

# UNITED THERAPEUTICS CORP

## FORM 10-K (Annual Report)

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

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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, 2006

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

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

**Title of each class**

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

**Name of each exchange on which registered**

Nasdaq Global Select Market

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

None

(Title of Class)

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐

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

The aggregate market value of the Common Stock held by non-affiliates of the registrant, based on the closing price on June 30, 2006, as reported by the NASDAQ National Market was approximately \$1,201,000.

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

**DOCUMENTS INCORPORATED BY REFERENCE**

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

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ITEM 1. BUSINESS

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

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

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

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

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

## Our Products

Our product portfolio includes the following:

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

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

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

### ***Remodulin***

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

Mexico, Peru and Argentina. Applications for approval for both subcutaneous and intravenous Remodulin infusion are under review in many other countries. In addition, we are continuing work on expanding commercialization to new territories such as Japan and South Korea.

### *Pulmonary Arterial Hypertension (PAH)*

We are focused primarily on developing Remodulin as our lead product for treating PAH. PAH is a life-threatening vascular disease that affects the blood vessels between the heart and lungs, known as the pulmonary blood vessels. PAH 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 100,000 and 200,000 individuals with PAH worldwide. With the introduction of new oral therapies and marketing efforts by the manufacturers of PAH drugs, we have seen an increase in the number of people diagnosed with the disease. However, due to the rareness of PAH and the complexities of diagnosing it, only a small fraction of these patients are being treated.

The complexity of PAH is due in part to the numerous causes associated with the disease. The three main disease pathways currently being treated are an increase in endothelin, an increase in the PDE5 enzyme and a reduction of prostacyclin in the PAH patient. A PAH patient could be affected by one, two or all three of these associated conditions. Endothelin and the PDE5 enzyme can cause the blood vessels to constrict. Prostacyclin, a naturally occurring hormone, appears to dilate blood vessels, prevent platelet aggregation, and prevent proliferation of smooth muscle cells surrounding the vessels. Endothelin antagonists (drugs that block endothelin) and PDE5 inhibitors (drugs that block the PDE5 enzyme) may be used in combination with prostacyclins. Together, these drugs provide symptomatic relief along different pathways and can complement each other to treat seriously ill patients.

A long-term outcome study published in the *European Respiratory Journal* (vol. 28, Number 6; December 2006) demonstrated improved survival with Remodulin therapy when compared to predicted survival (NIH registry formula) over a four-year period. One-, two-, three and four-year survival was 87%, 78%, 71%, and 68%, respectively, for all 860 patients (including 130 patients who received combination therapy) and 88%, 79%, 73%, and 70%, respectively, for patients receiving only treprostinil monotherapy (n=730). In patients with idiopathic PAH for whom baseline hemodynamics were available (n=332 patients), survival was 91%, 82%, 76%, and 72% at years 1-4, respectively. This compares to respective predicted survival estimates of 69%, 56%, 46%, and 38% over the four-year period based on the NIH registry formula.

The first FDA-approved prostacyclin for PAH 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 PAH.

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. Subcutaneous delivery of Remodulin also eliminates the risk of central venous catheter infection and related hospitalization associated with an IV infusion. Remodulin's extended duration in the body may also reduce the risk of rebound PAH, and possibly death, if treatment is abruptly interrupted. The stability of Remodulin also allows it to be packaged as an aqueous solution, eliminating the need for patients to reconstitute the drug one or more times each day, as is required with Flolan. Treprostinil, the active ingredient of Remodulin, is highly soluble in an aqueous solution and therefore Remodulin can be

manufactured at highly concentrated solutions. This allows therapeutic concentrations of Remodulin to be delivered at low flow rates via miniaturized infusion pumps for both subcutaneous and intravenous infusion. Lastly, Remodulin does not require the use of cooling packs or refrigeration to keep it stable, as is required with Flolan due to Flolan's chemical instability.

There are noteworthy adverse events associated with Remodulin infusion. When infused subcutaneously, Remodulin causes infusion site pain and infusion site reaction in most patients to 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 central venous catheter, similar to Flolan. When delivered intravenously, Remodulin bears a risk of infection, as does 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, unlike Flolan which must be mixed and refilled every 24 hours.

#### *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 PAH. 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 important clinical endpoints, including a composite index that measured exercise capacity and shortness of breath, cardiopulmonary hemodynamics 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 PAH in patients with NYHA class II-IV symptoms (with class IV representing the most severely ill patients) to diminish symptoms associated with exercise. Remodulin may be prescribed for all forms of PAH and is the only PAH treatment approved for NYHA class II, III and IV patients.

As a condition of Remodulin's Subpart H approval, we were required to perform a post-marketing Phase IV clinical study to confirm the clinical benefits of Remodulin. In August 2005, we performed an interim assessment after 22 patients completed the Phase IV study. The results of the interim assessment, as analyzed by an independent statistician, were positive. The p value was 0.0002, meaning the likelihood that the achieved result was incorrect was two out of ten thousand. Specifically, 13 of the 14 patients (93%) receiving Remodulin were able to successfully transition from Flolan, which they had previously been using to treat their condition. These patients were able to complete the eight-week study without the need to reinstitute Flolan therapy. Alternatively, only 1 of the 8 patients (13%) successfully transitioned without clinical deterioration during the eight week period from Flolan to a placebo. Based on this positive outcome, in March 2006, the FDA agreed that we had satisfied our obligation to perform the post-marketing Phase IV clinical study, that the study confirmed the clinical benefits of Remodulin, and expanded the use of Remodulin to specifically allow for transition of Flolan patients directly to Remodulin therapy.

#### *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 PAH. A bioequivalence study in 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 PAH. 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.

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 45 patients, we suspended enrollment of new patients, in accordance with 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.

Results in a prospective open-label study reported in January 2007 demonstrate that rapid transition from intravenous Flolan to intravenous Remodulin was achieved in 12 PAH patients with no serious adverse events and maintenance of baseline clinical status was maintained over 12 weeks. The patients were transitioned from Flolan to intravenous Remodulin by a direct switch from a Flolan medication cassette to a Remodulin medication cassette. Rapid transition to Remodulin was achieved without serious adverse events and baseline clinical status was maintained over 12 weeks. All patients reported fewer prostacyclin-related side effects with Remodulin and remained on Remodulin after study completion. The study demonstrated that stable patients with PAH can be safely transitioned from Flolan to intravenous Remodulin using a rapid switch protocol.

Although intravenous Remodulin does not possess all the safety and convenience benefits of subcutaneous Remodulin, it has one important advantage: it eliminates infusion site pain and reaction, a common side effect of using subcutaneous Remodulin. Many patients are unsuccessful in managing such infusion site pain even with using available pain management techniques. Intravenous Remodulin has many beneficial characteristics that differentiate it from intravenous Flolan. As Intravenous Remodulin does not require refrigeration, it serves as an alternative to Flolan which must be continuously refrigerated, even while being administered to a patient by continuous infusion. Furthermore, the active ingredient in Remodulin remains active for a few hours, whereas the active ingredient in Flolan is highly unstable and only remains active in the body for a few minutes. Because Remodulin remains active longer, it may reduce the risk of rebound PAH, a severe recurrence of the disease in the case of inadvertent therapy interruption. Remodulin can be infused continuously for up to 48 hours while Flolan can only be infused for 24 hours. This allows patients to prepare medication solutions every other day as opposed to daily. Also, because Remodulin can be made in highly concentrated solutions, a wide variety of pump options, including miniaturized pump platforms, are available to patients.

In February 2007, the Scientific Leadership Committee (SLC) of the Pulmonary Hypertension Association announced new guidance relating to the treatment of PAH patients on long-term intravenous therapy. The SLC guidance was issued in response to the release of a slide presentation prepared by researchers with the U.S. Centers for Disease Control and Prevention (CDC) entitled "*Bloodstream infections among patients treated with intravenous epoprostenol and intravenous treprostinil for pulmonary arterial hypertension, United States 2004—2006*". These slides accompanied a presentation to the SLC and may subsequently be published as a report in the CDC's *Morbidity and Mortality Weekly Report*. The slides were prepared in connection with a CDC retrospective inquiry at seven centers into a report of increased blood stream infections, particularly gram-negative blood stream infections, among PAH patients treated with intravenous Remodulin as compared to intravenous Flolan. The SLC guidance statement noted that the CDC observations were hypothesis-generating and did not permit definitive or specific conclusions. The SLC reminded physicians of the need to be aware of the range of possible gram negative and gram



positive infectious organisms in patients with long-term central catheters and to treat them appropriately. In response to the SLC guidance statement, we are planning to commence a multi-center, multi-national, multi-year and multi-agent prospective study to scientifically test the hypothesis of whether there are differences in the risk of sepsis and sepsis sub-types among parenterally-delivered prostanoids. We anticipate this study to enroll several hundred patients, which enrollment is expected to commence later this year. We also plan to coordinate a working group with the Pulmonary Hypertension Association and physicians and nurses, along with its network of specialty distributors and home health care providers, to develop unified best practice recommendations related to the chronic administration of IV prostanoids via central venous catheters. The risk of sepsis is already noted in the Remodulin package insert, but we will also revise the package insert to more fully describe the known infection risk and appropriate technique that should be practiced when preparing and administering Remodulin intravenously. Best practices for increased sterility, which, in turn, leads to lower risk of sepsis, is the over all goal for all of our efforts.

#### *Remodulin Commercialization*

Remodulin for subcutaneous use is approved in 32 countries throughout the world. 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, which should occur in 2007. Licenses and pricing approvals have been received in most European Union countries, with the remainder expected during 2007. In addition, we have submitted a variation of the license for approval of intravenous Remodulin in the European Union through the mutual recognition process. The application is currently under review by the host nation, France. In the meantime, we will continue to sell (but not market) Remodulin in European countries where we are not licensed under the named-patient system, under which system we are permitted to import and sell Remodulin to hospitals for use in specifically named patients.

We are working on expanding our sales of Remodulin into new territories through our existing distributors and new distributors. For example, we are negotiating with a potential distributor to enter the Japanese market for subcutaneous and intravenous Remodulin. However, certain countries, like Japan, may require that new clinical trials be conducted in order to show the efficacy and safety of the drug in their population, called bridging trials. Commercial sales in such countries could therefore be several years from realization.

#### *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 causes of peripheral vascular disease are unknown, diabetes, obesity, smoking and lack of exercise are associated with the disease. Peripheral vascular disease appears to be similar to PAH 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 often 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 pharmaceutical 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 patient recruitment. We believe that more convenient formulations of Remodulin, such as an inhaled or oral form, may be more appropriate for patients with peripheral vascular disease. Accordingly, we have recently commenced safety and tolerability studies with the sustained-release form of oral treprostinil in patients with peripheral vascular disease.

*TRIUMPH-1 (proposed to be marketed as Viveta)*

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 April 2004, the European Medicines Agency granted an orphan designation for inhaled treprostinil for the treatment of both PAH and chronic thromboembolic pulmonary hypertension. In June 2005, Lung Rx, Inc., a wholly-owned 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<sup>®</sup>. During the trial, dosing will be escalated to patient tolerance or a maximum equivalence of 45 micrograms per session. The primary end point of the trial is the peak six minute walk improvement test, which is a typical benchmark test of cardiovascular health. This trial, TRIUMPH-1 ( *T*reprostinil *I*nhalation *U*sed in the *M*anagement of *P*ulmonary *H*ypertension), is currently being conducted at approximately 36 centers in the United States and Europe. Additional centers are being added to the study. In May 2006, the FDA agreed to permit the inclusion in the trial of PAH patients who are also being treated with Revatio<sup>®</sup>. The FDA also agreed to expand the trial size to at least 200 patients, and to permit the assessment of efficacy after 150 patients have completed the trial. We do not intend to conduct the interim efficacy assessment. As a result, the TRIUMPH-1 trial is expected to conclude when 200 evaluable patients have completed the study, which is expected upon the enrollment of approximately 220 patients overall. As of December 31, 2006, approximately 155 patients had been enrolled in this trial. As of February 20, 2007, approximately 175 patients had been enrolled in this trial.

Currently, the only FDA approved inhaled prostacyclin is Ventavis<sup>®</sup>. Ventavis is marketed by Actelion Ltd. in the United States and by Schering AG in Europe. Ventavis' active ingredient, Iloprost, has a half-life of approximately 20 to 30 minutes and lacks selectivity to the lungs. The lack of lung selectivity can cause a drop in a patient's blood pressure if the drug is dosed too high. As a result, Ventavis is generally taken six to nine times a day using a nebulizer. Each session on the nebulizer requires continuous breathing of the drug for 10 to 15 minutes per session.

Due to the longer half-life of treprostinil and its apparent greater selectivity to the lungs, Viveta is designed to be inhaled for about one minute, four times a day using an ultra-sonic nebulizer with between six and nine breaths per session. The TRIUMPH-1 trial is using the Optineb device manufactured by Nebu-Tec in Germany. Optineb is approved in Germany and in other European countries. Optineb is not approved in the United States, but an application for approval is expected to be filed with the FDA concurrently with the results of the TRIUMPH-1 trial. The inhalation device market is ever-changing, with smaller devices being developed concurrently with the discovery of new technologies. We are also interested in new technologies that would enable a more efficient and convenient means of delivering Viveta to patients.

We are developing an oral formulation of treprostinil, treprostinil diethanolamine, a novel salt form of treprostinil. During 2004, we completed studies of various formulations of treprostinil diethanolamine in healthy volunteers. Based on these studies, a formulation was selected that uses technology licensed from Supernus Pharmaceuticals, Inc. (Supernus) to provide for sustained release of treprostinil. The coating technology, which is resistant to being broken down by the body's digestive system, allows for treprostinil to be released relatively evenly over a period of time through an extremely small hole that is laser-drilled into each tablet. In 2005, this formulation and coating technology was shown in further Phase 1 normal volunteer studies to provide sustained blood concentrations of treprostinil between 8 to 10 hours following a single oral dose. This duration may allow for dosing twice per day. In July 2005, the European Medicines Agency announced that oral treprostinil had been granted orphan product status in the European Union. Drugs with orphan status generally receive priority review of approval applications and may receive longer periods of protection against competition from generic drugs.

In October 2006, we commenced two multi-national placebo-controlled clinical trials of oral treprostinil in patients with PAH. These trials are a combination of Phase II and Phase III trials, in which both dosing and efficacy will be studied. During the trials, dosing will be escalated to patient tolerance. One trial, FREEDOM-C (Combination Study), is a 16-week study of up to 300 patients who are currently on an approved oral PAH background therapy consisting of Revatio, Tracleer or both therapies. There is a planned interim assessment after 150 patients complete this study. The second trial, FREEDOM-M (Monotherapy Study), is a 12-week study of up to 150 patients who are not on any background PAH therapy. There is a planned interim assessment after 90 patients complete this study. Both trials will be conducted at approximately 50 centers throughout the United States and the rest of the world. The trials currently use a 1 mg tablet of oral treprostinil, with a 0.5 mg tablet planned for 2007. We are also considering a 5 mg tablet and perhaps a 10 mg tablet in the future. Since the manufacturing process of the tablets on a commercial level is still new and being refined, failure of a manufacturing batch of tablets is not wholly unexpected. As a result, we are continuing to review and refine the manufacturing process to prevent and detect any faulty tablets. As of February 20, 2007, there were 52 and 20 patients enrolled in the FREEDOM-C and FREEDOM-M trials, respectively.

#### *Sales and Marketing*

Our marketing strategy for Remodulin relies upon our dedicated sales and marketing team to educate the prescriber community and to reach patients suffering from PAH. The marketing team consisted of approximately 20 employees as of December 31, 2006 with further growth expected in 2007. Additionally, we rely on chronic care specialty pharmacy distributors to handle physician and patient requests for Remodulin on a non-exclusive basis in the United States. For additional information, see *Domestic Distribution Agreements* below. These specialty distributors are experienced in all aspects of chronic therapies, including patient care, the sale and distribution of medicines and reimbursement from insurance companies and other payers. Outside of the United States, we have entered into exclusive distributor agreements covering most of Europe, South America, parts of Asia and Israel. Sales in Canada are currently conducted under the management of our wholly-owned subsidiary, Unither Biotech Inc., until such time as we reach an agreement with a third party distributor. We are working with our current distributors to expand Remodulin sales into other countries in which they have distribution rights.

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 \$152.5 million, \$109.2 million and \$66.1 million of revenues from the sales of Remodulin in 2006, 2005 and 2004, respectively.

In anticipation of a commercial launch of Viveta, our inhaled version of treprostinil, we have begun hiring a dedicated sales and marketing team to develop launch plans and materials.

### ***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 Medical Corp.) (AltaRex) to exclusively license certain rights to a platform of five immunotherapeutic monoclonal antibodies, including OvaRex, BrevaRex, 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 cancers. 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 double-blinded placebo-controlled Phase III pivotal clinical trials of OvaRex in patients with stage III/IV ovarian cancer, called IMPACT I and II, **I**Mmunotherapy **P**ivotal ov **A**rian **C**ancer **T**rial. Patients enrolled in these studies have successfully completed front-line therapy, consisting of surgery and chemotherapy. We are conducting these studies throughout the United States at approximately 60 centers. In June 2006, these trials were fully enrolled with a total of 367 patients across both trials. The primary endpoint for these trials is the difference in time to disease relapse between patients treated with OvaRex and patients receiving a placebo. The studies will not be stopped and the results obtained until both studies have each reached at least 118 relapse events. As of December 31, 2006, the reported number of relapse events was 122 and 97, respectively, in each of the trials. Following relapse, patients will also be followed to assess long-term survival.

