ended December 31,</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
Dividend yield	0 percent	0 percent	0 percent
Expected volatility	43.56 percent	63.68 percent	73.00 percent
Risk free interest rate	3.69 percent	3.16 percent	2.14 percent
Expected lives	2.40 years	3.77 years	3.75 years

A summary of the status of United Therapeutics' employee stock options as of December 31, 2005, 2004 and 2003, and changes during the years then ended is presented below:

	<b>2005</b>		<b>2004</b>		<b>2003</b>	
		<b>Weighted- Average Exercise</b>		<b>Weighted- Average Exercise</b>		<b>Weighted- Average Exercise</b>
	<b>Shares</b>		<b>Shares</b>		<b>Shares</b>	
Outstanding at beginning of period	3,717,368	\$ 21.54	4,313,222	\$ 26.81	4,032,871	\$ 26.13
Granted	2,564,303	55.35	672,192	34.53	765,236	20.90
Exercised	(831,640)	17.02	(485,687)	13.42	(388,616)	10.60
Forfeited	(51,172)	35.33	(50,427)	18.79	(95,335)	17.08
Canceled	—	—	(731,932)	66.79	(934)	3.00
Outstanding at end of period	<u>5,398,859</u>	<u>\$ 38.16</u>	<u>3,717,368</u>	<u>\$ 21.54</u>	<u>4,313,222</u>	<u>\$ 26.81</u>
Options exercisable at end of period	<u>3,476,850</u>	<u>\$ 31.74</u>	<u>2,445,493</u>	<u>\$ 18.68</u>	<u>3,033,647</u>	<u>\$ 30.09</u>
Weighted-average fair value of options granted during the period	<u>\$ 15.92</u>		<u>\$ 17.12</u>		<u>\$ 10.83</u>	



**UNITED THERAPEUTICS CORPORATION**  
**Notes to Consolidated Financial Statements (Continued)**

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

The following table summarizes information about employee stock options outstanding at December 31, 2005:

<u>Exercise Prices</u>	<u>Options Outstanding</u>			<u>Options Exercisable</u>	
	<u>Number</u>	<u>Weighted-Average Remaining Contractual Life</u>	<u>Weighted-Average Exercise Price</u>	<u>Number</u>	<u>Weighted-Average Exercise Price</u>
\$ 3.00 – \$ 10.00	28,712	5.5	\$ 9.29	25,337	\$ 9.27
10.01 – 20.00	1,468,413	5.3	15.29	1,371,838	15.28
20.01 – 30.00	894,350	7.3	23.43	599,826	23.85
30.01 – 40.00	8,750	6.0	33.91	8,750	33.91
40.01 – 50.00	1,937,605	7.6	45.26	1,062,136	43.61
50.01 – 60.00	38,628	7.0	55.45	18,628	56.96
60.01 – 70.00	389,507	10.0	69.11	370,507	69.08
70.01 – 80.00	622,568	9.9	71.31	9,502	71.74
80.01 – 90.00	7,126	4.5	84.81	7,126	84.81
90.01 – 116.38	3,200	4.2	99.68	3,200	99.68
<u>\$ 3.00 – \$116.38</u>	<u>5,398,859</u>	<u>7.3</u>	<u>\$ 38.16</u>	<u>3,476,850</u>	<u>\$ 31.74</u>

During the year ended December 31, 2005, 2004 and 2003, options to purchase a total of 831,640, 485,687 and 388,616 shares of common stock were exercised. The proceeds from these exercises totaled approximately \$15.0 million, \$6.5 million and \$4.1 million.

**UNITED THERAPEUTICS CORPORATION**  
**Notes to Consolidated Financial Statements (Continued)**

**8. Income Taxes**

Significant components of the provision for (benefit from) income taxes attributable to operations consist of the following (in thousands):

	<b>Year Ended December 31,</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
<b>Current:</b>			
Federal	\$ —	\$ —	\$ —
State	953	—	—
Total current	953	—	—
<b>Deferred</b>			
Federal	(18,706 )	—	—
State	259	—	—
Total deferred	(18,447 )	—	—
Total provision for (benefit from) income taxes	<u>\$ (17,494)</u>	<u>\$ —</u>	<u>\$ —</u>

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

	<b>Years Ended December 31,</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
Federal tax provision (benefit) computed at 35% in 2005 and 34% in 2004 and 2003	\$ 16,804	\$ 5,197	\$ (3,567)
State tax provision (benefit), net of federal tax provision (benefit)	1,212	807	(554 )
Change in the valuation allowance for deferred tax assets allocated to tax expenses	(36,934 )	(6,858 )	3,524
Nondeductible expenses	1,424	854	597
Total income tax expense (benefit)	<u>\$ (17,494)</u>	<u>\$ —</u>	<u>\$ —</u>

As of December 31, 2005, United Therapeutics had generated three years of cumulative profits. As a result of this positive earnings trend and projected future taxable income for fiscal year 2006, United Therapeutics reversed a portion of its valuation allowance. United Therapeutics recognized an income tax benefit of approximately \$17.5 million for the year ended December 31, 2005, primarily due to the recording of a reduction in the deferred tax asset valuation allowance of approximately \$19.7 million representing the anticipated utilization of a portion of its deferred tax assets in subsequent years offset by federal alternative minimum tax expense and state income taxes.