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

In March 2000, we entered into a license agreement with Synergy Pharmaceuticals, Inc. (Synergy) to obtain the exclusive worldwide rights to certain patents relating to novel antiviral compounds. Synergy was working with the Glycobiology Department at the University of Oxford to develop these compounds. In 2003, by mutual consent, we terminated our licensing agreement with Synergy. We are now working directly with Oxford University on the development of new compounds. These glycobiology antiviral agents are small molecules which may be effective as oral therapies for the treatment of hepatitis B and C 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 studied agent identified to date is UT-231B. An Investigational New Drug Application was submitted for UT-231B in 2002 and was 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 disease.

### ***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 affect 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 monitoring (a 24-hour continuous test of heart rhythms), event

monitoring (a test that typically extends to 30 days and looks for more elusive, intermittent arrhythmias) and analysis and pacemaker monitoring remotely via telephone 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. In March 2005, Medicomp received FDA market clearance for a patent pending p-wave analysis adjunct to its artificial intelligence algorithm that runs on all of its newly manufactured CardioPAL devices. The p-wave is a diminutive but important portion of the electrocardiograph that helps determine if an arrhythmia was generated from the top chambers of the heart, the atria, or from the bottom chambers of the heart, the ventricles. This level of analysis leads to more reliable, automatic detection of arrhythmias, like atrial fibrillation.

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 \$6.6 million, \$5.8 million and \$5.3 million from the sales of telemedicine products and services were earned in 2006, 2005 and 2004, 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, which are now operating as Unither Pharma, Inc. (Unither Pharma), our wholly-owned subsidiary. Arginine is required by the body to produce nitric oxide. Unither Pharma is the exclusive licensee of patents entitling it to claim that arginine is critical for maintaining vascular function and certain other natural functions.

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 sales of the HeartBar line of products, after evaluating recent clinical trial results and market potential, among other factors. Sales of non-HeartBar arginine products and license royalties from third parties selling arginine based products are continuing.

In November 2006, we settled litigation with three companies that we believed were infringing our arginine patents. We received a settlement payment and will receive additional royalties from sales of products containing arginine from one of the parties. We believe that there are a substantial number of additional infringers.

Approximately \$100,000, \$293,000 and \$531,000 of revenues were earned from the sales and royalties of arginine related products in 2006, 2005 and 2004, 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 for the treatment of peripheral vascular disease, although early European clinical studies by Aventis had demonstrated efficacy. However, we believe that sustained release oral doses of beraprost may be an important treatment for PAH. Toray Industries is currently testing beraprost SR in a Phase III clinical trial in Japan.

In June 2000, in connection with our license, we agreed to grant options to Toray to purchase 500,000 shares of our common stock 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 will be set at the fair market value of our common stock at that time. 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.

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

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

In October 2006, Northern Therapeutics agreed to grant us a license to develop and commercialize the autologous gene therapy in the United States for PAH. We are required under this license to make incremental milestone payments to Northern Therapeutics totaling \$1.5 million up to and during completion of the Phase I trial. For the twelve months ended December 31, 2006, we paid approximately \$500,000 in milestone payments to Northern Therapeutics. If the Phase I trial is successfully completed, we will assume the development program and related costs for the United States market. Northern Therapeutics will receive royalty payments following commercialization. As part of this agreement, we terminated the Remodulin distribution agreement with Northern Therapeutics for Canada. We are distributing Remodulin directly in Canada under the management of our Canadian wholly-owned subsidiary, Unither Biotech Inc., until we find a third-party distributor.

Due to our \$5.0 million investment, we currently own approximately 68% of Northern Therapeutics. Although we own approximately 68% of Northern Therapeutics, minority shareholders possess substantive participating rights as defined under 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* that preclude us from controlling Northern Therapeutics and consolidating the company's financial statements with our own.

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

Medtronic MiniMed partnered with us for the use of its 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 PAH utilizing MiniMed products and Remodulin. The guidelines required us to purchase infusion pumps exclusively from Medtronic MiniMed at a discount to MiniMed list prices. The agreement commenced on September 3, 1997, and was to continue for seven years after the May 2002 FDA approval of Remodulin. MiniMed advised us in May 2006 that it intended to discontinue manufacturing infusion pumps for subcutaneous delivery of Remodulin after first giving us and our distributors the opportunity to purchase desired quantities. In November 2006, we mutually entered into a termination agreement with MiniMed. We anticipate continuing to purchase Medtronic MiniMed pump supply products and reselling those products to several of our foreign distributors, although our distributors are free to purchase pumps and associated

supplies from other vendors. Approximately \$457,000, \$397,000 and \$1.7 million of revenues were earned from the resale of MiniMed pumps and supplies in 2006, 2005 and 2004, 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., which has accepted an offer by CVS Corporation to acquire it. Express Scripts has also offered to purchase Caremark. If either company is successful in purchasing Caremark, we do not have any information to indicate whether this merger would have an adverse impact on Remodulin distribution. Our distributors are responsible for assisting patients with obtaining reimbursement for the cost of the therapy and providing other support services. Under our distribution agreements, we sell Remodulin at a discount from an average wholesale price recommended by us and Medtronic MiniMed infusion pumps at list price. 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. Due to changes in the regulatory environment and with the termination of the MiniMed agreement, we intend to update our contracts with these distributors in 2007. None of the changes are expected to have a significant impact on our operations or relationships with these distributors. If these distributor agreements expire or terminate, under certain conditions, we may be required to repurchase unsold Remodulin inventory held by the distributors. We have also established a patient assistant program in the United States, which provides qualified uninsured or underinsured patients with Remodulin at no charge.

### **Patents and Proprietary Rights**

Our success depends 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. assigned to us all rights to the use of the stable prostacyclin analog now known as Remodulin. The patent covering the use of Remodulin for PAH 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 exclusively licensed to us certain patents, a patent application and know-how for the composition and production of the stable prostacyclin analog now known as Remodulin. 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 of synthesis 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 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 2016 to 2022 (subject to extension—see *Patent Term Extensions* below). Additional inventions relating to the compounds may be owned jointly by us and AltaRex or individually by AltaRex, depending on the source of the invention.

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

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

In 2000, we acquired the exclusive license to patents from Stanford University and New York Medical College related to arginine-based dietary supplements that work to enhance the level of naturally occurring nitric oxide in the vascular system. The licenses cover worldwide territories and are valid for the life of the patents (expiration dates ranging from 2010 to 2018). We will own all rights to any new products derived from these licenses.

### ***Supernus Pharmaceutical License***

In June 2006, United Therapeutics entered into an exclusive license agreement with Supernus for use of certain technologies developed by Supernus in the formulation of United Therapeutics' sustained release oral treprostinil. Under the agreement, in return for the license, United Therapeutics will pay Supernus certain amounts upon the achievement of specified milestones based on the development of oral treprostinil and its commercial launch. In addition, the agreement provides that we will pay a royalty to Supernus based on net worldwide sales of the initial product. Any such royalty will be paid for approximately twelve years commencing with the first product sale and is subject to adjustments as specified in the agreement. Additional milestone payments and royalty payments may be due for the development and the commercialization of other products developed using the technology granted in this license.

### ***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 under the Hatch-Waxman Act in the United States, 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 PAH using Remodulin. U.S. Patent Number 5,153,222, entitled "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 expenses generally include the cost of acquiring or inventing new technologies and products as well as their development. Research and development expenses during 2006, 2005 and 2004



totaled approximately \$57.6 million, \$36.1 million and \$30.7 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 sodium, the active ingredient for Remodulin and Viveta, and treprostinil diethanolamine, the active ingredient for oral treprostinil, in Chicago, Illinois. We are currently transitioning these activities to our new laboratory in Silver Spring, Maryland. The validation process for making these treprostinil-based compounds in the Silver Spring facility commenced in October 2006. We anticipate filing with the FDA and other regulatory agencies for approval to use the new facility for commercial purposes in mid-2007, with regulatory agency approvals expected in late 2007. We currently maintain a treprostinil sodium inventory for over two years of expected demand.

With the transfer of manufacturing operations to the Silver Spring facility, we are also changing our internal manufacturing process. Initially, in Chicago, we had produced treprostinil beginning with basic chemicals and completing the full manufacturing process. Over the last two years, we have been modifying the process to begin treprostinil development with advanced intermediate compounds made by outside vendors. These advanced intermediates have been used to produce treprostinil sodium for research and development purposes and for making treprostinil diethanolamine for our oral formulation. We anticipate that upon commercialization of oral treprostinil, the need for treprostinil diethanolamine will be greater than the need for treprostinil sodium for inhaled and infusion therapies. As a result, the manufacturing process will consist of starting with the advanced intermediate compound, making treprostinil diethanolamine and then converting that compound to treprostinil. We expect this to allow us the most flexibility and efficiency in meeting future demands for both forms of active ingredients. We have approved three vendors to supply the advanced intermediate compounds in order to reduce the risk of supply shortages.

Baxter Healthcare Corporation formulates Remodulin for us. The term of our initial agreement with Baxter ended in October 2004. The contract is renewable for successive eighteen month terms and has been renewed. We rely on Cardinal Health, Inc. for conducting stability studies on Remodulin, formulating treprostinil for inhalation use, formulating treprostinil diethanolamine for the oral clinical trials, and analyzing other products we are developing. Prior to November 2006, Medtronic MiniMed provided the delivery device used to administer subcutaneous Remodulin to patients.

In October 2006, we commenced the development process for making the active ingredient in OvaRex at our Silver Spring, Maryland facility. The current material being used in our clinical trials was made by Abbott Laboratories, which has subsequently closed the facility that had been used to manufacture this type of material. As a result, we will be producing this drug ourselves. The currently available drug expires in early 2008. We are required by FDA rules to demonstrate the comparability of our Silver Spring-produced antibody to the drug made by Abbott Laboratories. In parallel with this effort, we will be producing validation/registration batches for FDA approval. We expect that this process should be completed in early 2008.

Commercial products manufactured by contract manufacturers include arginine and telemedicine products.

Although we believe that other manufacturers and suppliers could provide similar products, services and materials, there are few companies that 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 production and 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 the treatment of PAH with which Remodulin competes. They are: Flolan, an intravenously delivered prostacyclin marketed by Gilead Sciences, Inc.; Tracleer, an oral endothelin antagonist marketed by Actelion Ltd; Revatio, a PDE-5 inhibitor, a formulation of the very successful drug Viagra<sup>®</sup> marketed by Pfizer, Inc.; and Ventavis, an inhaled prostacyclin marketed by Actelion Ltd in the United States and by Schering AG in Europe. Two additional oral endothelin antagonists are in development. One is Thelin<sup>™</sup>, being developed by Encysive Pharmaceuticals, Inc., and the other is ambrisentan<sup>™</sup>, being developed by Gilead Sciences, Inc. In addition, competitors may develop and commercialize other products that compete with our products and may do so more rapidly than us. Due to their ease of use, Tracleer and Revatio are generally considered front-line therapies for newly diagnosed patients. Flolan and Remodulin, which are more complex infusion therapies, are generally considered later-stage therapies for sicker patients. The use of Tracleer, Revatio and Ventavis, either alone or in combination with each other, will, for many patients delay their need for infusion therapy. As a result, while we may not currently compete head-to-head with these drugs as front-line therapy, the success of their use affects our commercial operations. As we develop both inhaled and oral treprostinil therapies, we will be expanding our range of therapeutics to front line. (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 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 PAH. 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 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. Three competitors have agreed to pay a royalty to us on their arginine products, and others have agreed to discontinue infringing activities.

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 pharmaceutical products are extensively regulated by governmental agencies 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, 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 it authorizes trials under specified terms. The Investigational New Drug Application process may be extremely costly and may 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 diverse clinical study sites.

After successful completion of the required clinical testing, a New Drug Application or a Biologics License Application (both referred to as an Application) is typically submitted. The FDA may request additional information before accepting an 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 reviews the Application and responds to the applicant. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the Application to an appropriate advisory committee for review, evaluation and recommendation as to whether it 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 an Application.

If FDA evaluations of the 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 Application and authorization of commercial marketing of the drug for certain indications. The FDA also may refuse to approve the 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 as against generic versions to market the drug for the orphan indication. The FDA has approved the orphan designation for Remodulin for the treatment of PAH by all routes of administration that we are currently developing, 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 address 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 PAH 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. Furthermore, 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 Hatch-Waxman 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 Application and the submission date of an Application, plus all of the time between the submission date of an Application and the approval of that Application, subject to a maximum extension of five years. Similar patent term extensions are available under European laws. Following FDA approval, we filed a patent term extension application with the United States Patent and Trademark Office for our patent covering the method of treating PAH using Remodulin following FDA approval. The application was approved in February 2005 and the patent now expires on October 6, 2014.

Outside of 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 through a centralized body or through 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 in that 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 PAH we used the mutual recognition 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 resubmitting the applications when we file for approval for intravenous Remodulin. We have to file for intravenous Remodulin approval using the mutual recognition process. We have filed our application with our host country, France. The application is currently under review. Regulatory applications are pending in other countries.

Arginine and telemedicine products are manufactured at contract facilities that are regulated by the FDA under different laws and 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 the 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 certain disabled and chronically ill persons, and Medicaid is the federal program administered by the states to provide health care benefits to certain indigent persons. The Medicare contractors who administer the program provide reimbursement for Remodulin at a rate generally equal to 95% 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. We anticipate that the new rules will not have an impact on Remodulin reimbursement rates in 2007. In return for including 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 (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% of Remodulin sales in the United States are reimbursed under the Medicare and Medicaid programs.

## **Employees**

We had approximately 285 employees as of February 19, 2007. 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 17, 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 Securities and Exchange Commission (SEC).

## EXECUTIVE OFFICERS OF THE REGISTRANT

The following is a list, as of February 21, 2007, 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 provides for an initial term of service of five years, which five-year term 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.	52	Chairman, Chief Executive Officer and Director
Roger Jeffs, Ph.D.	45	President, Chief Operating Officer and Director
John M. Ferrari	52	Chief Financial Officer and Treasurer
Paul A. Mahon, J.D.	43	Executive Vice President for Strategic Planning, General Counsel and Corporate Secretary

*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 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.

*John M. Ferrari*, joined United Therapeutics in May 2001 as Controller. Mr. Ferrari was promoted to Vice President of Finance in December 2003 and to Vice President of Finance and Treasurer in June 2004. In August 2006 Mr. Ferrari was promoted to Chief Financial Officer and Treasurer. Prior to joining United Therapeutics, Mr. Ferrari served as Controller for Blackboard, Inc. from 1998 to 2001. Prior to his employment with Blackboard, Inc., Mr. Ferrari served in various senior financial management positions since 1984.

*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 a law firm specializing in technology and media law.

## 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 (the Exchange Act) 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 availability of drug product;
- 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 expectation of reimbursement by third-party payers for intravenous Remodulin and the impact of any regulatory changes to the level of reimbursement;
- The expected levels and timing of bulk purchases of chemicals used to manufacture treprostinil, the active ingredient of Remodulin;
- The outcome of potential future regulatory actions from the FDA and other international regulatory agencies and any actions that may or may not be taken by the FDA and other international regulatory agencies as a result of any such regulatory actions;
- 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 and their expiration dates;
- 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 expectation of future repurchases of our common stock;
- The funding of operations from future revenues;
- The expectation of continued profits or losses;
- Expectations concerning milestone and royalty payments in 2007 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, the tax impact of our hedging contracts entered into in connection with the convertible debt offering 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 expectation, outcome and timing of marketing approvals in European Union countries for intravenous Remodulin;
- The expected levels and timing of Remodulin sales;
- The adequacy of our resources to fund operations;
- The expectation, outcome and timing of validation of, and level of spending to validate, our newly-constructed laboratory production facility in Silver Spring, Maryland;
- The potential amount of the minimum residual value guarantee under our synthetic lease agreement with Wachovia Bank, N.A. and Wachovia Development Corporation relating to our facility in Silver Spring, Maryland;
- The expected amounts and timing of resources for the construction of facility projects in Research Triangle Park, North Carolina and the expectation to finance the construction of our new facility in Silver Spring, Maryland
- Events that could occur upon termination of the Wachovia synthetic lease and related agreements;
- The potential impacts of new accounting standards;
- 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 differences 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.

## Risks Related to Our Business

**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, particularly because we do not generally provide forward-looking guidance to the public. 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 have been 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, 2006, our accumulated deficit was approximately \$41.4 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;
- 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>, Gleeevec<sup>®</sup>, Aviptadil<sup>™</sup> and other potential investigational competitive 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 and risk of line infections or sepsis relating to intravenous use of Remodulin;
- Changes in the current pricing and dosing levels 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;
- The ability of our distributors to transition to the use of other infusion pumps currently available on the market due to Medtronic's discontinuance of the 407C infusion pumps;
- 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 and their level of reimbursement of Remodulin;
- 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;
- 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, and our suppliers' abilities, to establish, defend and enforce intellectual property rights;
- Development of manufacturing resources or the establishment, continuation or termination of third-party manufacturing arrangements;
- The expected levels and timing of bulk purchases of advanced intermediate compounds and other chemicals used to manufacture treprostinil, the active ingredient of Remodulin;
- 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 and technology development 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 and, beginning in the second quarter of 2006, by Myogen, Inc. On October 6, 2006, Myogen announced that it signed a merger agreement to be acquired by Gilead Sciences, Inc., which is regarded as a large and successful biotechnology company in the United States. Generic formulations of Flolan could be available for commercial sale as early as May 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 was initially marketed by CoTherix, Inc. in the United States and Schering AG in Europe. In January 2007, CoTherix was acquired by Actelion Ltd, the manufacturer and distributor of Tracleer, which is regarded as a successful biotechnology company.
- 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, Inc. 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 they give to their patients if they prescribe our competitors' products in combination with Remodulin. In addition, certain of our competitors' products are less invasive than Remodulin and the use of these products may delay or prevent initiation of Remodulin therapy. Finally, as a result of Actelion's recent acquisition of CoTherix, Actelion now controls two of the five therapies approved for PAH in the United States. In addition to reducing competition through this consolidation, because Actelion is dominant in the sales and marketing of oral PAH therapies, it may bring its considerable influence with prescribers to the sales and marketing of Ventavis.

Many companies are marketing and developing products containing arginine that compete with our 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 that 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 they give 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.**

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

- Sitaxsentan (Thelin) is being developed by Encysive Pharmaceuticals, Inc. (Encysive) 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 FDA in the United States. In July 2006, Encysive announced that the FDA determined that Thelin was approvable with one substantive item remaining unresolved. In December 2006, Encysive announced that the FDA had accepted for review its complete response to its FDA's July 2006 approvable letter. In August 2006, Encysive announced that Thelin received marketing authorization in all nations in the European Union. If approved in the United States, Thelin would become the second drug available in the class known as endothelin receptor antagonists;
- Ambrisentan is being developed by Gilead Sciences, Inc. for the treatment of PAH. Ambrisentan, an oral tablet, has completed pivotal clinical testing and is also an endothelin receptor antagonist. In February 2007, Gilead Sciences announced that its New Drug Application for ambrisentan was accepted by the FDA for six-month priority review. Gilead Sciences is regarded as a large and successful biotechnology company in the United States;
- Cialis is an approved oral treatment for erectile dysfunction and is currently marketed by Lilly ICOS LLC, a joint venture of Eli Lilly and Company and ICOS Corporation. Cialis is currently being studied in patients with PAH, and is in the same class of drugs as Revatio. On October 17, 2006, ICOS Corporation announced that it signed a merger agreement to be acquired by Eli Lilly and Company, which is a large and successful pharmaceutical company in the United States;
- 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;
- Aviptadil, an inhaled formulation of vasoactive intestinal peptide, is being developed by mondoBIOTECH Holding SA, for the treatment of PAH. In September 2006, mondoBIOTECH announced that it had outlicensed Aviptadil for the treatment of PAH to Biogen-Idec Inc., which is regarded as a large and successful biotechnology company in the United States;
- 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 therapy which contains a metabolite of estradiol and has been shown in animal and cell models to address certain processes associated with PAH;
- Oral and inhaled formulations of Fasudil, a rho-kinase inhibitor, are being developed by Actelion Ltd for the treatment of PAH. Fasudil is currently approved in Japan as an intravenous drug to treat a disease unrelated to PAH;

- Sorafenib, marketed by Bayer AG as Nexavar for advanced renal cell cancer, is a small molecule which inhibits Raf kinase and which may interfere with the thickening of blood vessel walls associated with PAH. A Phase 1 clinical trial in PAH has been proposed; and
- Recombinant Elafin, being developed by PROTEO Biotech AG, is a protein that is produced naturally in the body that may inhibit inflammatory reactions. In February 2007, Elafin recently was granted orphan product status in the European Union for the treatment of PAH and chronic thromboembolic pulmonary hypertension.

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 distributors selling Remodulin to obtain reimbursement from these payers. 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 may not 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 could 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, products 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.

Until November 14, 2006, Medtronic MiniMed was our exclusive partner for the subcutaneous delivery of Remodulin using the MiniMed microinfusion device for PAH. Medtronic had advised us that it intended to discontinue making infusion pumps for subcutaneous delivery of Remodulin after first giving us and our distributors the opportunity to purchase desired quantities. On November 14, 2006, we mutually agreed with MiniMed to terminate our contract. We relied on Medtronic MiniMed's experience, expertise and performance in supplying the infusion pumps. Any disruption in the supply to PAH patients of infusion devices could delay or prevent patients from initiating or continuing Remodulin therapy, which

could adversely affect our revenues. Doctors and patients may not be able to obtain acceptable substitute delivery devices to replace the MiniMed microinfusion devices when the available supply held by our distributors has been depleted.

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. (which has agreed to merge with CVS Corporation and is also an acquisition target of Express Scripts) 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 distribution partners and contractors do not achieve acceptable profit margins, they may not continue to distribute our products. If our distribution 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. More recently, in November 2006, Caremark announced its agreement to merge with CVS. However, Express Scripts had also made an offer to acquire Caremark. If Express Scripts is successful in acquiring Caremark, then it is possible that the Remodulin distribution networks of Caremark and Express Scripts will be combined, leaving us with two distributors in the United States. Together, they account for the majority of our Remodulin sales. When these distributors were independently managed, the Remodulin franchise was a more significant business to them, because they were much smaller. As divisions or subsidiaries of much larger companies, however, Remodulin could be much less significant to these distributors. There can be no assurance that a merger among our distributors will not adversely affect Remodulin distribution. In addition, we have been informed that, effective January 1, 2007, Accredo will become the exclusive U.S. distributor for Flolan. It is possible that our 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 or upon the occurrence of adverse events following commercial introduction of the products. We received one warning letter from the FDA related to advertising in 2005, which was resolved satisfactorily.

We rely heavily on sales of Remodulin. During the year ended December 31, 2006, our Remodulin sales accounted for 96% of our total revenues. If approvals are withdrawn for Remodulin or any other 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, they 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 risk of line infections or sepsis associated with the use of intravenous Remodulin.

**Reports of side effects, such as sepsis, associated with intravenous Remodulin could cause physicians and patients to not accept Remodulin or to cease to use Remodulin in favor of alternative treatments.**

Sepsis is a serious and potentially life-threatening infection of the bloodstream caused by a wide variety of bacteria. Intravenous prostacyclins are infused continuously through a catheter placed in patients' chests, and sepsis is an expected consequence of this type of delivery. As a result, sepsis is included as a risk in both the Remodulin and Flolan package inserts. The Flolan package insert specifically documents the risk rate of sepsis at 0.32 events per patient per year, meaning one patient out of every three taking the drug is expected to have a sepsis infection each year. Or, each patient on Flolan is expected to have one sepsis infection every three years. The Remodulin package insert notes that two of 38 patients experienced catheter-related infections in an open-label 12-week study, but does not provide any data relating to expected risk rate. Historical data on intravenous prostacyclin administration does not identify the specific types of bacteria responsible for these infections.

In February 2007, the Scientific Leadership Committee (SLC) of the Pulmonary Hypertension Association announced new guidance relating to the treatment of PAH patients on long-term intravenous therapy. The SLC guidance was issued in response to the release of a slide presentation prepared by researchers with the U.S. Centers for Disease Control and Prevention (CDC) entitled "*Bloodstream infections among patients treated with intravenous epoprostenol and intravenous treprostinil for pulmonary arterial hypertension, United States 2004—2006*". These slides accompanied a presentation to the SLC and may subsequently be published as a report in the CDC's *Morbidity and Mortality Weekly Report*. The slides were prepared in connection with a CDC retrospective inquiry at seven centers into a report of increased blood stream infections, particularly gram-negative blood stream infections, among PAH patients treated with intravenous Remodulin as compared to intravenous Flolan. The SLC guidance statement noted that the CDC observations were hypothesis-generating and did not permit definitive or specific conclusions. The SLC reminded physicians of the need to be aware of the range of possible gram negative and gram positive infectious organisms in patients with long-term central catheters and to treat them appropriately. In response to the SLC guidance statement, we are planning to commence a multi-center, multi-national, multi-year and multi-agent prospective study to scientifically test the hypothesis of whether there are differences in the risk of sepsis and sepsis sub-types among parenterally-delivered prostanoids. We anticipate this study to enroll several hundred patients, which enrollment is expected to commence later this year. We also plan to coordinate a working group with the Pulmonary Hypertension Association and physicians and nurses, along with its network of specialty distributors and home health care providers, to develop unified best practice recommendations related to the chronic administration of IV prostanoids via central venous catheters. Finally, we will revise Remodulin package labeling to more fully describe the known infection risk and appropriate technique that should be practiced when preparing and administering Remodulin intravenously.

Although the risk of sepsis is currently included in the Remodulin label, and the occurrence of sepsis is familiar to physicians who treat PAH patients, concern about bloodstream infections may adversely impact physicians' prescribing practices in regard to Remodulin. If that occurs, Remodulin sales could suffer and our profitability could be adversely impacted.



**We have limited experience with production and 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 with reliance on third parties for certain raw and advanced intermediate materials.

The OvaRex material that is currently being used in our studies was made by a contract manufacturer and will expire in early 2008. In 2007, we plan to make the OvaRex antibody for the first time ourselves, in our new Silver Spring laboratory. Biological drugs are generally the most complex drugs to manufacture, and we have never attempted to manufacture them in-house before. After we manufacture our own OvaRex, we must then demonstrate that it is comparable to the drug used in the Phase III clinical trials. Even if our OvaRex trials are successful, we will not be able to obtain approval for OvaRex unless we can demonstrate that the OvaRex antibody we manufacture is comparable to the drug used in the trials. If we cannot demonstrate the comparability prior to the expiration date, then we may have to repeat the OvaRex trials with the new drug that we manufacture. Although the laboratory is completed and is occupied by our personnel, we are still performing test runs and finalizing procedures for our developmental production runs prior to our process scale-up and validation production runs of OvaRex. In addition, we are working with our builders to complete or repair certain aspects of the laboratory. We hope to commence process scale-up and validation production of the OvaRex antibody in early 2007.

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 conducting stability studies on Remodulin, formulating treprostinil for inhalation use, formulating tablets for the oral clinical trials, and analyzing 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 and devices for use in trials.

Although there are few 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 and process validation could delay clinical studies, regulatory submissions and commercialization of our products;
- A long lead time is needed to manufacture treprostinil and Remodulin, and the manufacturing process is complex;
- We and the manufacturers and formulators of our products are subject to the FDA's and international drug regulatory authorities' good manufacturing practices regulations and similar international 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 and formulators of our products comply with the FDA's and international drug regulatory authorities' good manufacturing practices regulations and similar international standards, the sterility and quality of the products being manufactured and formulated may be deficient. If this occurred, such products would not be available for sale or use;

- If we have to change to another manufacturing or formulation contractor for any reason or abandon our own manufacturing operations, the FDA and international drug regulators would require new testing and compliance inspections, and the new manufacturer would have to be educated in the processes necessary for the validation and production of the affected product. We were recently notified that Cardinal Health intends to sell its formulation business and there can be no assurances that a purchaser of this business will continue formulating treprostinil for both our inhalation and oral clinical trials;
- We may not be able to develop or commercialize our products, other than Remodulin, as planned or at all and may have to rely solely on internal manufacturing capacity;
- We are transferring our entire drug laboratory operations to the Silver Spring, Maryland facility we recently 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 international drug regulators will require new testing and compliance inspections for approval of the facility, and this could result in delays;
- The supply of raw and advanced intermediate materials and components used in the manufacture and packaging of treprostinil, 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 and international drug regulators before any manufactured product can be sold. The timing of such FDA and international drug regulatory approval is difficult to predict and approvals may not be timely obtained;
- Without substantial experience in operating our new production facility, we may not be able to successfully produce treprostinil 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 international 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 and international drug regulators for a product, that product cannot be sold, and our revenues will suffer.

We are conducting a Phase III clinical study of Viveta, an inhaled formulation of treprostinil, and Phase II/III clinical studies of an oral formulation of treprostinil. Our lead glycobiology antiviral agent, UT-231B, completed a Phase II, proof-of-concept study in late 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 are also currently conducting two identical Phase III pivotal studies of OvaRex for the treatment of advanced 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: immediate release 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;
- 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 international regulatory authorities have substantial discretion in the approval process. The FDA and international 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 international 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 international regulation. While we have developed and instituted corporate compliance programs, we cannot ensure that we or our employees are or will be in compliance with all potentially applicable federal, state and international 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 and all of the other products in the prostacyclin platform, 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. We have also obtained licenses to other third-party technology to conduct our business. 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 terminates its assignment agreement or Pfizer 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, 2006, sales of Remodulin accounted for approximately 96% 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 market 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 market 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 Industries the conditional right to approve our North American distributor, establishing a conditional restricted non-competition clause, and requiring minimum annual sales in order to maintain our exclusive rights to beraprost, although we are currently negotiating with Toray Industries to restate some of these provisions. The restrictions that we have accepted in our license and assignment agreements affect our freedom to develop and market our products in the future.

**If our, or our suppliers', 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 PAH 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 2016 to 2022. 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 under the Hatch-Waxman Act in the United States. 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. In addition, if our suppliers' intellectual property protection is inadequate, our sales and profits could be adversely affected.

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 international 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. While we have recently settled pending litigation against two parties related to our arginine patents, we may in the future choose to initiate litigation against other parties who we come to believe have violated our patents or other proprietary rights. If such litigation is unsuccessful or if the patents are invalidated or canceled, we may have to write off the related intangible assets which 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 Chief Financial Officer and Treasurer, John Ferrari; 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, Ph.D.; our Senior Vice President for Pharmaceutical Development, David Zaccardelli, PharmD; 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, although we do incentivize them to remain employed by the company until age 60 through our Supplemental Executive Retirement Plan. 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. Few individuals possess expertise in the field of cardiovascular medicine, infectious disease and oncology, 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 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 properties 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 and we are expanding these activities to new locations. 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 in order to comply with current or future environmental laws and regulations, and substantial fines and penalties for failure to comply with those 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 costs associated with the cleanup of any release of hazardous materials, 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.

#### **Risks Related to Our Common Stock**

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

The market prices for securities of pharmaceutical and biotechnology companies, including our company, are highly volatile, and there are significant price and volume fluctuations in the market that may be unrelated to particular companies' operating performances. 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;
- The pace of enrollment in and the results of clinical trials;
- Physician, patient, investor or public concerns as to the efficacy and/or safety of products marketed or being developed by us or by others;
- Changes in or new legislation and regulations affecting reimbursement of Remodulin by Medicare or Medicaid and changes in reimbursement policies of private health insurance companies;

- 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;
- Future sales of common stock by our directors and officers;
- Failure to maintain approvals to sell Remodulin;
- The adoption of significant short positions in our common stock by hedge funds or other significant investors or the accumulation of our stock by hedge funds or other institutional investors with investment strategies that may lead to short-term holdings;
- 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. Three of our four executive officers have announced their adoption of 10b5-1 prearranged trading plans. In accordance with these plans, these executives periodically sell a specified number of our shares of common stock either owned by them or acquired through the exercise of stock options. However, our executives and 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 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.

Furthermore, the conversion of some or all of our 0.50% convertible secured notes due 2011 (Convertible Notes) after our stock price reaches \$105.67 per share will dilute the ownership interests of our existing stockholders. We have filed a resale registration statement covering sales of such shares. The Convertible Notes initially are convertible into an aggregate of 3.3 million shares of our common stock. Any sales in the public market of our common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock. In addition, the existence of the Convertible Notes may encourage short selling by market participants because the conversion of the Convertible Notes could depress the price of our common stock.

**The Convertible Note Purchase Call Option and call warrant transactions we entered into in connection with the sale of the Convertible Notes may affect the trading price of our common stock.**

In connection with the issuance of the Convertible Notes, we entered into a privately-negotiated convertible note hedge transaction with Deutsche Bank AG London, which is expected to reduce the potential dilution to our common stock upon any conversion of the Convertible Notes. We also entered into a warrant transaction with Deutsche Bank AG London with respect to our common stock pursuant to which we may issue shares of our common stock. In connection with hedging these transactions, Deutsche Bank AG London or its affiliates were expected to enter into various over-the-counter derivative transactions with respect to our common stock at, and possibly after, the pricing of the Convertible Notes and may have purchased or may purchase shares of our common stock in secondary market transactions

following the pricing of the Convertible Notes. These activities could have had, or could have, the effect of increasing the price of our common stock. Deutsche Bank AG London or its affiliates are likely to modify their hedge positions from time to time prior to conversion or maturity of the Convertible Notes by purchasing and selling shares of our common stock, other of our securities or other instruments it may wish to use in connection with such hedging. The effect, if any, of any of these transactions and activities on the market price of our common stock or the Convertible Notes will depend in part on market conditions and cannot be ascertained at this time, but any of these activities could adversely affect the value of our common stock (including during any period used to determine the amount of consideration deliverable upon conversion of the Convertible Notes).

**The fundamental change purchase feature of the Convertible Notes may delay or prevent an otherwise beneficial attempt to take over our company.**

The terms of the Convertible Notes require us to purchase the Convertible Notes for cash in the event of a fundamental change. A takeover of our company would trigger the requirement that we purchase the Convertible Notes. This may have the effect of delaying or preventing a takeover of our company that would otherwise be beneficial to investors.

**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.

**We will need cash to pay at least a portion of the conversion value of the Convertible Notes, as required by the indenture governing the notes.**

At least a portion of the repayment of the Convertible Notes will be required to be made in cash. Our product development plans and product offerings could be negatively impacted if we do not have sufficient financial resources, or are not able to arrange suitable financing, to pay required amounts upon conversion or tender of the notes and fund our operations.