**UNITED THERAPEUTICS CORPORATION**  
**Notes to Consolidated Financial Statements (Continued)**

Deferred tax assets reflect the net effect of net operating loss carryforwards and the temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of United Therapeutics' net deferred tax asset as of December 31, 2005 and 2004, respectively, are approximately as follows (in thousands):

	<b>December 31,</b>	
	<b>2005</b>	<b>2004</b>
Deferred tax assets:		
Net operating loss carryforwards	\$ 34,526	\$ 43,165
General business credits	30,819	26,971
Impairment losses on investments	3,069	3,260
Realized losses on marketable investments	2,518	2,675
License fees capitalized for tax purposes	6,091	7,214
In-process research and development capitalized for tax purposes	3,721	4,859
Other	3,917	3,094
Total deferred tax assets	84,661	91,238
Deferred tax liabilities:		
Furniture and equipment principally due to differences in depreciation	(401 )	(334 )
Total deferred tax liabilities	(401 )	(334 )
Net deferred tax asset before valuation allowance	84,260	90,904
Valuation allowance	(64,549 )	(90,904 )
Net deferred tax asset	<u>\$ 19,711</u>	<u>\$ —</u>

In assessing the valuation allowance on its net deferred tax asset, United Therapeutics considers whether it is more likely than not that some portion or all of its net deferred tax assets are realizable. Based on a review of both historical and projected taxable income, United Therapeutics has concluded that it is more likely than not that some portion of its deferred tax assets will be utilized in subsequent years and that a reduction in the deferred tax asset valuation allowance was necessary. The components of the \$19.7 million reduction in the valuation allowance, net of current year activity, related to the anticipated utilization of its net operating loss carryforwards of approximately \$17.0 million, business credits of approximately \$1.7 million and amortization of tax intangible assets of approximately \$1.0 million. Approximately \$1.0 million of the reduction in the valuation allowance is attributable to exercised stock options, the benefit of which directly increased additional paid-in-capital.

The realization of deferred tax assets is contingent upon the generation of future taxable income. Due to the uncertainty of the amounts of future taxable income which impacts the realization of these tax benefits, United Therapeutics did not reverse the portion of the valuation allowance for the net operating loss carryforwards related to the exercise of stock options and the research and development credits and the amount of net operating loss carryforwards expected to expire unused.

Prior to the year ending December 31, 2004, United Therapeutics had experienced significant operating losses and operated in an industry subject to rapid technological change. Therefore, United Therapeutics believed that there was sufficient uncertainty regarding its ability to generate future taxable income and use its net operating loss and tax credit carryforwards that a full valuation allowance for deferred tax assets was required for the year ended December 31, 2004. Substantially all of the remaining deferred tax asset valuation allowance associated with the net operating loss carryforwards at December 31, 2005, if released, will be reflected as a direct increase to stockholders' equity.

**UNITED THERAPEUTICS CORPORATION**  
**Notes to Consolidated Financial Statements (Continued)**

United Therapeutics reviews its deferred tax assets on a quarterly basis to determine if a valuation allowance is required, primarily based on its estimates of future taxable income. Changes in the valuation allowance based on the assessment could result in the period of change in the recording of tax expense if the valuation allowance is increased or the recording of either a tax benefit or an increase to additional paid-in-capital if the valuation allowance is decreased.

At December 31, 2005, United Therapeutics had for federal income tax purposes net operating loss carryforwards of approximately \$98.3 million and business tax credit carryforwards of approximately \$30.8 million which expire at various dates from 2012 through 2024. Approximately, \$50.0 million of the net operating loss carryforwards is attributable to exercised stock options, the benefit of which, when realized, directly increases additional paid-in-capital. Business tax credits can offset future tax liabilities and arise from qualified research expenditures. United Therapeutics has been and may continue to be subject to federal alternative minimum tax and state income taxes, even though it has significant net operating loss and credit carryforwards.

Section 382 of the Internal Revenue Code limits the utilization of net operating losses when ownership changes occur as defined by that section. United Therapeutics has reviewed its ownership change positions pursuant to Section 382 and has determined that ownership changes occurred in December 1997, June 1999, and November 2004 and, as a result, the utilization of certain of its net operating loss carryforwards may be limited. However, the Company does not expect any significant portion of its net operating loss carry forwards or business tax credits will expire unused.

## **9. Notes and Leases Payable**

### ***Notes Payable***

In January 2003, United Therapeutics purchased a building and land adjacent to its Silver Spring, Maryland headquarters. United Therapeutics paid approximately \$171,000 in cash and issued a non-interest bearing note payable for \$1.0 million due to the seller in January 2004. The note payable was recorded at its present value using an imputed interest rate of approximately 2.6 percent, 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 was paid in January 2004.

### ***Laboratory Operating Lease***

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

Upon completion of the construction, Wachovia will receive rents from United Therapeutics generally based on applying the 30-day LIBOR rate plus approximately 55 basis points to the amount funded by

**UNITED THERAPEUTICS CORPORATION**  
**Notes to Consolidated Financial Statements (Continued)**

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

In addition, United Therapeutics agreed to pledge, as collateral, a portion of its marketable investments to secure its lease obligations. At December 31, 2005, approximately \$20.7 million of marketable investments and cash were pledged as collateral and are reported as restricted marketable investments and cash in the consolidated balance sheets.

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

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

If, at the end of the lease term, United Therapeutics does not renew the lease or purchase the improvements, then the facility will be sold to a third party. In that event, United Therapeutics has guaranteed that Wachovia will receive a guaranteed minimum residual value for the laboratory facility. This guaranteed residual is generally equal to 86 percent of the amount funded by Wachovia towards construction. The maximum potential amount of this guarantee is approximately \$27.5 million, equivalent to 86 percent of expected total construction costs of \$32.0 million.