**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 11.3% of our outstanding common stock as of December 31, 2006, 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 headquarters office in Silver Spring, Maryland, and two offices in Satellite Beach, Florida. We also own four buildings adjacent to our corporate headquarters in Silver Spring, Maryland. We lease our completed laboratory facility in Silver Spring, Maryland, which will be used for the production of treprostinil-based compounds and the OvaRex antibody. In June 2006, we purchased approximately 54 acres of land in Research Triangle Park, North Carolina, which will be used to build a new office and manufacturing facility. The manufacturing facility will formulate oral treprostinil and the office will be used by our clinical development and Remodulin commercialization staff currently occupying leased space in the area. We anticipate that this building project will begin in early 2007. In addition, we intend to begin construction on a new combination office and laboratory building which will connect to the existing laboratory building in Silver Spring in mid-to-late 2007. In January 2007, we settled on a contract to purchase additional land and a building adjacent to our leased legal and governmental affairs office in Washington, D.C. Our original office in Satellite Beach, Florida, is scheduled for demolition in early 2007 as a condition of the building permit approval we received for the new office adjacent to this property. The land will be returned to its natural state. We also lease laboratory and office space in Chicago, Illinois, where the bulk active ingredient in Remodulin is synthesized. This facility is scheduled to close in May 2007, after all of its operations have been transferred to the Silver Spring laboratory. Our subsidiary, Lung Rx, Inc., occupies the owned 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 space in Melbourne, Florida and one of the offices in Silver Spring, Maryland 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 and 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 Global Select Market under the symbol "UTHR". The table below sets forth the high and low closing prices for the common stock for the periods indicated:

	2006		2005	
	High	Low	High	Low
January 1 – March 31	\$ 71.33	\$ 61.57	\$ 45.82	\$ 41.37
April 1 – June 30	\$ 66.61	\$ 47.96	\$ 57.10	\$ 44.21
July 1 – September 30	\$ 59.60	\$ 50.69	\$ 73.90	\$ 48.06
October 1 – December 31	\$ 62.17	\$ 51.12	\$ 77.82	\$ 60.46

As of February 20, 2007, there were 74 holders of record of common stock. We estimate that included within the holders of record are approximately 7,100 beneficial owners of common stock. As of February 21, 2007, the closing price for the common stock was \$58.07.

#### Dividend Policy

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

#### Recent Sales of Unregistered Securities; Use of Proceeds from Unregistered Securities

On October 30, 2006, we closed the sale of \$250.0 million aggregate principal amount (after giving effect to the exercise in full by the initial purchaser, Deutsche Bank Securities Inc. (Deutsche Bank), of its over-allotment option) of 0.50% Convertible Senior Notes due October 15, 2011. United Therapeutics offered and sold the Convertible Notes to Deutsche Bank in reliance on the exemption from registration provided by Section 4(2) of the Securities Act. Deutsche Bank then sold the Convertible Notes to qualified institutional buyers pursuant to the exemption from registration provided by Rule 144A under the Securities Act. The Convertible Notes pay interest semiannually at a rate of 0.50% per annum, beginning October 30, 2006. Net proceeds to United Therapeutics in the offering, after deducting Deutsche Bank's discount and commission and estimated expenses, were approximately \$242.0 million.

United Therapeutics used approximately \$35.4 million of the net proceeds of the offering to pay the net cost of certain convertible note hedge and warrant transactions entered into in connection with the offering, consisting of a call in favor of United Therapeutics and a warrant issued to an affiliate of Deutsche Bank. These transactions are intended to reduce the potential dilution to United Therapeutics' common stock upon any conversion of the Convertible Notes. United Therapeutics used approximately \$112.4 million of the net proceeds of the offering to repurchase, concurrently with the closing of the offering, approximately 1.8 million outstanding shares of its common stock in privately-negotiated transactions at the closing price of the common stock on October 24, 2006, of \$62.17. See Stock Repurchases below. The remainder of the net proceeds is used for general corporate purposes.

The Convertible Notes are convertible into cash and shares of United Therapeutics common stock, if any, prior to the close of business on July 15, 2011, under the following circumstances: (1) during any calendar quarter commencing after the date of original issuance of the Convertible Notes, if the closing sale price of United Therapeutics common stock for at least 20 trading days in the period of 30 consecutive trading days ending on the last trading day of the calendar quarter preceding the quarter in which the

conversion occurs is more than 120% of the conversion price of the Convertible Notes in effect on that last trading day; (2) during the ten consecutive trading-day period following any five consecutive trading-day period in which the trading price for the Convertible Notes for each such trading day was less than 95% of the closing sale price of United Therapeutics common stock on such date multiplied by the then current conversion rate; or (3) if United Therapeutics makes specific significant distributions to holders of United Therapeutics common stock, United Therapeutics enters into specified corporate transactions, or the United Therapeutics common stock ceases to be approved for listing on The NASDAQ Global Select Market and is not listed for trading on another U.S. national or regional securities exchange. The Convertible Notes are convertible after July 15, 2011 irrespective of the satisfaction of any of the foregoing conditions. The initial conversion rate will be 13.2933 shares of United Therapeutics stock per \$1,000 principal amount of Convertible Notes, which is equivalent to an initial conversion price of \$75.2257 per share of United Therapeutics common stock. The Convertible Notes provide for “net share settlement” of any conversions, meaning that, upon any conversion, United Therapeutics will pay the noteholder an amount in cash equal to the lesser of the conversion value or the par value of the Convertible Notes and will settle any excess of the conversion value above the par value of the Convertible Notes in United Therapeutics common stock.

Holders of the Convertible Notes who convert their notes in connection with a qualifying change in control, as defined in the related indenture, may be entitled to a make-whole premium in the form of an increase in the conversion rate. Additionally, following the occurrence of a fundamental change as defined in the related indenture holders may require that United Therapeutics repurchase some or all of the Convertible Notes for cash at a repurchase price equal to 100% of the principal amount of the notes being repurchased, plus accrued and unpaid interest, if any.

United Therapeutics has filed a shelf registration statement covering resales of the Convertible Notes and the shares of United Therapeutics common stock issuable upon conversion of the Convertible Notes.

## Stock Repurchases

<u>Period</u>	<u>Total Number of Shares Purchased</u>	<u>Average Price Paid per Share</u>	<u>Total Number of Shares</u>	<u>Maximum Number of Shares That May yet be</u>
			<u>Purchased as Part of Publicly Announced Program</u>	<u>Purchased Under the Program(1)</u>
October 1 – October 31	1,808,809(1)	\$ 62.17	1,808,809	2,191,191
November 1 – November 30	0	N/A	N/A	2,191,191
December 1 – December 31	55,000(1)	\$ 55.55	55,000	2,136,191
Total	<u>1,863,809</u>	<u>\$ 55.36</u>	<u>1,863,809</u>	<u>N/A</u>

- (1) On October 17, 2006, the Board of Directors of United Therapeutics authorized the company to repurchase up to 4.0 million shares prior to October 17, 2008. On October 30, 2006, United Therapeutics purchased 1,808,809 shares of its outstanding common stock under this share repurchase program in a privately-negotiated transaction at a per share price of \$62.17.

**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,				
	2006	2005	2004	2003	2002
<b>Consolidated Statements of Operations Data:</b>					
Revenues	\$ 159,632	\$ 115,915	\$ 73,590	\$ 53,341	\$ 30,120
Operating expenses:					
Research and development	57,570	36,052	30,713	35,417	26,778
Selling, general and administrative	54,028	24,655	21,418	22,667	15,889
Impairment of HeartBar <sup>®</sup> trade name	2,024	—	—	—	—
Cost of sales	17,028	12,315	8,250	6,783	5,456
Total operating expenses	130,650	73,022	60,381	64,867	48,123
Income (loss) from operations	28,982	42,893	13,209	(11,526)	(18,003)
Other income (expense):					
Interest income	10,700	5,359	2,986	2,435	4,954
Interest expense	(482)	(29)	(4)	(112)	(117)
Equity loss in affiliate	(491)	(754)	(785)	(953)	(209)
Write-down of investment	—	—	—	—	(2,893)
Loss on marketable investments	—	—	—	—	(7,428)
Other, net	1,199	53	43	187	45
Total other income (expense), net	10,926	4,629	2,240	1,557	(5,648)
Net income (loss) before income tax	39,908	47,522	15,449	(9,969)	(23,651)
Income tax benefit	34,057	17,494	—	—	—
Net income (loss)	<u>\$ 73,965</u>	<u>\$ 65,016</u>	<u>\$ 15,449</u>	<u>\$ (9,969)</u>	<u>\$ (23,651)</u>
Net income (loss) per share:					
Basic(1)	<u>\$ 3.21</u>	<u>\$ 2.85</u>	<u>\$ 0.71</u>	<u>\$ (0.47)</u>	<u>\$ (1.15)</u>
Diluted(1)	<u>\$ 3.06</u>	<u>\$ 2.58</u>	<u>\$ 0.66</u>	<u>\$ (0.47)</u>	<u>\$ (1.15)</u>
Weighted average number of common shares outstanding:					
Basic	<u>23,010</u>	<u>22,825</u>	<u>21,726</u>	<u>21,135</u>	<u>20,644</u>
Diluted	<u>24,138</u>	<u>25,206</u>	<u>23,351</u>	<u>21,135</u>	<u>20,644</u>
	Years Ended December 31,				
	2006	2005	2004	2003	2002
<b>Consolidated Balance Sheet Data:</b>					
Cash, cash equivalents and marketable investments (2)	\$ 303,151	\$ 191,013	\$ 139,140	\$ 117,337	\$ 132,655
Total assets	478,550	291,413	207,158	179,502	184,566
Notes and leases payable(3)	250,025	23	26	798	1,878
Accumulated deficit	(41,360)	(115,325)	(180,341)	(195,790)	(185,821)
Total stockholders’ equity	204,606	275,102	191,636	167,765	171,658

- (1) See Note 2 of Notes to Consolidated Financial Statements for a description of the computation of basic and diluted net income per share.
- (2) Includes restricted marketable investments and cash of \$38,988, \$20,606 and \$10,121 for the years ending December 31, 2006, 2005 and 2004, respectively.
- (3) Includes current portion of notes and leases payable.

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

The following discussion should be read in conjunction with the consolidated financial statements and related notes appearing 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 SEC. 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, a prostacyclin analog. Our prostacyclin analog acts as 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) for the treatment of pulmonary arterial hypertension (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.

As a condition of Remodulin's Subpart H approval, we were required to perform a post-marketing Phase IV clinical study to confirm the clinical benefits of Remodulin. In August 2005, we performed an interim assessment after 22 patients completed the Phase IV study. The results of the interim assessment, as analyzed by an independent statistician, were positive. The p value was 0.0002, meaning the likelihood that the achieved result was incorrect was two out of ten thousand. Specifically, 13 of the 14 patients (93%) receiving Remodulin were able to successfully transition from Flolan, the other FDA-approved intravenous prostacyclin, which they had previously been using to treat their condition. These patients were able to complete the study without the need to return to Flolan. In contrast, 1 of the 8 patients (13%) successfully transitioned without clinical deterioration during the eight-week period from Flolan to placebo. Based on this positive outcome, we submitted the interim study results to the FDA in July 2005 with a supplement filed in October 2005. In March 2006, the FDA agreed that we had satisfied our obligation to perform the post-marketing Phase IV clinical study and that the study confirmed the clinical benefits of Remodulin.

In November 2004, the FDA approved intravenous (through a vein or artery) infusion of Remodulin for patients who are not able to tolerate subcutaneous infusion. This approval was based on data establishing the bioequivalence of intravenous with subcutaneous Remodulin. In March 2006, the FDA also approved the use of Remodulin for patients requiring transition from Flolan. Remodulin has been approved for intravenous use in Canada, Israel, Mexico, Argentina and Peru. Marketing authorization applications are currently under review in other countries.

Remodulin is approved for subcutaneous use in 32 countries throughout the world. 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. We anticipate resubmitting our application with these three countries at the same time we file our application for intravenous Remodulin approval. Licenses and pricing approvals have been received in most European Union countries, with the remainder expected during 2007. We have filed a variation to our license for approval of intravenous Remodulin through the mutual recognition process. Currently, our application is under review in France, our reference member state in the mutual recognition process.

We have generated revenues from sales of Remodulin and arginine royalties and 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 in the United States with abnormal heart rhythms, called cardiac arrhythmias, and ischemic heart disease, a condition that causes poor blood flow to the heart. We have funded our operations from the proceeds of sales of our common stock and from revenues generated from the sales of our products and services.

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

Remodulin is currently marketed by our own internal marketing staff, which was made up of approximately 20 employees as of December 31, 2006. Our marketing team interacts directly with physicians and their staff, comprised mainly of cardiologists and pulmonologists, who specialize in treating PAH. We face stiff competition from several other companies that market and sell competing therapies, including large and successful biotechnology companies, 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., which has accepted an acquisition offer by CVS Corp. Express Scripts has also offered to purchase Caremark. If Express Scripts is successful in its attempt to purchase Caremark, the possibility exists that the Remodulin operations of CuraScripts and Caremark could be combined. Remodulin is distributed outside of the United States by various international distributors. We sell Remodulin in bulk shipments to our distributors. The U.S.-based distributors typically place one order per month, usually prior to the middle of the month. The timing and magnitude of our sales of Remodulin are impacted by the timing and volume of these bulk orders from distributors. Bulk orders placed by our distributors are based on their estimates of the amount of drug required for current and newly starting patients, as well as maintaining an inventory that can meet approximately thirty to sixty days' demand as a contingent supply. Effective January 1, 2007, all of the U.S.-based distributors' minimum inventory requirement must be 30 days. This inventory must be maintained in accordance with the distributors' contractual obligations, because discontinuation of therapy can be life-threatening to patients. Because of the contractual requirements for inventory maintenance, sales of Remodulin to distributors in any given quarter may not be indicative of patient demand in that quarter. In addition, inventory levels reported by distributors are impacted by the timing of their sales around the end of the reporting period. Sales of Remodulin and associated pumps and supplies are recognized as revenue when delivered to our distributors.

Effective July 1, 2006, United Therapeutics increased the selling price of Remodulin to its U.S.-based distributors. The price was increased approximately 3.5% to \$67.25 per milligram, and applies to sales of Remodulin made on or after July 1, 2006.

### ***Remodulin Manufacturing***

We are in the process of transferring our treprostinil manufacturing operations from Chicago, Illinois, to our new facility in Silver Spring, Maryland. This transfer is expected to be completed during the first half of 2007. Historically, we have made treprostinil beginning with basic compounds that were either manufactured by us or purchased from vendors, advancing these compounds through a complex chemical synthesis process. We will be modifying our manufacturing process for treprostinil in our new facility to begin instead with advanced intermediate compounds. Advanced intermediate compounds are those compounds that are typically found at the later stages of our manufacturing process. This change is being made to address anticipated future demand for treprostinil in both our clinical and commercial programs. We have approved three vendors that have a greater manufacturing capacity to make these intermediate compounds than we have. These vendors also have the ability to manufacture these compounds less expensively than if we did so ourselves. As a result, we have begun receiving bulk shipments of these intermediate compounds from these vendors. To the extent that these intermediate compounds will be used for research and development programs, the cost of these compounds will be expensed when received. Intermediate compounds that will be used for commercial purposes will be placed into raw materials inventory.

We anticipate that upon commercialization of oral treprostinil, the need for treprostinil diethanolamine, its active ingredient, will be greater than the need for treprostinil sodium, the active ingredient for Remodulin and Viveta. As a result, the manufacturing process at the Silver Spring facility will consist of starting with the advance intermediate compound, making treprostinil diethanolamine and then converting that compound to treprostinil. We believe that this will allow us the most flexibility and efficiency to meet future demands for both forms of active ingredients.

### ***Future Prospects***

While we have been profitable in each quarter since April 1, 2004; we incurred net losses for all quarters from inception through March 31, 2004. At December 31, 2006, we had an accumulated deficit of approximately \$41.4 million. Future profitability will depend on many factors, including the price, level of sales, level of reimbursement by public and private insurance payers, the impact 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 treprostinil 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, Dengue Fever, and Japanese encephalitis.

### ***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. Material net cash inflows from the sales of Remodulin for PAH commenced in May 2002 after we received FDA approval.

Remodulin is also approved in 32 countries throughout the world for similar uses. Marketing authorization applications are currently under review in other countries.

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 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, a panel of independent experts. Preliminary results from the 45 patients were positive ( $p=0.008$ ). After 12 weeks, patients who took Remodulin walked, on average, 83 meters further in a six-minute time period than patients who took a placebo. The six-minute walk test is a typical benchmark test of cardiovascular health.

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 April 2004, the European Medicines Agency granted an orphan designation of inhaled treprostinil for the treatment of PAH and chronic thromboembolic pulmonary hypertension. In June 2005, Lung Rx, Inc., a wholly-owned subsidiary of ours, commenced a 12-week placebo-controlled trial of inhaled treprostinil in at least 150 patients with PAH who are also being treated with Tracleer. During the trial, dosing will be escalated to patient tolerance or a maximum equivalence of 45 micrograms per session. The primary end point of the trial is peak six minute walk improvement. Additional centers are being added to the study. This trial, TRIUMPH-1, **T**reprostinil **I**nhalation **U**sed in the **M**anagement of **P**ulmonary **H**ypertension, is currently being conducted at approximately 36 centers in the United States and Europe. In May 2006, the FDA agreed to permit the inclusion of patients with PAH who are also being treated with Revatio, to expand the trial size to at least 200 patients, and to permit the assessment of efficacy after 150 patients have completed the trial. We do not intend to conduct this interim efficacy assessment. As a result, the TRIUMPH-1 trial is expected to conclude when 200 evaluable patients have completed the study, which is expected upon the enrollment of approximately 220 patients overall. As of December 31, 2006, approximately 155 patients had been enrolled in this trial. As of February 20, 2007, approximately 175 patients have been enrolled in this trial.

We are developing an oral formulation of treprostinil, treprostinil diethanolamine. During 2004, we completed dosage studies of oral formulations of treprostinil in healthy volunteers. We filed an Investigational New Drug Application in January 2005 to perform an additional Phase I healthy volunteer study. In July 2005, the European Medicines Agency announced that oral treprostinil had been granted orphan product status in the European Union. Drugs with orphan status generally receive priority review of approval applications and may receive longer periods of protection against competition from generic drugs. Using technology licensed from Supernus Pharmaceuticals, Inc., we have developed a sustained released formulation of oral treprostinil which achieves level blood concentrations of treprostinil, similar to that achieved with our subcutaneous and infusion therapies, for between 8 and 10 hours in normal volunteers. This supports a two times a day dosing regimen in the ongoing clinical studies.

Two multi-national placebo-controlled clinical trials of oral treprostinil in patients with PAH commenced in October 2006. These trials are a combination of Phase II and Phase III trials, in which both dosing and efficacy will be studied. During the trials, dosing will be escalated to patient tolerance or a maximum equivalence of 80 nanograms per kilogram. One trial, FREEDOM-C, is a 16-week study of up to 300 patients, with an interim assessment at 150 patients, currently on background therapy using Revatio or Tracleer or a combination of both. The second trial, FREEDOM-M, is a 12-week study of up to 150 patients with an interim assessment at 90 patients, who are not on any background therapy. Both trials will be conducted at approximately 50 centers in the United States and the rest of the world. As of December 31, 2006, there were 35 and 10 patients enrolled in FREEDOM-C and FREEDOM-M, respectively. As of February 20, 2007, there were 52 and 20 patients enrolled in FREEDOM-C and FREEDOM-M, respectively.

We are also developing a sustained release formulation of beraprost, an oral analog of prostacyclin, for PAH. We are currently awaiting receipt of clinical trial materials from our license partner, Toray



Industries, and are in the process of negotiating with Toray Industries to restate our license agreement for this development program.

We incurred expenses of approximately \$33.0 million, \$20.1 million, and \$16.2 million during the years ended December 31, 2006, 2005 and 2004, respectively, on Remodulin development. Approximately \$193.9 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 is our lead product and is currently being studied in two identical Phase III clinical trials in advanced ovarian cancer (Stage III and IV) patients. In January 2003, we initiated two identical Phase III pivotal clinical trials of OvaRex called IMPACT I and II. Patients enrolled in these studies have successfully completed front-line therapy, consisting of surgery and chemotherapy. We are conducting these studies at approximately 60 centers throughout the United States. In June 2006, these trials were fully enrolled with 367 patients. The primary endpoint for these trials is the difference in time to disease relapse between patients treated with OvaRex and patients receiving a placebo. The study will not be stopped and the results obtained until each study has reached at least 118 relapse events. Following relapse, patients will also be followed to assess survival rate. As of December 31, 2006, the reported number of relapse events was 122 and 97, respectively, in each of the trials. We incurred expenses of approximately \$10.5 million, \$8.7 million, and \$7.3 million during the years ended December 31, 2006, 2005 and 2004, respectively, on OvaRex development. Approximately \$42.9 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 a wide variety of viruses. We completed acute and chronic Phase I clinical dosing studies using UT-231B, for the treatment of hepatitis C, 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 these glycobiology drug candidates. We incurred expenses of approximately \$753,000, \$3.2 million, and \$3.3 million during the years ended December 31, 2006, 2005 and 2004, respectively, for our infectious disease programs. Approximately \$35.7 million from inception to date has been incurred for infectious disease programs.

### ***Project Risks***

Due to the inherent uncertainties involved in the drug development, regulatory review and approval processes, the anticipated completion dates, the cost of completing the research and development and the period in which material net cash inflows from these projects are expected to commence are not known or estimable. There are many risks and uncertainties associated with completing the development of the 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 or ourselves may reduce the number of patients available for our studies;
- Patients may not enroll in the studies at the rate we expect;
- The FDA, international regulatory authorities or local internal review boards may delay or withhold approvals to commence clinical trials or to manufacture drugs;
- The FDA or international 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 could be delayed and our operations, liquidity and financial position could suffer. Without regulatory approvals, we cannot commercialize and sell these products and, therefore, potential revenues and profits from these products could be delayed or impossible to achieve.

### **Financial Position**

Cash, cash equivalents and marketable investments (including all unrestricted and restricted amounts and all amounts classified as current and non-current) at December 31, 2006, were approximately \$303.2 million, as compared to approximately \$191.0 million at December 31, 2005. The increase of approximately \$112.2 million was due primarily to the net proceeds after repurchase of our common stock from the issuance of Convertible Senior Notes of approximately \$94.6 million. Restricted marketable investments and cash pledged to secure our obligations under the synthetic operating lease (discussed below under *Off Balance Sheet Arrangement* ) at December 31, 2006, totaled approximately \$39.0 million, as compared with approximately \$20.7 million at December 31, 2005.

Accounts receivable, net of allowances at December 31, 2006, were approximately \$22.5 million, as compared to approximately \$13.9 million at December 31, 2005. The increase was due primarily to increased sales of Remodulin.

Prepaid expenses and other current assets at December 31, 2006, were approximately \$9.2 million, as compared to approximately \$6.4 million at December 31, 2005. The increase was primarily due to the prepayment of assets to be used in operations during 2007.

Property, plant and equipment at December 31, 2006, were approximately \$34.7 million as compared to \$21.8 million at December 31, 2005. The increase was due to the purchase of land and a building adjacent to our Silver Spring, Maryland, headquarters in May 2006 for approximately \$1.8 million, the purchase of land in Research Triangle Park, North Carolina, in June 2006 for approximately \$3.2 million, pre-construction costs on our facility projects in Maryland and North Carolina of approximately \$3.9 million, and the purchase of laboratory equipment for the new laboratory facility in Silver Spring, Maryland, of approximately \$4.1 million.

Other intangible assets, net, at December 31, 2006 were approximately \$3.1 million, as compared to approximately \$5.5 million at December 31, 2005. The decrease was due primarily to the \$2.0 million impairment write-down of the HeartBar trade name, as commercial activities for that product were discontinued in January 2006.

Investments in affiliates at December 31, 2006, were approximately \$4.7 million, as compared to approximately \$8.3 million at December 31, 2005. The decrease was due primarily to a decline in the fair market value of our investment in ViRexx Medical Corp. (formerly AltaRex Medical Corp.), which we mark to market, based on quoted market prices since the investment is classified as an available-for-sale security..

Other assets at December 31, 2006, were approximately \$8.9 million as compared to \$988,000 at December 31, 2005. The increase was primarily due to capitalizing of offering costs and fees of approximately \$7.7 million related to the issuance of our offering of \$250.0 million aggregate principal amount of Convertible Senior Notes, net of amortization during the year.

Deferred tax assets (including amounts classified as current and non-current) at December 31, 2006, were approximately \$69.6 million, as compared to approximately \$19.7 million at December 31, 2005. The increase was due to the reduction of approximately \$45.7 million of the valuation allowance on most of our deferred tax assets in 2006.

Accrued expenses at December 31, 2006, were approximately \$15.3 million, as compared to approximately \$10.4 million at December 31, 2005. The increase was due primarily to an increase in accrued expenses for royalty fees of approximately \$1.6 million, and an increase in accrued bonuses of approximately \$2.2 million. Prior to 2006, employee bonuses were paid in June and December of each year. In 2006, we changed the payment dates to September for the mid-year bonuses and March for the year-end bonuses.

Other current liabilities at December 31, 2006, were approximately \$882,000, as compared to none at December 31, 2005. The amount represents the remaining balance of a final draw received in May 2006 from Wachovia Development Corporation under the synthetic operating lease agreements to fund the remaining cost of constructing the laboratory facility in Silver Spring, Maryland.

Notes payable increased approximately \$250.0 million during 2006 due to the issuance of \$250.0 million aggregate principal amount of Convertible Senior Notes.

Total stockholders' equity at December 31, 2006, was approximately \$204.6 million, as compared to \$275.1 million at December 31, 2005. For the twelve-month period, we repurchased approximately 2.6 million shares of our stock for \$157.7 million and paid a net cost of \$35.4 million for the derivative note hedge and warrant transactions entered into in connection with the issuance of the Convertible Senior Notes. These costs were offset by approximately \$74.0 million of net income, \$14.4 million of proceeds from stock option exercises, \$11.3 million from the recognition of a tax benefit related to the use of net operating losses attributable to stock option deductions, and \$24.1 million from the recognition of stock option expense.

## **Results Of Operations**

### ***Years ended December 31, 2006 and 2005***

Revenues for the year ended December 31, 2006, were approximately \$159.6 million, as compared to approximately \$115.9 million for the year ended December 31, 2005. The increase of approximately \$43.7 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,	
	2006	2005
Remodulin	\$ 152,478	\$ 109,191
Telemedicine services and products	6,597	5,773
Other products	557	689
License fees	—	262
Total revenues	<u>\$ 159,632</u>	<u>\$ 115,915</u>

For the year ended December 31, 2006 and 2005, approximately 89% and 90% of our Remodulin revenues, respectively, were earned from our three distributors 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, fees to distributors for services, and prompt pay discounts as well as the net amount of reductions to revenues for these items are presented as follows (in thousands):

	Years Ended December 31,	
	2006	2005
Liability accounts, at beginning of period	\$ 1,590	\$ 2,121
Additions to liability attributed to sales in:		
Current period	9,442	6,789
Prior period	—	—
Payments or reductions attributed to sales in:		
Current period	(7,163)	(5,701)
Prior period	(1,503)	(1,619)
Liability accounts, at end of period	<u>\$ 2,366</u>	<u>\$ 1,590</u>
Net reductions to revenues	<u>\$ 9,442</u>	<u>\$ 6,789</u>

Research and development expenses were approximately \$57.6 million for the year ended December 31, 2006, as compared to approximately \$36.1 million for the year ended December 31, 2005. The increase in expenses was due primarily to increased expenses for treprostinil-related programs of approximately \$12.9 million, primarily in our oral program, the adoption of SFAS No. 123(R) effective January 1, 2006, which resulted in the recognition of employee stock option expense of approximately \$6.7 million, an increase in expenses of approximately \$1.6 million related to stock option expense for option grants to scientific advisory board members, and an increase in spending in our cancer program of approximately \$1.7 million. These increases were offset by a reduction of approximately \$2.5 million in

expenses associated with our infectious disease research program. During 2006, we purchased approximately \$6.5 million of advanced intermediate compounds, which were either used or earmarked for use in the production of clinical trial material for our oral program. Because these compounds are for research and development purposes, they were expensed during the year. See *Major Research and Development Projects* above, for additional information regarding our research programs.

Selling, general and administrative expenses were approximately \$54.0 million for the year ended December 31, 2006, as compared to approximately \$24.7 million for the year ended December 31, 2005. The increase in selling, general and administrative expenses was due primarily to approximately \$14.2 million of employee stock option expense related to our adoption of SFAS No. 123(R). Also contributing to this expense increase were an increase in marketing related expenses of approximately \$6.3 million, representing an increase in marketing staff and marketing initiatives, an increase in non-marketing related salaries (mainly due to an increase in headcount and salary increases) of approximately \$5.0 million and an increase in rent and other operating expenses, primarily due to the opening of the new laboratory facility in Silver Spring, Maryland, of approximately \$2.1 million. In December 2006, Fred Hadeed, our Executive Vice President for Business Development, resigned from his position with the company. In accordance with his employment contract, Mr. Hadeed received a salary payout of two times his annual salary and the average bonus received over the last two years, as well as immediate vesting of all of his unvested stock option grants. As a result, in December, we recognized a cash salary expense of approximately \$1.5 million and a non-cash stock option expense of approximately \$3.9 million, representing 225,000 options which were immediately vested.

An impairment of intangible assets related to the HeartBar product trade name totaling approximately \$2.0 million was recorded during the year ended December 31, 2006. This impairment was required since the HeartBar product was discontinued in January 2006 and is no longer sold. The decision to discontinue HeartBar did not impact other aspects of our arginine business, which includes sales of non-HeartBar arginine products and license royalties from third parties selling arginine based products. We made this decision after evaluating the recent clinical trial results and market potential, among other things.

Cost of product sales was approximately 10% of net product sales for the year ended December 31, 2006, which is consistent with approximately 9% for the year ended December 31, 2005. Cost of service sales was approximately 33% of service sales for the year ended December 31, 2006, as compared to approximately 40% for the year ended December 31, 2005. The improvement in the cost of service sales as a percentage of service revenues was due to the growth in telemedicine service sales during 2006, with no corresponding increase in costs, as a result of staffing and scheduling efficiencies.

Interest income for the year ended December 31, 2006, was approximately \$10.7 million, as compared to interest income of approximately \$5.4 million for the year ended December 31, 2005. The increase was due primarily to an increase in cash available for investing during 2006 and increased market interest rates.

Equity loss in affiliate represents our share of Northern Therapeutics' losses. The equity loss in affiliate was approximately \$491,000 for the year ended December 31, 2006, as compared to approximately \$754,000 for the year ended December 31, 2005. Northern Therapeutics' loss was due primarily to expenditures for its cell-based gene transfer technology research for PAH.

An income tax benefit of approximately \$34.1 million was recognized for the year ended December 31, 2006, as compared to \$17.5 million for the year ended December 31, 2005. The benefit in 2006 was due to an approximately \$45.7 million reduction in the valuation allowance of our deferred tax assets as of December 31, 2006. 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 realized. As a result, a reduction of the valuation allowance related to our net operating loss carry forwards, all of our business credits and other temporary assets was required. The

remaining valuation allowance of approximately \$6.8 million is on those deferred tax assets that need either a capital gain to occur in order to be recognized or profits from our affiliate Northern Therapeutics. Because these events are not likely to occur in the near future, the realizability of these assets is not more-likely-than not and we continue to maintain a valuation allowance. 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. In 2005, we reduced the valuation reserve by approximately \$19.7 million.

***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).

	<b>Revenues for the Years Ended December 31,</b>	
	<b>2005</b>	<b>2004</b>
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% and 87% 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 sales of Remodulin in the United States. 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 attributed to sales in:		
Current period	6,789	7,642
Prior period	—	—
Payments or reductions attributed to sales in:		
Current period	(5,701)	(5,684)
Prior period	(1,619)	(773)
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 U.S.-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 European Union member countries, 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 of \$3.2 million for the Remodulin-related programs and \$1.5 million for the cancer disease programs during the year ended December 31, 2005, as compared to lower expenses for 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. Also contributing were 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' 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' loss was due primarily to expenditures for its autologous (non-viral vector) gene therapy research for PAH 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 carryforwards, 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 totaling approximately \$631,000. Additionally, the use of approximately \$1.6 million of state net operating loss carryforwards were 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.

### **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 May 2002, we have funded our operations from revenues, mainly Remodulin-related, and this is expected to continue. 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"*.

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 was withdrawn in March 2006 and is no longer effective.

Our working capital at December 31, 2006, was approximately \$258.1 million, as compared to approximately \$152.2 million at December 31, 2005.



At December 31, 2006, restricted cash and marketable investments pledged to secure our obligations under the synthetic operating lease (discussed below under *Off Balance Sheet Arrangement*) totaled approximately \$39.0 million, as compared with approximately \$20.7 million at December 31, 2005. The increase in restricted cash and marketable investments was due to additional funds placed in escrow to provide adequate collateral under the lease and also represents interest received on these investments. Approximately \$1.3 million, representing excess funds in escrow, will be taken out of the escrow account in early 2007.

Net cash provided by operating activities was approximately \$61.9 million, excluding the excess tax benefit from stock-based compensation of \$10.8 million, for the year ended December 31, 2006, as compared to approximately \$43.7 million for the year ended December 31, 2005. The increase in cash provided by operating activities was due primarily to growth in sales and collections of Remodulin. For the year ended December 31, 2006, we invested approximately \$15.6 million in cash for property, plant and equipment—mainly for new properties, equipment for the new facility in Silver Spring, Maryland, and pre-construction related expenses, of approximately \$5.0 million, \$4.1 million and \$3.9 million, respectively—as compared to approximately \$6.1 million in the year ended December 31, 2005. For the years ended December 31, 2006 and 2005, we received approximately \$14.4 million and \$15.0 million in stock option exercise proceeds, respectively.

We are currently in the planning phase for building a new approximately 200,000 square foot facility in Research Triangle Park, North Carolina, which will house a manufacturing operation and offices. The manufacturing operation will be for formulating oral treprostinil and the offices will be used by our clinical development and sales and marketing staff, which currently occupies a leased facility in the area. Construction of this facility is expected to begin in early 2007, may cost up to \$100 million, and may take up to two years to complete, although the cost and timetable for construction is still being determined. We expect to fund the construction of this facility from our working capital.

We are also in the planning phase for a new office and laboratory building, which will connect to our current laboratory facility in Silver Spring, Maryland. The building of this facility is anticipated to begin in the latter half of 2007. The costs are still being estimated due to continuing design and related estimation work. We anticipate that the construction of this facility will be financed through a synthetic operating lease.

We made milestone payments totaling \$20,000 pursuant to existing license agreements during each of the years ended December 31, 2006 and 2005. We are obligated to make royalty payments on sales of Remodulin that 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 and up to 20% of arginine royalty payments received.

#### ***Convertible Senior Notes***

On October 30, 2006, we issued \$250.0 million of 0.50% Convertible Senior Notes due October 2011 (the Convertible Senior Notes). Proceeds from the offering, after deducting the initial purchaser's, Deutsche Bank Securities Inc. (Deutsche Bank), discount and commission and estimated expenses were approximately \$242.0 million. The Convertible Senior Notes were issued at par value and pay interest in cash semi-annually in arrears on April 15 and October 15 of each year, beginning on April 15, 2007. The Convertible Senior Notes are unsecured unsubordinated obligations and rank equally with all other unsecured and unsubordinated indebtedness. The Convertible Senior Notes have an initial conversion price of \$75.2257 per share. The Convertible Senior Notes may only be converted: (i) anytime after July 15, 2011; (ii) during any calendar quarter commencing after the date of original issuance of the notes, if the closing sale price of our common stock for at least 20 trading days in the period of 30 consecutive trading days ending on the last trading day of the calendar quarter preceding the quarter in which the conversion

occurs is more than 120% of the conversion price of the notes in effect on that last trading day; (iii) during the ten consecutive trading-day period following any five consecutive trading-day period in which the trading price for the notes for each such trading day was less than 95% of the closing sale price of our common stock on such date multiplied by the then current conversion rate; or (iv) if specified significant distributions to holders of our common stock are made, specified corporate transactions occur, or our common stock ceases to be approved for listing on The NASDAQ Global Select Market and is not listed for trading on another U.S. national or regional securities exchange. Upon conversion, a holder will receive: (i) cash equal to the lesser of the principal amount of the note or the conversion value; and (ii) to the extent the conversion value exceeds the principal amount of the note, shares of our common stock. In addition, upon a change in control, as defined in the indenture under which the Convertible Senior Notes have been issued, the holders may require us to purchase all or a portion of their Convertible Senior Notes for 100% of the principal amount plus accrued and unpaid interest, if any, plus a number of additional shares of our common stock, as set forth in the related indenture. The indenture under which the Convertible Senior Notes were issued contains customary covenants.