FASB Interpretation No. (FIN) 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*, requires that the fair value of the residual value guarantee be reported as a liability in United Therapeutics' consolidated balance sheet, regardless of whether an event triggering the payment of the guarantee has occurred. In accordance with FIN 45, United Therapeutics has reported this guarantee as a non-current asset (prepaid rent) and non-current liability (other liability). The prepaid rent and guarantee liability will be amortized in a straight-line manner over the term of the lease. The value of the guarantee reported in the balance sheet was approximately \$839,000. At December 31, 2005, approximately \$16.1 million towards the laboratory's development had been incurred and funded by Wachovia.

United Therapeutics has concluded that it is not required to consolidate Wachovia pursuant to FIN 46, *Consolidation of Variable Interest Entities* as United Therapeutics does not have a controlling financial interest in Wachovia. In accordance with the guidance in SFAS No. 13, *Accounting for Leases*, EITF No. 97-1, *Implementation Issues in Accounting for Lease Transactions, Including Those Involving Special-Purpose Entities*, EITF No. 97-10, *The Effect of Lessee Involvement in Asset Construction*, and FIN 46,

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**Notes to Consolidated Financial Statements (Continued)**

United Therapeutics has determined that the lease is properly classified as an operating lease for accounting purposes.

In March 2005, United Therapeutics entered into a construction management agreement with Turner Construction Company (Turner), under which Turner will be responsible for managing the construction of the new laboratory facility in Silver Spring, Maryland. The agreement has a guaranteed maximum price clause in which Turner has agreed that the construction cost of the facility will not exceed approximately \$27.0 million, which amount is subject to change based on agreed-upon changes to the scope of work. Turner will be responsible for covering any costs in excess of the guaranteed maximum price. If the ultimate cost of the project is less than the guaranteed maximum price of \$27.0 million, then a portion of the costs savings will be shared with Turner. In addition, Turner must pay penalties to United Therapeutics if the construction is not completed by April 2006, which date is subject to change based on agreed-upon changes to the scope of work. Construction costs to be incurred under this agreement will be reimbursed to United Therapeutics by Wachovia Development Corporation in accordance with the synthetic operating lease and related agreements.

***Capital Leases***

United Therapeutics also leased certain equipment under capital leases with interest rates of approximately 4.2 percent and terms up to 5 years.

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

<u>Years ending December 31,</u>	<u>Capital Leases</u>
2006	\$ 15
2007	6
2008	2
2009	—
2010	—
2011 and thereafter	—
	<u>23</u>
Less amounts representing interest	(2)
Less current portion	<u>(15)</u>
	<u>\$ 6</u>

At December 31, 2005 and 2004, the carrying value of equipment under capital leases was approximately \$91,000 and \$75,000, respectively, and accumulated depreciation was approximately \$70,000 and \$54,500, respectively. Amortization of equipment under capital leases is included within depreciation expense.

***Other Operating Leases***

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

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**Notes to Consolidated Financial Statements (Continued)**

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

<u>Years ending December 31,</u>	
2006	\$ 2,685
2007	2,802
2008	2,415
2009	2,300
2010	1,931

These minimum annual rent payments shown above include estimated amounts for the synthetic operating lease described above and are based on LIBOR rates in effect at December 31, 2005. Total rent expense was approximately \$1.4 million for each of the years ended December 31, 2005, 2004, and 2003.

**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, 2005, 2004 and 2003 (in thousands):

	<u>Years ended December 31,</u>		
	<u>2005</u>	<u>2004</u>	<u>2003</u>
Net income (loss)	\$ 65,016	\$ 15,449	\$ (9,969)
Other comprehensive income:			
Foreign currency translation adjustments	(220 )	48	13
Unrealized gain on available-for-sale securities	1,136	955	1,653
Comprehensive income (loss)	<u>\$ 65,932</u>	<u>\$ 16,452</u>	<u>\$ (8,303)</u>

**11. Marketable Investments**

***Held-to-maturity investments***

At December 31, 2005 and 2004, a portion of United Therapeutics' investments consisted of federally-sponsored debt securities that are classified as held-to-maturity investments. The market value of these investments fluctuates with changes in current market interest rates. In general, as rates increase, the market value of a debt investment would be expected to decrease. Likewise, as rates decrease, the market value of a debt investment would be expected to increase. To minimize such market risk, United Therapeutics holds such instruments to maturity at which time these instruments will be redeemed at their stated or face value. The amortized cost approximates fair value of these investments at December 31, 2005 and 2004. Certain of these marketable investments have been pledged as collateral to Wachovia Development Corporation under the laboratory lease described in Note 9, and are classified as restricted marketable investments and cash on the consolidated balance sheet.

**UNITED THERAPEUTICS CORPORATION**  
**Notes to Consolidated Financial Statements (Continued)**

Held-to-maturity marketable investments were as follows (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Agency notes at December 31, 2005	\$ 72,788	\$ —	\$ (2,154)	\$ 70,634
Agency notes at December 31, 2004	\$ 56,192	\$ 2	\$ (891)	\$ 55,303

The unrealized losses at December 31, 2005 and 2004 on the federally-sponsored securities were caused by market interest rate fluctuations. As a result, United Therapeutics does not consider these investments to be other-than-temporarily impaired.

The following table summarizes maturities of United Therapeutics' held-to-maturity marketable investment securities at December 31, 2005 and 2004 (in thousands):

	December 31, 2005		December 31, 2004	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Less than one year	\$ 7,954	\$ 7,886	\$ —	\$ —
Due in one to two years	11,498	11,400	2,894	2,854
Due in three to five years	33,443	32,231	17,460	17,352
Due after five years	19,893	19,117	35,838	35,097
Total	\$ 72,788	\$ 70,634	\$ 56,192	\$ 55,303

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

	Years Ended December 31,		
	2005	2004	2003
Gross proceeds	\$ 200	\$ 30,000	\$ 6,000
Realized gains	\$ —	\$ —	\$ —
Realized losses	\$ —	\$ —	\$ —

***Available-for-sale investments***

At December 31, 2005, a portion of United Therapeutics' investments consisted of auction rate debt securities issued by state and local government sponsored agencies. While these securities have long term maturities, their interest rates are reset approximately every 7-28 days through an auction process. As a result, the interest income from these securities is subject to market risk since the rate is adjusted to accommodate market conditions on each reset date. However, since the interest rates are reflective of current market conditions, the fair value of these securities typically does not fluctuate from par or cost. These securities are classified as current assets in the consolidated balance sheets since United Therapeutics may sell the securities at its discretion on the auction day with penalty or loss of principal.



**UNITED THERAPEUTICS CORPORATION**  
**Notes to Consolidated Financial Statements (Continued)**

Available-for-sale investments were as follows (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Agency notes at December 31, 2005	\$ 48,350	\$ —	\$ —	\$ 48,350
Agency notes at December 31, 2004	\$ —	\$ —	\$ —	\$ —

The following table summarizes maturities of United Therapeutics' available-for-sale investment securities at December 31, 2005 and 2004 (in thousands):

	December 31, 2005		December 31, 2004	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Less than one year	\$ —	\$ —	\$ —	\$ —
Due in one to two years	—	—	—	—
Due in three to five years	—	—	—	—
Due after five years	48,350	48,350	—	—
Total	<u>\$ 48,350</u>	<u>\$ 48,350</u>	<u>\$ —</u>	<u>\$ —</u>

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

	Years Ended December 31,		
	2005	2004	2003
Gross proceeds	\$ 12,700	\$ —	\$ —
Realized gains	\$ —	\$ —	\$ —
Realized losses	\$ —	\$ —	\$ —

## 12. Acquisitions and Investments in Affiliates

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

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

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

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

**UNITED THERAPEUTICS CORPORATION**  
**Notes to Consolidated Financial Statements (Continued)**

***Northern Therapeutics, Inc.***

In December 2000, Lung Rx, Inc. formed a new company in Canada, Northern Therapeutics, Inc. (Northern Therapeutics), with the inventor of a new form of autologous (non-viral vector) gene therapy for pulmonary hypertension and other diseases. The purpose of Northern Therapeutics is to develop the gene therapy and also to distribute Remodulin and other United Therapeutics products in Canada. Lung Rx received approximately 59 percent of the initial outstanding common stock of Northern Therapeutics in exchange for \$5.0 million in cash. United Therapeutics agreed to provide the services of its Chief Executive Officer as Chairman of the Northern Therapeutics' Board. United Therapeutics' CEO served as the acting CEO of Northern Therapeutics until March 2005. 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 EITF 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, 2005, Lung Rx's investment in Northern Therapeutics was reported at approximately \$2.1 million, which is comprised of \$5.0 million paid in cash, net of Lung Rx's share of Northern Therapeutics' losses since its formation. Lung Rx's equity in the underlying net assets was approximately \$1.1 million at December 31, 2005. The difference between Lung Rx's investment in Northern Therapeutics and its equity in the underlying net assets is accounted for as goodwill.

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

	As of and for the years ended December 31,		
	2005	2004	2003
Total assets	\$ 1,883	\$ 2,874	\$ 3,660
Total liabilities	\$ 206	\$ 140	\$ 75
Net loss	\$ (1,102)	\$ (1,148)	\$ (1,394)

In February 2006, Northern Therapeutics agreed to grant a license to United Therapeutics to develop and commercialize the gene therapy in the United States. The license will require United Therapeutics to make payments to Northern Therapeutics upon achieving certain milestones totalling \$1.5 million in increments during and upon completion of the Phase I trial. After successful completion of the Phase I trial, United Therapeutics will assume the development program and related costs for the United States. As part of this agreement, United Therapeutics and Northern Therapeutics terminated the Remodulin distribution agreement for Canada. United Therapeutics now distributes Remodulin directly in Canada through its Canadian wholly-owned subsidiary, Unither Biotech Inc.

**UNITED THERAPEUTICS CORPORATION**  
**Notes to Consolidated Financial Statements (Continued)**

**13. Employees' Retirement Plan**

Effective January 1, 1999, United Therapeutics adopted the United Therapeutics Corporation Employees' Retirement Plan (the Plan), a salary reduction 401(k) Plan. Employees employed on or after July 15, 1999 are eligible to participate in the Plan. The Plan provides for annual discretionary employer contributions. Employees may also contribute to the Plan at their discretion subject to statutory limitations. Beginning January 1, 2004, United Therapeutics began matching qualifying employee contributions at a rate of 20 percent, subject to certain limitations. For the years ended December 31, 2005 and 2004, United Therapeutics contributed and expensed \$223,000 and \$207,000 respectively, to the plan as a result of this matching.