Concurrent with the issuance of the Convertible Senior Notes, we purchased call options on our common stock in a private transaction. The call options allow us to receive up to approximately 3.3 million shares of its common stock from counterparties, equal to the amount of common stock related to the excess conversion value that we would pay to the holders of the Convertible Senior Notes upon conversion. These call options will terminate upon the earlier of the maturity dates of the related Convertible Senior Notes or the first day all of the related Convertible Senior Notes are no longer outstanding due to conversion or otherwise. The call options, which cost approximately \$80.8 million, will be recorded as a reduction of shareholders' equity. The cost of call option for tax purposes creates a tax deduction since it is classified as Original Issue Discount (OID). The deduction is considered a permanent difference and as such does not create a deferred tax asset. The benefit of deduction is recorded as an increase to additional paid-in-capital.

In a separate transaction, we sold warrants to issue shares of its common stock at an exercise price of \$105.689 per share. Pursuant to this transaction, warrants for approximately 3.3 million shares of our common stock were issued. If the average price of our common stock during a defined period, ending on or about the respective settlement dates, exceeds the exercise price of the warrants, the warrants will be settled in shares of our common stock. Proceeds received from the issuance of the warrants totaled approximately \$45.4 million and were recorded as an addition to additional paid-in-capital.

We also used approximately \$112.4 million to repurchase approximately 1.8 million outstanding shares of our common stock as part of this transaction. We intend to use the remainder of the net proceeds for working capital or other general corporate purposes, which may include acquisitions, strategic investments or joint venture arrangements.

### ***Stock Repurchases***

In July 2006, in a privately negotiated transaction, we repurchased 766,666 shares of our common stock, par value \$0.01 per share, from Toray Industries for a cash purchase price of approximately \$42.2 million (or \$55.08 per share), pursuant to a stock purchase agreement between Toray Industries and us. The purchase price was the average of the closing prices of our common stock for the 30 consecutive trading days ending on July 26, 2006. Toray Industries retains ownership of 100,000 shares of our common stock.

Due to our desire to return value to our shareholders, on October 17, 2006, our Board of Directors approved a stock repurchase program to repurchase up to 4 million shares of our common stock over a two year period. As of December 31, 2006, a total of approximately 1.9 million shares were repurchased at a cost of approximately \$115.4 million. Approximately 1.8 million shares of our stock were repurchased using approximately \$112.4 million of the net proceeds from the issuance of the Convertible Senior Notes, based on the closing price of the common stock on October 24, 2006 of \$62.17. The remaining shares were repurchased on the open market under a structured repurchase program in which buy orders that are automatically placed at preset prices below the market open of stock. The program has daily share limits as well as quarterly share and/or dollar limits. We may also repurchase shares outside of this program.

### ***Income taxes***

We recognized an income tax benefit of approximately \$34.1 million and \$17.5 million for the years ended December 31, 2006 and 2005, due primarily to our expectation of incurring taxable income during 2006.

At December 31, 2006, we had, for federal income tax purposes, net operating loss carryforwards of approximately \$52.2 million and business tax credit carryforwards of approximately \$46.4 million, which expire at various dates from 2012 through 2024. The majority of the net operating loss carryforwards is attributable to exercised stock options, the benefit of which was realized as direct increases in 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 tax 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 through December 31, 2004 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. We are currently reviewing our ownership change position through December 31, 2006. We do not expect any significant portion of our net operating loss carry forwards or business tax credits to expire unused.

We recognized an income tax benefit of approximately \$34.1 million and \$17.5 million for the years ended December 31, 2006 and 2005, respectively, due primarily to approximately \$45.7 million and \$19.7 million respective reductions in the valuation allowance against our deferred tax assets based on our determination that certain of these deferred tax assets are more likely than not realizable.

### **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 funded \$32.0 million towards the construction of the laboratory facility on land owned by us. The construction phase commenced in 2004 and was completed in May 2006. Following construction, Wachovia leased 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.

Wachovia receives 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 monthly rents commenced when the laboratory construction was completed and will continue 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% of the amount it funded towards the construction.

We pledged a portion of our marketable investments as collateral to secure our lease obligations. At December 31, 2006, approximately \$39.0 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 enabled us to construct our laboratory facility without using our own working capital. There will not be any depreciation expense associated with the laboratory facility, since these improvements are owned by Wachovia. The amount of rent to be paid to Wachovia during the term of the laboratory lease 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.

Rent payments under the laboratory lease commenced in May 2006 after completion of construction and will continue through termination of the lease in May 2011. Upon the completion of the building in May 2006, Wachovia advanced to us the remaining funds available, approximately \$5.2 million for construction due to the lengthy process involved in finalizing construction costs. When the final construction costs have been agreed upon, any remaining funds that were advanced will be returned to Wachovia. We anticipate that the finalization of construction costs will be completed in late 2006. Until then, the rent payments will be based on the full \$32.0 million lease facility. Upon the return of unspent funds, the remaining rent payments will be based on the actual funded costs of the building. At December 31, 2006, the remaining construction advance totaled approximately \$882,000 and is classified as other current liability in the balance sheet.

Based on construction costs of approximately \$32.0 million and the current effective rate of approximately 5.9% (equivalent to the current 30-day LIBOR rate plus approximately 55 basis points at December 31, 2006), the rents to be paid are approximately \$1.9 million annually. In addition, Wachovia paid us ground rent in June 2004 covering the period through May 2011 and totaled an aggregate of approximately \$307,000. This amount is being 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% 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% of total expected construction costs of \$32.0 million. We have reported this guarantee as a non-current asset (prepaid rent) and non-current liability (other liability). We have estimated the fair value of this guarantee liability and the corresponding asset at approximately \$734,000, net of accumulated amortization at December 31, 2006.

In October 2006, we amended the laboratory lease to eliminate a covenant that we maintain a consolidated current debt ratio of not less than 1.2:1.0. The laboratory lease and other agreements continue to require, among other things, that we maintain a consolidated net worth of at least \$70.0 million. The agreements contain other covenants and conditions with which we must comply throughout the lease periods and upon termination of the lease. If we were unable to comply with these covenants and conditions, if the noncompliance went uncured, and if the parties could not agree otherwise, the agreements could terminate. A termination of these agreements could result in our acquisition of the improvements from Wachovia or the loss of our liquid collateral.

In March 2005, we entered into a construction management agreement with Turner Construction Company (Turner) under which Turner became responsible for the construction of the facility. The agreement contains a guaranteed maximum price clause in which Turner 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 is responsible for covering any costs in excess of the guaranteed maximum price guarantee.

### Contractual Obligations

At December 31, 2006, we had contractual obligations coming due approximately as follows (in thousands):

	Payment Due In				
	Total	2007	2008 to 2009	2010 to 2011	2012 and Later
Notes payable and capital lease obligations(1)	\$ 256,223	\$ 1,208	\$ 2,515	\$ 252,500	\$ —
Operating lease obligations	12,427	3,230	5,828	3,264	105
Construction agreement(2)	882	882	—	—	—
Purchase obligations	684	684	—	—	—
Other long-term liabilities reflected in the statement of financial position(3)	734	—	—	734	—
Milestone payments(4)	11,045	2,170	5,090	765	3,020
	<u>\$ 281,995</u>	<u>\$ 8,174</u>	<u>\$ 13,433</u>	<u>\$ 257,263</u>	<u>\$ 3,125</u>

- (1) In October 2006, we issued \$250.0 million aggregate principal amount of Convertible Senior Notes. The principal balance of the notes is repaid in cash with any increase of our stock price above \$75.22 paid in our stock. While the notes can be redeemed by the bondholder once our stock price exceeds \$75.22, we have assumed that the bondholders will hold the bonds until maturity.
- (2) Upon the completion of the laboratory in May 2006, Wachovia advanced to us the remaining funds available for construction due to the lengthy process involved in finalizing construction costs. When the final construction costs have been agreed upon, any remaining funds that were advanced will be returned to Wachovia. At December 31, 2006, the remaining construction advance totaled approximately \$882,000 and is classified as other current liability in the balance sheet.
- (3) Upon termination of the lease with Wachovia for the laboratory facility, 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% of the amount it funded towards the construction. We estimate 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.
- (4) 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 assets reported in the balance sheet. Based on the weight of available evidence at December 31, 2006, it was determined that a partial valuation allowance totaling approximately \$6.8 million was necessary at December 31, 2006.

### *Remodulin Revenue Recognition*

Product sales of Remodulin are recognized when delivered to distributors, which comprise 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, 2006, 2005 and 2004, approximately \$16.6 million, \$5.3 million, and \$3.1 million, respectively, of Remodulin products were sold to this distributor and recognized as revenue, respectively, and this distributor has made voluntary purchases since June 30, 2005.

We closely monitor levels of inventory in the distribution channel for contractual compliance. The shelf life associated with our products is 30 months. Obsolescence due to dating expiration has not been a historical concern, given the rapidity in which our products move through the channel. Changes due to our competitors' price movements have not adversely affected us. We do not provide incentives to our distributors to assume additional inventory levels beyond what is customary in the ordinary course of business.

United Therapeutics records Remodulin and related product sales net of the following significant categories of product sales allowances: prompt payment discounts; Medicaid discounts; and fees paid to distributors. Calculating each of these items involves significant estimates and judgments and requires United Therapeutics to use information from external sources.

**Prompt payment discounts**—United Therapeutics offers its distributors a 2% prompt-pay cash discount as an incentive to remit payment within the first thirty days after the date of the invoice. Prompt-pay discount calculations are based on the gross amount of each invoice. These discounts are accounted for by reducing sales by the 2% discount amount when product is sold, and applying earned cash discounts at the time of payment. United Therapeutics' customers have routinely taken advantage of this discount. Based on common industry practices and on distributors' overall payment history, United Therapeutics accrues for cash discounts on all Remodulin product sales recorded during the period unless information is available, such as an outstanding invoice, which would indicate that the invoice will not be paid within the discount period. United Therapeutics adjusts the accrual to reflect actual experience as necessary and, as a result, the actual amount recognized in any period may be slightly different from the accrual amount.

**Medicaid discounts**—United Therapeutics records accruals for rebates to be provided through governmental rebate programs, such as the Medicaid Drug Rebate Program, as a reduction of sales when product is sold. These reductions are based on historical rebate amounts and trends of sales eligible for these governmental programs for a period, as well as any expected changes to the trends of its total product sales. In addition, United Therapeutics estimates the expected unit rebate amounts to be used and adjusts the rebate accruals based on the expected changes in rebate pricing. Rebate amounts are generally invoiced and paid a quarter in arrears, so that the accrual consists of an estimate of the amount expected to be incurred for the current quarter's activity, and an estimated accrual for prior quarters' unpaid rebates.

### ***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, 2006, 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 licensing 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 totaling approximately \$2.0 million from the write-off of the HeartBar trademark intangible. These impairment charges were 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, 2006, the amortized cost of these debt securities was approximately \$162.1 million and their fair values were approximately \$160.1 million.

### **Stock Options**

Effective January 1, 2006, we adopted the fair value recognition provisions of SFAS No. 123(R), *Share-Based Payment*, using the modified prospective transition method. Under the modified prospective transition method, compensation cost recognized in 2006 includes compensation cost for all equity-based payments granted prior to but not yet vested as of January 1, 2006. This estimation is based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123 and compensation cost for all equity-based payments granted subsequent to January 1, 2006, based on the grant date fair value estimated in accordance with the provisions of SFAS No. 123(R). Results for prior periods have not been restated.

We have utilized the Black-Scholes-Merton valuation model for estimating the fair value of the stock options granted during the year ended December 31, 2006, as well as for option grants during all prior periods. The Black-Scholes-Merton valuation model includes many assumptions that are subject to substantial judgments, such as risk-free rate of interest, expected dividend yield, expected volatility, expected term of options and expected forfeiture rate.

*Expected Volatility*— Volatility is a measure of the amount by which a financial variable such as a share price has fluctuated (historical volatility) or is expected to fluctuate (expected volatility) during a period. United Therapeutics uses the historical volatility based on the weekly price observations of its common stock during the period immediately preceding the share-based award grant that is equal in length to the award's expected term (up to a maximum of five years). United Therapeutics believes that historical volatility within the last five years represents the best estimate of future long term volatility.

*Risk-Free Interest Rate*— This is the average interest rate consistent with the yield available on a U.S. Treasury note (with a term equal to the expected term of the underlying grants) at the date the option was granted.

*Expected Term of Options*— This is the period of time that the options granted are expected to remain outstanding. United Therapeutics adopted SAB 107's simplified method for estimating the expected term of share-based awards granted during the year ended December 31, 2006.

*Expected Dividend Yield*— United Therapeutics has never declared or paid dividends on its common stock and does not anticipate paying any dividends in the foreseeable future. As such, the dividend yield percentage is assumed to be zero.

*Expected Forfeiture Rate*— This is the estimated percentage of options granted that are expected to be forfeited or cancelled on an annual basis before becoming fully vested. United Therapeutics estimates the forfeiture rate based on historical forfeiture experience for similar levels of employees to whom options were granted.



### ***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%, minority shareholders possess substantive participating rights that preclude Northern Therapeutics' financial statements from being consolidated.

Other investments in affiliates are accounted for on the cost method generally due to the lack of significant influence over these affiliates and a less than 20% ownership by 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.

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

In June 2000, in connection with our license from Toray Industries for the sustained release formulation of beraprost (an oral prostacyclin analog), we agreed to grant options to Toray Industries to purchase 500,000 shares of our common stock upon Toray Industries' 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 Industries has met this milestone. If and when the milestone is met, the exercise price of the options will be set at the fair market value of our common stock at that time. Due to the uncertainties in drug development, it is not yet known if Toray Industries 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 construction of the laboratory facility was completed in May 2006. The total amount of the construction is expected to be \$32.0 million. The laboratory facility is owned by Wachovia, the lessor. We are the lessee and pay rent to Wachovia now that the facility is completed. This arrangement is a form of off balance sheet financing under which Wachovia funded 100% of the costs for the construction of the property and now leases 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**

### ***Fair Value Measurements***

In September 2006, the FASB issued SFAS 157, *Fair Value Measurements*. SFAS 157 defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. United Therapeutics is currently evaluating the impact the adoption of this statement could have on its financial condition, results of operations or cash flows.

### ***Uncertain Tax Positions***

In July 2006, the FASB issued FIN 48, *Accounting for Uncertainty in Income Taxes*, an interpretation of Statement of Financial Accounting Standards No. 109, *Accounting for Income Taxes*. FIN 48 clarifies the accounting for income taxes by prescribing the minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. FIN 48 also provides guidance on derecognition, measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition. The interpretation applies to all tax positions related to income taxes subject to SFAS 109. FIN 48 is effective for fiscal years beginning after December 15, 2006. United Therapeutics is currently evaluating the impact the adoption of this interpretation, but believes that the adoption will not have a significant impact on its financial condition, results of operations or cash flows.

### ***Hybrid Financial Instruments***

In February 2006, the FASB issued SFAS 155, *Accounting for Certain Hybrid Financial Instruments* which amends SFAS 133, *Accounting for Derivative Instruments and Hedging Activities* and SFAS 140, *Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities*. SFAS 155 simplifies the accounting for certain derivatives embedded in other financial instruments by allowing them to be accounted for as a whole if the holder elects to account for the whole instrument on a fair value basis. SFAS 155 also clarifies and amends certain other provisions of SFAS 133 and SFAS 140. SFAS 155 is effective for all financial instruments acquired, issued or subject to a remeasurement event occurring in fiscal years beginning after September 15, 2006. United Therapeutics does not believe the adoption of this statement will have a material impact on its financial condition, results of operations or cash flows.

### ***Accounting for Changes and Error Corrections***

In May 2005, the FASB issued SFAS 154, *Accounting Changes and Error Corrections* which supersedes APB Opinion No. 20, *Accounting Changes* and SFAS 3, *Reporting Accounting Changes in Interim Financial Statements*. SFAS 154 changes the requirements for the accounting for and reporting of a change in accounting principle. SFAS 154 also carries forward without change the guidance contained in APB 20 for reporting the correction of an error in previously issued financial statements and a change in accounting estimate. SFAS 154 requires retrospective application to prior periods' financial statements of changes in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. The correction of an error in previously issued financial statements is not

a change in accounting principle. However, the reporting of an error correction involves adjustments to previously issued financial statements similar to those generally applicable to reporting an accounting change retroactively. Therefore, the reporting of a correction of an error by restating previously issued financial statements is also addressed by SFAS 154. SFAS 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. United Therapeutics does not believe that the adoption of this statement will have a material impact on its financial condition, results of operations or cash flows.

On September 13, 2006, the SEC issued Staff Accounting Bulletin No. 108, *Considering the Effects of Prior Year Misstatements When Quantifying Misstatements in Current Year Financial Statements (SAB 108)*. SAB 108 provides guidance on how prior year misstatements should be taken into consideration when quantifying misstatements in current year financial statements for the purposes of determining whether the current year's financial statements are materially misstated. SAB 108 becomes effective for accounting years ending after November 15, 2006. The adoption of this SAB did not have any impact on United Therapeutics' financial statements.