**14. Relocation Costs**

United Therapeutics is constructing a laboratory facility adjacent to its headquarters in Silver Spring, Maryland to replace its current laboratory in Chicago, Illinois. Certain Chicago-based employees will be relocated to the new facility beginning in 2006. It is anticipated that approximately \$1.0 million will be incurred in total during 2006 and 2007 in connection with relocating these employees. Costs associated with these transfers will be reported in the period in which the employees actually move and incur the relocation costs.

Additionally, United Therapeutics has agreed to pay bonuses to a small number of employees in Chicago to remain employed there until the laboratory closes in the middle of 2007. Such retention bonuses will be accrued ratably over the period from the date of agreement in October 2005 with the employees to the date of payment in 2007. As of December 31, 2005, approximately \$25,000 has been accrued for these bonuses and they are classified in selling, general and administrative expenses.

**15. Accrued Expenses**

Accrued expenses consisted of the following (in thousands):

	December 31,	
	2005	2004
Professional fees	\$ 64	\$ 126
Research	1,778	856
Payroll related	2,902	1,876
Royalties and rebates	4,148	3,565
Contracted services	382	564
Other	1,120	702
Total	<u>\$ 10,394</u>	<u>\$ 7,689</u>

**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, design, and delivery of patient monitoring services. The telemedicine segment is managed separately because diagnostic services require different technology and marketing strategies.

**UNITED THERAPEUTICS CORPORATION**  
**Notes to Consolidated Financial Statements (Continued)**

Segment information as of and for the year ended December 31, 2005 was as follows (in thousands):

	<u>Pharmaceutical</u>	<u>Telemedicine</u>	<u>Consolidated Totals</u>
Revenues from external customers	\$ 110,142	\$ 5,773	\$ 115,915
Net income (losses)	65,672	(656)	65,016
Interest income	5,344	15	5,359
Interest expense	(29)	—	(29)
Income tax benefit	17,494	—	17,494
Depreciation and amortization	(1,696)	(838)	(2,534)
Equity loss in affiliate	(754)	—	(754)
Total investments in equity method investees	2,059	—	2,059
Expenditures for long-lived assets	(5,294)	(823)	(6,117)
Goodwill, net	1,287	6,178	7,465
Total assets	281,613	9,800	291,413

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

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

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

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

**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**

*Stock-Based Compensation*

On December 16, 2004, the Financial Accounting Standards Board (FASB) issued FASB Statement No. 123 (revised 2004), *Share-Based Payment*, which is a revision of FASB Statement No. 123, *Accounting for Stock-Based Compensation*. Statement 123(R) supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and amends FASB Statement No. 95, *Statement of Cash Flows*. Generally, the approach in Statement 123(R) is similar to the approach described in Statement 123. However, Statement 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative.

A “modified prospective” method in which compensation cost is recognized beginning with the effective date (a) based on the requirements of Statement 123(R) for all share-based payments granted after the effective date and (b) based on the requirements of Statement 123 for all awards granted to employees prior to the effective date of Statement 123(R) that remain unvested on the effective date.

A “modified retrospective” method which includes the requirements of the modified prospective method described above, but also permits entities to restate, based on the amounts previously recognized under Statement 123 for purposes of pro forma disclosures, either (a) all prior periods presented or (b) prior interim periods of the year of adoption.

United Therapeutics plans to adopt Statement 123(R) using the “modified prospective” method.

Statement 123(R) originally required adoption no later than July 1, 2005. In April 2005, the Securities and Exchange Commission (“SEC”) issued a release that amends the compliance dates for Statement 123(R). Under the SEC’s new rule, United Therapeutics will be required to apply Statement 123(R) as of January 1, 2006. We expect to adopt Statement 123(R) on January 1, 2006.

The full impact of adoption of Statement 123(R) on the 2006 consolidated financial statements cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had United Therapeutics adopted Statement 123(R) in prior periods, the impact of that standard would have approximated the impact of Statement 123 as described in the disclosure of pro forma net income and earnings per share in Note 2 to the consolidated financial statements. Statement 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption. United Therapeutics is unable to estimate what those amounts will be in the future because they depend on, among other things, when employees exercise stock options.

**UNITED THERAPEUTICS CORPORATION**  
**Notes to Consolidated Financial Statements (Continued)**

*Inventory Costs*

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

**18. Quarterly Financial Information (Unaudited)**

The following presents certain quarterly financial information for each of the years ended December 31, 2005 and 2004 (in thousands, except per share amounts):

	<b>Quarters Ending During 2005</b>			
	<b>December 31,</b>	<b>September 30,</b>	<b>June 30,</b>	<b>March 31,</b>
	<b>2005</b>	<b>2005</b>	<b>2005</b>	<b>2005</b>
Net sales	\$ 29,641	\$ 33,010	\$ 30,057	\$ 23,207
Gross profit	26,488	29,578	26,882	20,652
Net income	29,410	15,763	12,182	7,661
Income per share—basic	\$ 1.27	\$ 0.69	\$ 0.54	\$ 0.34
Income per share—diluted	\$ 1.14	\$ 0.61	\$ 0.49	\$ 0.31

  

	<b>Quarters Ending During 2004</b>			
	<b>December 31,</b>	<b>September 30,</b>	<b>June 30,</b>	<b>March 31,</b>
	<b>2004</b>	<b>2004</b>	<b>2004</b>	<b>2004</b>
Net sales	\$ 21,613	\$ 19,995	\$ 18,299	\$ 13,683
Gross profit	19,361	17,835	16,256	11,888
Net income (loss)	6,890	6,266	4,140	(1,847 )
Income (loss) per share—basic	\$ 0.31	\$ 0.29	\$ 0.19	\$ (0.09)
Income (loss) per share—diluted	\$ 0.28	\$ 0.27	\$ 0.18	\$ (0.09)

**United Therapeutics Corporation**  
**Schedule II—Valuation and Qualifying Accounts**  
**Years Ended December 31, 2005, 2004, and 2003**  
(in thousands)

	<u>Allowance for Doubtful Accounts Receivable</u>			
	<u>Balance at Beginning of Year</u>	<u>Additions charged to expenses</u>	<u>Deductions</u>	<u>Balance at End of Year</u>
Year ended December 31, 2005	\$ 23	\$ 9	\$ (17)	\$ 15
Year ended December 31, 2004	\$ 119	\$ 24	\$ (120)	\$ 23
Year ended December 31, 2003	\$ 268	\$ 228	\$ (377)	\$ 119

	<u>Reserve for Inventory Obsolescence</u>			
	<u>Balance at Beginning of Year</u>	<u>Additions charged to expenses</u>	<u>Deductions</u>	<u>Balance at End of Year</u>
Year ended December 31, 2005	\$ 447	\$ 315	\$ (192)	\$ 570
Year ended December 31, 2004	\$ 321	\$ 316	\$ (190)	\$ 447
Year ended December 31, 2003	\$ 421	\$ 93	\$ (193)	\$ 321

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

None.

### **ITEM 9A. CONTROLS AND PROCEDURES**

#### ***Evaluation of Disclosure Controls and Procedures***

Our management, with participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as of December 31, 2005. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2005.

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

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

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2005 based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control—Integrated Framework*. Management's assessment included an evaluation of the design of our internal control over financial reporting and testing of the operational effectiveness of our internal control over financial reporting. Based on this assessment, our management concluded that, as of December 31, 2005, our internal control over financial reporting was effective.

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

#### ***Attestation of Independent Registered Public Accounting Firm***

The attestation report of our independent registered public accounting firm regarding internal control over financial reporting is set forth in Item 8 of this Annual Report on Form 10-K under the caption "Report of Independent Registered Public Accounting Firm" and incorporated herein by reference.

#### ***Changes in Internal Control over Financial Reporting***

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2005 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

### **ITEM 9B. OTHER INFORMATION**

None.



## 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 our definitive proxy statement for our 2006 annual shareholders meeting (the 2006 Proxy Statement) is hereby incorporated herein by this reference. Information regarding our executive officers appears in Part I, Item I of this Form 10-K under the heading *Executive Officers of the Registrant*. Information regarding the Audit Committee's financial expert appearing under *Board Meetings and Committees—Audit Committee* in the 2006 Proxy Statement is hereby incorporated herein by this reference.

Information appearing under *Section 16(a) Beneficial Ownership Reporting Compliance* in the 2006 Proxy Statement is hereby incorporated herein by this reference.

We have a written Code of Conduct and Ethics that applies to our principal executive officer, principal financial officer and our principal accounting officer and every other director, officer and employee of United Therapeutics. The Code of Conduct and Ethics is available on our 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 our corporate headquarters offices to the attention of Vice President, Investor Relations. If any amendment to, or a waiver from, a provision of the Code of Conduct and Ethics that applies to the principal executive officer, principal financial officer and principal accounting officer is made, such information will be posted on our 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 2006 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 our capital stock required by Item 12 appears under *Security Ownership of Certain Beneficial Owners and Management* in the 2006 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, 2005 regarding our 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	4,694,164	\$ 41.44	8,941,291
Equity compensation plans not approved by security holders	875,874	\$ 19.53	none
Total	<u>5,570,038</u>	<u>\$ 38.00</u>	<u>8,941,291</u>

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

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

Information concerning related party transactions required by Item 13 appears under *Certain Relationships and Related Transactions* in the 2006 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 2006 Proxy Statement and is hereby incorporated by reference.

**PART IV**

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

- (a) (1) Our financial statements 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:

<u>Exhibit No.</u>	<u>Description</u>
3.1	Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
3.2	Amended and Restated Bylaws of the Registrant, incorporated by reference to Exhibit 3.2 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
3.3	Certificate of Designations, Preferences and Rights of Series A Junior Participating Preferred Stock, incorporated by reference to Exhibit 4 to the Registrant's Current Report on Form 8-K, filed December 18, 2000.
4.1	Reference is made to Exhibits 3.1 and 3.2.
4.2	Form of Purchase Agreement dated as of December 22, 1999, incorporated by reference to Exhibit 4.6 of the Registrant's Registration Statement on form S-1 (Registration No. 333-93853).
4.3	Registration Rights Agreement, dated as of June 27, 2000 by and between the Registrant and Toray Industries, Inc., incorporated by reference to Exhibit 4.7 of the Registrant's Registration Statement on Form S-3 (Registration No. 333-40598).
4.4	Stock Option Grant issued on June 27, 2000 to Toray Industries, Inc., incorporated by reference to Exhibit 4.8 of the Registrant's Registration Statement on Form S-3 (Registration No. 333-40598).
4.5	Form of Stock Purchase Agreement dated July 13, 2000 incorporated by reference to Exhibit 99.2 of the Registrant's Current Report on Form 8-K filed July 14, 2000.
4.6	Rights Agreement, dated as of December 17, 2000 between Registrant and The Bank of New York, as Rights Agent, incorporated by reference to Exhibit 4 of Registrant's Form 8-K dated December 17, 2000.
10.1**	Amended and Restated Equity Incentive Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
10.2	Form of Scientific Advisor Compensation Agreement, incorporated by reference to Exhibit 10.2 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
10.3**	Executive Employment Agreement (as amended) dated as of April 2, 1999, between the Registrant and Martine A. Rothblatt, incorporated by reference to Exhibit 10.3 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
10.4**	Amendment dated December 21, 2000 to the Employment Agreement between the Registrant and Martine A. Rothblatt, which appears as Exhibit 10.5 to Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2002, which exhibit is incorporated herein by reference.
10.5**	Employment Agreement dated June 16, 2001 between the Registrant and Paul A. Mahon, which appears as Exhibit 10.4 to Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2002, which exhibit is incorporated herein by reference.