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

At December 31, 2006, 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, 2006, we had approximately \$162.1 million in debt securities issued by federally-sponsored agencies with a weighted average stated interest rate of approximately 4.6% maturing through March 2012 and callable annually. The fair market value based on quoted market prices of this held-to-maturity portfolio at December 31, 2006, was approximately \$160.1 million.

At December 31, 2006, 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, 2006, we had approximately \$46.3 million in these debt securities with a weighted average stated interest rate of approximately 5.3%. The fair market value based on quoted market prices of these available-for-sale debt securities as of December 31, 2006 was approximately \$46.3 million.

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. Under these agreements, we 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. These rents, therefore, are subject to the risk that the LIBOR rate will increase or decrease during the period until termination in May 2011. At December 31, 2006, the 30-day LIBOR rate was approximately 5.3%. For every movement of 100 basis points (1%) 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, 2006 and 2005, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2006. Our audits also included the financial statement schedule listed in the Index at Item 15 (a)(2). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits 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, 2006 and 2005, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2006, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

As discussed in Note 6 of the consolidated financial statements, in fiscal year 2006, United Therapeutics Corporation changed its method of accounting for equity based on compensation in accordance with guidance provided in Statement of Financial Accounting Standards No. 123(R), "Share-Based Payment."

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, 2006, 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 27, 2007 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

McLean, Virginia  
February 27, 2007

**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, 2006, 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 audits 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, 2006, 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, 2006, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2006 consolidated financial statements of United Therapeutics Corporation and our report dated February 27, 2007 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

McLean, Virginia  
February 27, 2007

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

	<b>December 31,</b>	
	<b>2006</b>	<b>2005</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 91,067	\$ 69,180
Marketable investments	136,682	56,304
Accounts receivable, net of allowance of \$1 for 2006 and \$15 for 2005	22,453	13,873
Other receivable	1,581	4,201
Interest receivable	1,545	733
Due from affiliate	66	179
Prepaid expenses	9,242	6,384
Inventories, net	12,047	11,263
Deferred tax assets	2,691	4,611
Other current assets	—	29
Total current assets	<u>277,374</u>	<u>166,757</u>
Marketable investments	36,414	44,863
Marketable investments and cash—restricted	38,988	20,666
Goodwill, net	7,465	7,465
Other intangible assets, net	3,140	5,487
Property, plant, and equipment, net	34,681	21,802
Investments in affiliates	4,700	8,259
Receivable from employees	27	26
Deferred tax assets	66,887	15,100
Other assets	8,874	988
Total assets	<u>\$ 478,550</u>	<u>\$ 291,413</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 2,843	\$ 3,974
Accounts payable to affiliates and related parties	250	6
Accrued expenses	15,265	10,394
Due to affiliates and related parties	—	134
Current portion of notes and leases payable	10	15
Other current liabilities	882	—
Total current liabilities	<u>19,250</u>	<u>14,523</u>
Notes and leases payable, excluding current portion	250,015	8
Deferred tax liability	1,579	—
Other liabilities	3,100	1,780
Total liabilities	<u>273,944</u>	<u>16,311</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, 24,632,153 and 23,845,004 shares issued at December 31, 2006 and 2005, respectively, and 21,475,078 and 23,318,404 outstanding at December 31, 2006 and 2005, respectively	246	239
Additional paid-in capital	408,804	393,469
Accumulated other comprehensive income	1,476	3,593
Treasury stock at cost, 3,157,075 shares and 526,600 shares at December 31, 2006 and 2005, respectively	(164,560)	(6,874)
Accumulated deficit	<u>(41,360)</u>	<u>(115,325)</u>
Total stockholders' equity	<u>204,606</u>	<u>275,102</u>
Total liabilities and stockholders' equity	<u>\$ 478,550</u>	<u>\$ 291,413</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,		
	2006	2005	2004
<b>Revenues:</b>			
Net product sales	\$ 153,448	\$ 110,412	\$ 69,539
Service sales	6,184	5,241	4,051
License fees	—	262	—
Total revenue	159,632	115,915	73,590
<b>Operating expenses:</b>			
Research and development, including stock options expense totaling \$6.7 million in 2006 and none for the years ended in 2005 and 2004, respectively	57,570	36,052	30,713
Selling, general and administrative, including stock option expense totaling \$14.2 million in 2006 and none for the years ended in 2005 and 2004, respectively	54,028	24,655	21,418
Impairment of HeartBar® trade name	2,024	—	—
Cost of product sales	14,973	10,242	6,347
Cost of service sales, including stock option expense totaling \$117,000 in 2006 and none for the years ended in 2005 and 2004, respectively.	2,055	2,073	1,903
Total operating expenses	130,650	73,022	60,381
Income from operations	28,982	42,893	13,209
<b>Other income (expense):</b>			
Interest income	10,700	5,359	2,986
Interest expense	(482)	(29)	(4)
Equity loss in affiliate	(491)	(754)	(785)
Other, net	1,199	53	43
Total other income (expense), net	10,926	4,629	2,240
Net income before income tax	39,908	47,522	15,449
Income tax benefit	34,057	17,494	—
Net income	<u>\$ 73,965</u>	<u>\$ 65,016</u>	<u>\$ 15,449</u>
<b>Net income per common share:</b>			
Basic	<u>\$ 3.21</u>	<u>\$ 2.85</u>	<u>\$ 0.71</u>
Diluted	<u>\$ 3.06</u>	<u>\$ 2.58</u>	<u>\$ 0.66</u>
<b>Weighted average number of common shares outstanding:</b>			
Basic	<u>23,010</u>	<u>22,825</u>	<u>21,726</u>
Diluted	<u>24,138</u>	<u>25,206</u>	<u>23,351</u>

See accompanying notes to consolidated financial statements.

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

	<u>Common Stock</u>		<u>Additional</u>	<u>Accumulated</u>	<u>Treasury</u>	<u>Accumulated</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>	<u>Paid-in</u>	<u>Other</u>	<u>Stock</u>	<u>Deficit</u>	
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 (loss) on available-for-sale securities	—	—	—	1,136	—	—	1,136
Total other comprehensive income	—	—	—	916	—	65,016	65,932
Exercise of stock options	889,875	10	14,955	—	—	—	14,965
Tax benefit from exercises of non-qualified stock options	—	—	1,586	—	—	—	1,586
Options issued in exchange for services	—	—	983	—	—	—	983
Balance, December 31, 2005	23,845,004	239	393,469	3,593	(6,874)	(115,325)	275,102
Net income	—	—	—	—	—	73,965	73,965
Foreign currency translation adjustments	—	—	—	336	—	—	336
Unrealized (loss) on available-for-sale securities	—	—	—	(2,453)	—	—	(2,453)
Total other comprehensive income	—	—	—	(2,117)	—	73,965	71,848
Exercise of stock options	787,149	7	14,437	—	—	—	14,444
Tax benefit from exercises of non-qualified stock options	—	—	12,236	—	—	—	12,236
Treasury stock repurchases	—	—	—	—	(157,686)	—	(157,686)
Cost of call spread options, net	—	—	(35,400)	—	—	—	(35,400)
Options issued in exchange for services	—	—	24,062	—	—	—	24,062
Balance, December 31, 2006	<u>24,632,153</u>	<u>\$ 246</u>	<u>\$ 408,804</u>	<u>\$ 1,476</u>	<u>\$ (164,560)</u>	<u>\$ (41,360)</u>	<u>\$ 204,606</u>

See accompanying notes to consolidated financial statements.

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

	<b>Years Ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
Cash flows from operating activities:			
Net income	\$ 73,965	\$ 65,016	\$ 15,449
Adjustments to reconcile net income to net cash provided by (used in) operating activities:			
Depreciation and amortization	2,713	2,534	2,381
Loss on disposals of equipment	240	58	—
Provisions for bad debt and write downs	(151)	90	37
Stock and options issued in exchange for services	24,062	983	329
Impairment of intangible asset	2,024	—	—
Deferred tax benefit	(37,047)	(18,125)	—
Provisions for inventory obsolescence and write downs	407	228	487
Amortization of premiums and discounts on marketable investments	(1,249)	(120)	(105)
Unrealized foreign translation gain (loss)	336	(220)	—
Equity loss in affiliate	490	754	785
Excess tax benefit from stock-based compensation	(10,761)	—	—
Changes in operating assets and liabilities:			
Accounts receivable	(8,869)	(220)	(3,630)
Interest receivable	(812)	(234)	(38)
Inventories	(1,006)	(3,461)	(385)
Prepaid expenses	(2,867)	(2,377)	(1,356)
Other current assets	2,404	(2,534)	(1,221)
Other noncurrent assets	(15)	203	2,781
Due from affiliate	112	332	680
Accounts payable	(1,082)	(2,122)	1,854
Accrued expenses	4,892	2,705	2,230
Due to affiliate and related parties	110	79	(21)
Other liabilities	3,888	131	521
Net cash provided by operating activities	<u>51,784</u>	<u>43,700</u>	<u>20,778</u>
Cash flows from investing activities:			
Purchases of property, plant and equipment	(15,634)	(6,117)	(5,217)
Proceeds from disposals of property, plant and equipment	—	—	821
Investment in Northern Therapeutics, Inc.	—	—	(1,000)
Purchases of held-to-maturity investments	(122,801)	(17,009)	(37,474)
Purchases of available-for-sale investments	(84,350)	(61,050)	—
Maturities of held-to-maturity investments	32,360	—	30,000
Sales of available-for-sale investments	86,400	12,900	—
Net cash (used in) investing activities	<u>(104,025)</u>	<u>(71,276)</u>	<u>(12,870)</u>
Cash flows from financing activities:			
Proceeds from exercise of stock options	14,445	14,965	7,090
Proceeds from the issuance of Convertible Senior Notes, net of issuance costs	242,024	—	—
Payments to repurchase common stock	(157,686)	—	—
Purchase of call spread options, net	(35,400)	—	—
Proceeds from excess tax benefits	10,761	—	—
Payments of principal on notes payable	—	(777)	(750)
Principal payments under capital lease obligations	(16)	(18)	(24)
Net cash provided by financing activities	<u>74,128</u>	<u>14,170</u>	<u>6,316</u>
Net increase (decrease) in cash and cash equivalents	21,887	(13,406)	14,224
Cash and cash equivalents, beginning of year	<u>69,180</u>	<u>82,586</u>	<u>68,362</u>
Cash and cash equivalents, end of year	<u>\$ 91,067</u>	<u>\$ 69,180</u>	<u>\$ 82,586</u>
Supplemental schedule of noncash investing and financing activities:	<u>\$ 18</u>	<u>\$ —</u>	<u>\$ —</u>
Supplemental cash flow information—cash paid for interest	<u>\$ 7</u>	<u>\$ 29</u>	<u>\$ 2</u>
Cash paid for income taxes	<u>\$ 304</u>	<u>\$ 185</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<sup>®</sup>. Remodulin was first approved for use on May 21, 2002, by the United States Food and Drug Administration (FDA) as a continuous subcutaneous infusion for the treatment of pulmonary arterial hypertension (PAH) in patients with NYHA class II-IV symptoms to diminish symptoms associated with exercise. On November 24, 2004, the FDA approved intravenous infusion of Remodulin, based on data establishing intravenous bioequivalence with subcutaneous Remodulin, for patients who are not able to tolerate a subcutaneous infusion. On March 21, 2006, the FDA expanded its approval of Remodulin to include patients requiring transition from Flolan<sup>®</sup>, the only other FDA-approved intravenous prostacyclin. The FDA also agreed that United Therapeutics fulfilled its Subpart H approval requirement for a Phase IV post-marketing study to confirm the clinical benefit of Remodulin. In addition to the United States, Remodulin is approved for subcutaneous infusion in most of Europe, Canada, Israel, Australia and several countries in South America. It is also approved for intravenous infusion in Canada, Israel, Mexico, Argentina and Peru. Other international applications for the approval of Remodulin are pending.

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

### 2. Summary of Significant Accounting Policies

#### *Principles of Consolidation*

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

#### *Cash Equivalents*

Cash equivalents consist of highly liquid investments with original maturities of three months or less. Cash equivalents consist of money market funds, commercial paper, and certificates of deposit and amounted to approximately \$91.1 million and \$69.2 million at December 31, 2006 and 2005, respectively. Approximately \$1.5 million at December 31, 2006 and 2005, 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.

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

***Inventories***

United Therapeutics manufactures certain compounds, such as treprostinil, and purchases advanced intermediate compounds for its manufacturing process and medical supplies, such as delivery devices, for use in its product sales and ongoing clinical trials. United Therapeutics subcontracts the manufacture of cardiac monitoring equipment. United Therapeutics contracts with third-party manufacturers to make arginine-based products, and for the formulation of Remodulin and for clinical trial materials of inhaled and oral formulations of treprostinil. Inventories are accounted for under the first-in, first-out method and are carried at the lower of cost or market.

In October 2006, United Therapeutics began the validation process for regulatory approval of its new laboratory facility in Silver Spring, Maryland, for commercial production of treprostinil-based compounds - the active ingredients used by or in United Therapeutics' PAH drugs. United Therapeutics has changed its manufacturing process for the new facility. Due to the expectation that the oral formulation of treprostinil currently in clinical trials will have a much higher demand for commercial drug substance than the inhaled and infused formulations, United Therapeutics will begin by first producing treprostinil diethanolamine, the active ingredient for the oral therapy, first and then converting that substance to treprostinil, the active ingredient for the inhaled and infusion therapies .

At December 31, 2006 and 2005, inventories consisted of the following, net of reserves of approximately \$440,000 and \$570,000, respectively (in thousands):

	<b>December 31,</b>	
	<b>2006</b>	<b>2005</b>
Remodulin:		
Raw materials	\$ 149	\$ 814
Work in progress	7,807	7,582
Finished goods	3,355	2,052
Remodulin delivery pumps and medical supplies	661	673
Cardiac monitoring equipment components	38	59
Arginine related product lines	37	83
Total inventories	<u>\$ 12,047</u>	<u>\$ 11,263</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

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

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

	<b>December 31,</b>	
	<b>2006</b>	<b>2005</b>
Land	\$ 9,789	\$ 6,076
Buildings, building improvements and leasehold improvements	13,023	10,941
Buildings under construction	4,363	413
Holter and event cardiac monitoring systems	3,540	4,002
Furniture, equipment and vehicle	13,230	7,999
	43,945	29,431
Less—accumulated depreciation	(9,264 )	(7,629 )
Property, plant and equipment, net	<u>\$ 34,681</u>	<u>\$ 21,802</u>

Depreciation expense for the years ended December 31, 2006, 2005 and 2004, was approximately \$2.4 million, \$2.1 million, and \$1.9 million, respectively.

The laboratory facility in Silver Spring, Maryland was completed in May 2006. It was financed through a synthetic operating lease with Wachovia Development Corporation. This project and its related financing are discussed in Note 9.

In June 2006, United Therapeutics purchased 54 acres of land in Research Triangle Park, North Carolina, for approximately \$3.2 million which will be used to build a new approximately 200,000 square foot office and manufacturing facility. The manufacturing facility will formulate oral treprostinil and future glycobiology antiviral compounds, and the office will be used by United Therapeutics' clinical development and Remodulin commercialization staff currently occupying leased space in the area. United Therapeutics anticipates that the building project will begin in early 2007 with current estimated cost of approximately \$100.0 million. This building project is expected to be funded from working capital and could take up to two years to complete. In May 2006, United Therapeutics purchased land and a building adjacent to its Silver Spring, Maryland, headquarters for approximately \$1.8 million. In January 2007, United Therapeutics paid \$5.5 million to purchase a building adjacent to its leased Washington, D.C. office. In addition, United Therapeutics intends to begin construction on a new combination office and laboratory building which will connect to its current laboratory facility in Silver Spring, Maryland. Construction of this facility should commence in mid-to-late of 2007. Due to ongoing design work, cost estimates are not available, but are not expected to exceed \$100 million. United Therapeutics anticipates that the construction of this facility will be financed through a synthetic operating lease.

***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.

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

***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 that 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. For the years ended December 31, 2006 and 2005, United Therapeutics released a portion of the valuation allowance on the remaining deferred tax assets. See Note 7 for further information.

In connection with the implementation of SFAS 123(R) on January 1, 2006, United Therapeutics adopted the tax law approach for determining the order in which deductions, carryforwards and business credits are realized. Consistent with the tax law approach, United Therapeutics recorded increases to additional paid-in-capital of approximately \$12.2 million, of which approximately \$10.8 million related to the realization of the tax benefit associated with the exercises of stock options in 2006, approximately \$588,000 related to the use of state net operating losses attributable to stock option deductions.

***Marketable Investments***

Approximately \$162.1 million and \$72.8 million of United Therapeutics' marketable investments were considered held-to-maturity securities at December 31, 2006 and 2005, 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. 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. United Therapeutics monitors its investment portfolio for impairment on a periodic basis. In the event that the carrying value of an investment exceeds its fair value and the decline in value is determined to be other-than-temporary, United Therapeutics records an impairment charge and establishes a new cost basis for the investment at its then current fair value. In order to determine whether a decline in value is other-than-temporary, United Therapeutics evaluates, among other factors: the duration and extent to which the fair value has been less than the carrying value; the financial condition of and business outlook for the company, including key operational and cash flow metrics, current market conditions and future trends in the company's industry; the company's relative competitive position within the industry; and United Therapeutics' intent and ability to retain the investment for a period of time sufficient to allow for any anticipated recovery in fair value. Declines in market values below amortized cost that are considered other-than-temporary are reported in the statement of operations as losses.