- 10.6\*\* Employment Agreement dated December 29, 2000 between the Registrant and Ricardo A. Balda, which appears as Exhibit 10.2 to Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2002, which exhibit is incorporated herein by reference.
- 10.7\* Exclusive License Agreement dated as of December 3, 1996, between the Registrant and an affiliate of Pharmacia & Upjohn Company, incorporated by reference to Exhibit 10.8 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
- 10.8\* Assignment Agreement dated as of January 31, 1997, between the Registrant and affiliates of Glaxo Wellcome Inc., incorporated by reference to Exhibit 10.9 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
- 10.9\* Cooperation and Strategic Alliance Agreement dated as of September 3, 1997, between Registrant and MiniMed Inc., incorporated by reference to Exhibit 10.10 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
- 10.10\* Exclusive License Agreement dated as of September 24, 1998, between the Registrant and Toray Industries, Inc., incorporated by reference to Exhibit 10.11 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
- 10.11\*\* Employment Agreement dated January 3, 2000 between the Registrant and Fred T. Hadeed, which appears as Exhibit 10.6 to Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2002, which exhibit is incorporated herein by reference.
- 10.12\*\* Amendment dated August 16, 2001 to the Employment Agreement between the Registrant and Fred T. Hadeed, which appears as Exhibit 10.7 to Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2002, which exhibit is incorporated herein by reference.
- 10.13\* Exclusive License Agreement dated as of March 15, 1999, between the Registrant and Toray Industries, Inc., incorporated by reference to Exhibit 10.14 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
- 10.14\*\* Employment Agreement dated November 29, 2000 between the Registrant and Roger Jeffs, which appears as Exhibit 10.9 to Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2002, which exhibit is incorporated herein by reference.
- 10.15 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).
- 10.16 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).\*
- 10.17 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).
- 10.18 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.
- 10.19 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.
- 10.20 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.

- 10.21 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.
- 10.22\*\*\* 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.
- 10.23\*\* 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.
- 10.24\*\* 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.
- 10.25\*\* 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.
- 10.26\*\* 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.
- 10.27 Real Estate Purchase Agreement dated October 31, 2003 by and between Unither Pharmaceuticals, Inc. and Montgomery County, incorporated by reference to Exhibit 10.34 to the Registrant's Form 10-K for the year ended December 31, 2003.
- 10.28\*\* United Therapeutics Corporation Amended and Restated Equity Incentive Plan, as amended effective as of September 24, 2004 incorporated by reference to Exhibit 10.1 to the Registrant's Form 10-Q for the quarter ended September 30, 2004.
- 10.29 Lease Agreement dated as of June 28, 2004, by and among United Therapeutics Corporation and Wachovia Development Corporation, incorporated by reference to Exhibit 99.1 of the Registrant's Form 8-K filed on July 6, 2004.
- 10.30 Assignment of Liquid Collateral Account dated June 28, 2004, by and among United Therapeutics Corporation and Wachovia Development Corporation, incorporated by reference to Exhibit 99.2 of the Registrant's Form 8-K filed on July 6, 2004.
- 10.31 Ground Lease dated June 28, 2004, by and among United Therapeutics Corporation and Wachovia Development Corporation, incorporated by reference to Exhibit 99.3 of the Registrant's Form 8-K filed on July 6, 2004.
- 10.32 Participation Agreement dated June 28, 2004, by and among United Therapeutics Corporation, Wachovia Development Corporation, Various Other Banks and Financial Institutions and Wachovia Bank, NA, incorporated by reference to Exhibit 99.4 of the Registrant's Form 8-K filed on July 6, 2004.
- 10.33 Agency Agreement dated June 28, 2004, by and among United Therapeutics Corporation and Wachovia Development Corporation, incorporated by reference to Exhibit 99.5 of the Registrant's Form 8-K filed on July 6, 2004.
- 10.34\*\* Amendment to Executive Employment Agreement between Martine A. Rothblatt and United Therapeutics Corporation, dated April 2, 1999, as previously amended, incorporated by reference to Exhibit 10.1 of the Registrar's Form 8-K filed on December 29, 2004.
- 10.35\*\* Amendment to Employment Agreement between Roger Jeffs, Ph.D. and United Therapeutics Corporation dated November 29, 2000, as previously amended, incorporated by reference to Exhibit 10.2 of the Registrar's Form 8-K filed on December 29, 2004.

- 10.36\*\* Amendment to Employment Agreement between Fred Hadeed and United Therapeutics Corporation dated January 3, 2000, as previously amended, incorporated by reference to Exhibit 10.3 of the Registrar's Form 8-K filed on December 29, 2004.
- 10.37\*\* Amendment to Employment Agreement between Paul A. Mahon and United Therapeutics Corporation dated June 16, 2001, as previously amended, incorporated by reference to Exhibit 10.4 of the Registrar's Form 8-K filed on December 29, 2004.
- 10.38\*\* Form of Employee Stock Option Award Agreement, incorporated by reference to Exhibit 10.1 of the Registrar's Form 8-K filed on December 17, 2004.
- 10.39\*\* Form of Non-Employee Stock Option Award Agreement, incorporated by reference to Exhibit 10.2 of the Registrar's Form 8-K filed on December 17, 2004.
- 16 Letter from KPMG LLP regarding change in certifying accountant, which appears as Exhibit 99.1 to Registrant's Form 8-K filed on September 8, 2003, which exhibit is incorporated herein by reference.
- 21 Subsidiaries of the Registrant.
- 23.1 Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm
- 31.1 Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.
- 31.2 Certification of Chief Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.
- 32.1 Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2 Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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

\*\* Designates management contracts and compensation plans.

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

## SIGNATURES

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

### UNITED THERAPEUTICS CORPORATION

February 27, 2006

By: /s/ MARTINE A. ROTHBLATT  
Martine A. Rothblatt, Ph.D.  
*Chairman of the Board and Chief Executive Officer*

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.

<u>Signatures</u>	<u>Title</u>	<u>Date</u>
<u>/s/ MARTINE A. ROTHBLATT</u> Martine A Rothblatt	Chairman of the Board and Chief Executive Officer	February 27, 2006
<u>/s/ ROGER A. JEFFS</u> Roger A. Jeffs	President, Chief Operating Officer and Director	February 27, 2006
<u>/s/ FRED T. HADEED</u> Fred T. Hadeed	Executive Vice President for Business Development and Chief Financial Officer	February 27, 2006
<u>/s/ CHRISTOPHER CAUSEY</u> Christopher Causey	Director	February 27, 2006
<u>/s/ RAYMOND DWEK</u> Raymond Dwek	Director	February 27, 2006
<u>/s/ R. PAUL GRAY</u> R. Paul Gray	Director	February 27, 2006
<u>/s/ RAYMOND KURZWEIL</u> Raymond Kurzweil	Director	February 27, 2006
<u>/s/ CHRISTOPHER PATUSKY</u> Christopher Patusky	Director	February 27, 2006
<u>/s/ LOUIS W. SULLIVAN</u> Louis W. Sullivan	Director	February 27, 2006

**SUBSIDIARIES OF THE REGISTRANT**

Lung Rx, Inc., a Delaware Corporation

Unither Telmed, Ltd. (f/k/a 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

Unither Biotech Inc., a Canadian Company

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\* Doing business in Florida as Unither Telmed Corp.

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**Consent of Independent Registered Public Accounting Firm**

We consent to the inclusion in this Annual Report (Form 10-K) of United Therapeutics Corporation of our report dated February 23, 2006, with respect to the consolidated financial statements and schedules of United Therapeutics Corporation and United Therapeutics Corporation management's assessment of the effectiveness of internal control over financial reporting and the effectiveness of internal control over financial reporting of United Therapeutics Corporation, included in the 2005 Annual Report for the year ended December 31, 2005.

We consent to the incorporation by reference in the following Registration Statements:

- (1) Registration Statement (Form S-3 No. 333-118699) of United Therapeutics Corporation,
- (2) Registration Statement (Form S-3 No. 333-122703) of United Therapeutics Corporation,
- (3) Registration Statement (Form S-8 No. 333-108169) pertaining to the United Therapeutics Corporation's Equity Incentive Plan,
- (4) Registration Statement (Form S-8 No. 333-56922) pertaining to the United Therapeutics Corporation's Equity Incentive Plan;  
and
- (5) Registration Statement (Form S-8 No. 333-95419) pertaining to the United Therapeutics Corporation's Equity Incentive Plan.

/s/ Ernst & Young LLP

McLean, Virginia  
February 24, 2006

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

I, Martine A. Rothblatt, certify that:

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

Date: February 27, 2006

/s/ MARTINE A. ROTHBLATT

By: Martine A. Rothblatt, Ph.D.

Title: Chairman and Chief Executive Officer

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

I, Fred T. Hadeed, certify that:

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

Date: February 27, 2006

/s/ FRED T. HADEED

By: Fred T. Hadeed

Title: Executive Vice President for Business  
Development and Chief Financial Officer

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

In connection with the annual report of United Therapeutics Corporation (the "Company") on Form 10-K for the period ended December 31, 2005 as filed with the Securities and Exchange Commission (the "Report"), I, Martine A. Rothblatt, Chief Executive Officer of the Company, certify, to the best of my knowledge, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

/s/ MARTINE A. ROTHBLATT

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Martine A. Rothblatt  
Chairman and Chief Executive Officer  
United Therapeutics Corporation  
February 27, 2006

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

In connection with the annual report of United Therapeutics Corporation (the "Company") on Form 10-K for the period ended December 31, 2005 as filed with the Securities and Exchange Commission (the "Report"), I, Fred T. Hadeed, Chief Financial Officer of the Company, certify, to the best of my knowledge, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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

/s/ FRED T. HADEED

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Fred T. Hadeed  
Executive Vice President for Business Development  
and Chief Financial Officer  
United Therapeutics Corporation  
February 27, 2006

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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