Approximately \$46.3 million and \$48.4 million of United Therapeutics' marketable investments were considered available-for-sale securities at December 31, 2006 and 2005, respectively. Available-for-sale securities are those securities which United Therapeutics neither intends to hold until maturity nor intends

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

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. 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, 2006.

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

	As of December 31, 2006 Accumulated			As of December 31, 2005 Accumulated		
	Gross	Amortization	Net	Gross	Amortization	Net
Goodwill	<u>\$ 7,465</u>	<u>\$ —</u>	<u>\$ 7,465</u>	<u>\$ 7,465</u>	<u>\$ —</u>	<u>\$ 7,465</u>
Intangible assets:						
Trademarks	—	—	—	2,802	(1,230)	1,572
Technology and patents	6,164	(3,024)	3,140	6,164	(2,249)	3,915
Total intangible assets	<u>\$ 6,164</u>	<u>\$ (3,024)</u>	<u>\$ 3,140</u>	<u>\$ 8,966</u>	<u>\$ (3,479)</u>	<u>\$ 5,487</u>

Total amortization expense for the years ended December 31, 2006, 2005 and 2004, was approximately \$324,000, \$479,000 and \$479,000, respectively. The weighted average amortization period for the non-fully amortized technology and patents intangibles is approximately 17 years. The intangible asset related to patents for arginine has a remaining amortization period of approximately 12 years as of December 31, 2006. As of December 31, 2006, 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>	
2007	\$ 276
2008	276
2009	276
2010	276
2011	276



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

On January 19, 2006, United Therapeutics decided to discontinue the sales, marketing and production of its HeartBar line of products, which are arginine-enriched dietary supplements. 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 licensing royalties from third parties selling arginine based products. In connection with this discontinuance, United Therapeutics recognized a non-cash impairment charge totaling approximately \$2.0 million from the write-off of the HeartBar trademarks.

***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% of Northern Therapeutics, but only holds 49.9% 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, based on quoted market prices, 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 7.2% of ViRexx.

At December 31, 2006 and 2005, the investment in ViRexx's common stock was reported at its fair market value of approximately \$3.1 million and \$6.2 million, respectively, and is classified within investments in affiliates on the consolidated balance sheet. The unrealized gain at December 31, 2006 and 2005, was approximately \$678,000 and \$3.7 million, respectively.

As part of the AltaRex Corp. merger and reorganization with Nova Bancorp Investments Ltd. in February 2004, United Therapeutics received approximately 913,000 shares of Twin Butte Energy Ltd. (Twin Butte) a newly formed company. Twin Butte was not an operating entity and did not retain any substantial assets. As a result, United Therapeutics did not transfer any of its cost basis in AltaRex Corp. to Twin Butte. In 2006, as the result of a series of equity raises and acquisitions, the latest of which was a reverse takeover with a publicly traded company, Twin Butte's stock is now traded on the Toronto Stock Exchange. As of December 31, 2006, United Therapeutics owns less than 1% of Twin Butte. United Therapeutics accounts for this investment as an available-for-sale security. The fair value of the investment was approximately \$612,000 at December 31, 2006, based on quoted market prices. These changes in fair market value were reported as other comprehensive income or loss. The investment is recorded as a marketable investment on the consolidated balance sheet.

***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

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

investments and notes payable approximated its fair value based on quoted market prices. The fair values of leases payable approximate their carrying values based on notes that are currently available to United Therapeutics for obligations with similar terms and maturities.

***Earnings per Common Share***

Basic earnings per common share are computed by dividing net income or by the weighted average number of shares of common stock outstanding during the respective periods. Diluted earnings per common share is computed by dividing net income by the weighted average number of shares of common stock outstanding during the period plus share issuable upon the exercise of outstanding stock options and warrants using the treasury stock method.

At December 31, 2006, the holders of the components of basic and dilutive earnings per share are as follows (in thousands, except per share amounts):

	Years ended December 31,		
	2006	2005	2004
Net income (Numerator)	\$ 73,965	\$ 65,016	\$ 15,449
Shares (Denominator):			
Weighted average outstanding shares for basic EPS	23,010	22,825	21,726
0.50% Senior Convertible Note	—	—	—
Dilutive effect of stock options	1,128	2,381	1,625
Adjusted weighted average shares for diluted EPS	<u>24,138</u>	<u>25,206</u>	<u>23,351</u>
Earnings per share			
Basic	\$ 3.21	\$ 2.85	\$ 0.71
Diluted	<u>\$ 3.06</u>	<u>\$ 2.58</u>	<u>\$ 0.66</u>

At December 31, 2006, 2005 and 2004 approximately 1.6 million, 2.0 million and 18.8 million shares, respectively, representing the weighted average number of shares underlying stock options and warrants, are considered anti-dilutive because the exercise price of these equity awards is greater than the average per share closing price during the year and are not considered in the diluted earnings per share calculation.

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

***Use of Estimates***

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

***Stock Option Plan***

Effective January 1, 2006, United Therapeutics adopted the fair value recognition provisions of SFAS No. 123 (revised 2004), *Share-Based Payment* ("SFAS 123R"), using the modified prospective transition method and therefore has not restated results for prior periods. Under this transition method, stock-based compensation expense in fiscal year 2006 included stock-based compensation expense for all share-based payment awards granted prior to, but not yet vested as of, January 1, 2006, based on the grant-date fair value estimated in accordance with the original provisions of SFAS No. 123, *Accounting for Stock-Based Compensation* ("SFAS 123"). Stock-based compensation expense for all share-based payment awards granted after January 1, 2006 is based on the grant-date fair value estimated in accordance with the provisions of SFAS 123R. United Therapeutics recognizes these compensation costs on a straight-line basis over the requisite service period of the award, which is generally the option vesting term of three years. For awards that contain a performance condition, United Therapeutics recognizes compensation costs on an accelerated attribution model. 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*. Prior to the adoption of SFAS 123R, United Therapeutics recognized stock-based compensation expense in accordance with Accounting Principles Board ("APB") Opinion No. 25, *Accounting for Stock Issued to Employees* ("APB 25"). In March 2005, the Securities and Exchange Commission (the "SEC") issued Staff Accounting Bulletin No. 107 ("SAB 107") regarding the SEC's interpretation of SFAS 123R and the valuation of share-based payments for public companies. United Therapeutics has applied the provisions of SAB 107 in its adoption of SFAS 123R.

In November 2005, the Financial Accounting Standards Board ("FASB") issued FASB Staff Position ("FSP") No. FAS 123(R)-3, *Transition Election Related to Accounting for Tax Effects of Share-Based Payment Awards* ("FSP 123R-3"). United Therapeutics has elected to adopt the alternative transition method provided in the FSP 123R-3 for calculating the tax effects of stock-based compensation pursuant to SFAS 123R. The alternative transition method includes simplified methods to establish the beginning balance of the additional paid-in capital pool ("APIC pool") related to the tax effects of employee stock-based compensation, and to determine the subsequent impact on the APIC pool and consolidated statements of cash flows of the tax effects of employee stock-based compensation awards that are outstanding upon adoption of SFAS 123R. See Note 6 to the consolidated financial statements for a further discussion of stock-based compensation.

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

***Revenues***

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

Product sales of Remodulin are recognized when delivered to distributors, which are United Therapeutics' customers for Remodulin. Product sales of Remodulin delivery pumps and related supplies are recognized when delivered to distributors on a gross basis in accordance with EITF Issue No. 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent*. Title to these products passes upon delivery. Prompt payment discounts and government rebates are estimated and recognized as reductions in revenue for 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.

United Therapeutics records Remodulin and related product sales net of the following significant categories of product sales allowances: prompt payment discounts; Medicaid discounts; and fees paid to distributors. Calculating each of these items involves significant estimates and judgments and requires United Therapeutics to use information from external sources.

Prompt payment discounts—United Therapeutics offers its distributors a 2% prompt-pay cash discount as an incentive to remit payment within the first thirty days after the date of the invoice. Prompt-pay discount calculations are based on the gross amount of each invoice. These discounts are accounted for by reducing sales by the 2% discount amount when product is sold, and applying earned cash discounts at the time of payment. United Therapeutics' customers have routinely taken advantage of this discount. Based on common industry practices and on distributors' overall payment history, United Therapeutics accrues for cash discounts on all Remodulin product sales recorded during the period unless information is available, such as an outstanding invoice, which would indicate that the invoice will not be paid within the discount period. United Therapeutics adjusts the accrual to reflect actual experience as necessary and, as a result, the actual amount recognized in any period may be slightly different from the accrual amount.

Medicaid discounts—United Therapeutics records accruals for rebates to be provided through governmental rebate programs, such as the Medicaid Drug Rebate Program, as a reduction of sales when product is sold. These reductions are based on historical rebate amounts and trends of sales eligible for these governmental programs for a period, as well as any expected changes to the trends of its total product sales. In addition, United Therapeutics estimates the expected unit rebate amounts to be used and adjusts the rebate accruals based on the expected changes in rebate pricing. Rebate amounts are generally invoiced and paid a quarter in arrears, so that the accrual consists of an estimate of the amount expected to be incurred for the current quarter's activity, and an estimated accrual for prior quarters' unpaid rebates.

Fees paid to a distributors—United Therapeutics pays two of its distributors fees for services that they render on its behalf. These fees are recorded as a reduction to revenue. Fees to distributors are accrued monthly and are estimated based on contractual rates for specific services applied to estimated units of service provided by the distributors for the period.

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 L-arginine related products 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.

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

License fees, derived from an agreement with a third party, are recognized when received. The agreement provided 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 the period, the third party could terminate the agreement at any time and subsequent installments would no longer be due. United Therapeutics had 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 consist primarily of recoverable import duties on shipments of Remodulin to other countries and for December 31, 2005, 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, 2006, United Therapeutics moved to a fully insured group health plan. United Therapeutics is still responsible for funding trailing claims for up to one year from the self-insured plan that ended June 30, 2006. United Therapeutics maintains a commercial insurance policy for claims liabilities exceeding these limits. Liabilities of approximately \$6,000 and \$638,000 at December 31, 2006 and 2005, 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, 2006, 2005 and 2004, were approximately \$630,000, \$31,000 and \$174,000, respectively.

***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 corporate, state and local government agencies with high credit ratings and by federally sponsored agencies.

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

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, the formulation of oral treprostinil and Viveta, and to analyze other products. Additionally, Remodulin is formulated and packaged by a single formulator. Although there is a limited number of companies that could replace these suppliers, United Therapeutics 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, 2006, Remodulin drug sales accounted for approximately 96% 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. In March 2006, based on the results of the interim analysis of the Phase IV trial, the FDA concluded that United Therapeutics had satisfied its obligation to perform the Phase IV clinical study.

The majority of Remodulin drug sales were made to United States distributors. In the United States, United Therapeutics has contracted with three distributors which 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 make its cardiac monitoring devices. Although there are a limited number of companies that could replace this supplier, United Therapeutics 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 2006, 2005 and 2004, approximately 89%, 90% and 87% of United Therapeutics' Remodulin revenues, respectively, were earned from customers located in the United States. Foreign revenues were derived from several countries mainly located in Europe. Virtually all of United Therapeutics' long-lived assets are located in the United States. At December 31, 2006 and 2005, trade receivables were due primarily from two customers in the pharmaceutical segment.

United Therapeutics earned over 78% of its consolidated revenues from two customers in the pharmaceutical segment. Gross revenues from such customers totaled as follows (in thousands):

	<b>Years Ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
Accredo Therapeutics	\$ 101,584	\$ 75,317	\$ 41,777
CuraScripts	\$ 27,437	\$ 24,008	\$ 17,696

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

**3. Related Party Transactions**

***Receivable from Employees***

At December 31, 2006 and 2005, United Therapeutics had approximately \$38,000 and \$26,000, respectively, in interest and non-interest bearing advances due from employees. The advances are classified as receivable from employees in the consolidated 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 2006, 2005 and 2004, United Therapeutics incurred approximately none, \$16,000, and \$22,000, in expenses, 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 paid 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 agreed to pay KTI a 5% 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 was terminated by the parties as of December 31, 2006. During the years ended December 31, 2006, 2005 and 2004, United Therapeutics incurred approximately \$568,000, \$541,000, and \$520,000, respectively, of fees and expenses related to this agreement, of which approximately none and \$134,000 were payable to KTI at December 31, 2006 and 2005, respectively.

In 2002, United Therapeutics entered into a consulting agreement with a company affiliated with Raymond Kurzweil with a total value of \$15,000. United Therapeutics paid a total of none, \$15,000, and \$15,000 under these agreements during the years ended December 31, 2006, 2005 and 2004, respectively.

**4. License Agreements**

***Glaxo Wellcome Assignment***

In January 1997, Glaxo Wellcome, Inc. (now GlaxoSmithKline PLC) assigned to United Therapeutics patents and patent applications for the use of the stable prostacyclin analog UT-15 (now known as Remodulin) for the treatment of PAH 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. 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

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

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 by utilizing technology licensed from Pharmacia and royalties between 2.5% (in the United States) and 5% (in certain other countries) of all net sales, subject to certain offsets, until the later of the expiration of the applicable patent or ten years after the date of the first commercial sale of a product in a country defined as a milestone country under the agreement. In October 2002, United Therapeutics and Pharmacia amended the license agreement to change the royalties to Pharmacia to 4% on annual net sales of Remodulin in excess of \$25.0 million. This 4% royalty is subject to a 50% reduction for royalties due to other parties. Under the amended license agreement, Pharmacia is entitled to these royalties from United Therapeutics for a period of ten years from date of the first commercial sale in the applicable country of any product containing Remodulin.

***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 PAH and peripheral vascular disease utilizing MiniMed products with subcutaneous Remodulin. The term of the agreement was for seven years following the May 2002 FDA approval of Remodulin and would automatically extend for additional 12-month periods unless otherwise terminated. The guidelines implementing the agreement provided that United Therapeutics and its distributors would from time to time purchase subcutaneous infusion pumps and supplies from MiniMed at a discount off of MiniMed's list prices. 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.

In May 2006, MiniMed advised United Therapeutics that it intended to discontinue making infusion pumps for subcutaneous delivery of Remodulin after first giving United Therapeutics and its distributors the opportunity to purchase desired quantities. In November 2006, United Therapeutics and MiniMed mutually entered into a termination agreement. United Therapeutics anticipates continuing to purchase Medtronic MiniMed pumps and associated supplies and reselling those products to several of its foreign distributors, although the distributors are free to purchase products for other vendors. Approximately \$457,000, \$397,000 and \$1.7 million of revenues were earned from the resale of MiniMed pumps and supplies in 2006, 2005 and 2004, respectively.



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

***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 (beraprost SR) in the United States and Canada for the treatment of all vascular indications (including cardiovascular indications). In exchange, United Therapeutics paid Toray Industries \$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 Industries an option to purchase 500,000 shares of common stock upon Toray Industries' 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 have not yet occurred. Beraprost SR is currently in Phase III testing in Japan by Toray Industries.

***Supernus Pharmaceutical License***

In June 2006, United Therapeutics entered into an exclusive license agreement with Supernus Pharmaceuticals, Inc. (Supernus) for use of certain technologies developed by Supernus in the formulation of United Therapeutics' sustained release oral treprostinil. Under the agreement, in return for the license, United Therapeutics will pay Supernus certain amounts upon the achievement of specified milestones based on the development of oral treprostinil and its commercial launch. In addition, the agreement provides that United Therapeutics will pay a royalty to Supernus based on net worldwide sales of the initial product. Any such royalty will be paid for approximately twelve years commencing with the first product sale and is subject to adjustments as specified in the agreement. Additional milestone payments and royalty payments may be due for the development and the commercialization of other products developed using the technology granted in this license.

***Northern Therapeutics Licenses***

On October 15, 2006, Lung Rx entered into an exclusive license agreement with Northern Therapeutics to obtain the developmental and commercial rights to Northern Therapeutics' cell-based gene transfer technology for the United States treatment of PAH. Under the terms of the agreement, Lung Rx would assume the development activities of this technology upon the successful completion of the current Phase I trial being conducted by Northern Therapeutics in Canada, PHACeT. In addition, Lung Rx will pay Northern Therapeutics certain milestone payments during the PHACeT trial, totaling approximately \$1.5 million, if the trial is successful. The first milestone payment of \$250,000 was paid upon the execution of the licensing agreement. The second milestone payment of \$250,000 was paid upon the enrollment of the first patient. Upon successful commercial launch of a product using this technology, royalties would be due to Northern Therapeutics at various rates from 5% to 10% depending on sales level. These rates may be reduced for royalty payments made for other licenses implicated by the development or used in the commercial product and for certain other reasons, but in no event will the royalty rate be less than 3%.

***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 1% of net sales of amino acid

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

based products to each licensor respectively, subject to reductions. Minimum annual royalties of \$10,000 are due to each licensor.

***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, 2006, were 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 and 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. On October 1, 2006, the research agreement was extended through September 30, 2011, with United Therapeutics obligated to make 60 equal monthly payments totaling approximately £1.9 million, or approximately \$3.7 million, based on December 31, 2006 exchange rates.

***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>	
2007	\$ 2,170
2008	3,520
2009	1,570
2010	20
2011 and thereafter	3,765

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

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% of net product revenues as defined in the respective agreements.

## **6. Stockholders' Equity**

### ***Stock Incentive Plan***

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 that increased the total number of shares of common stock that may be issued pursuant to the Plan to 14,939,517 shares, which includes 7,939,517 shares reserved for issuance to the CEO under her employment agreement. The Plan provides for the grant of awards to eligible participants, including options (qualified and nonqualified), stock appreciation rights, restricted stock awards, and other rights as defined in the Plan. Options currently granted under the Plan generally vest over a period of up to three years, 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% 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% 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. United Therapeutics has historically issued new shares to satisfy share option exercises.

### ***Employee Options***

Prior to January 1, 2006, United Therapeutics accounted for its employee equity-based compensation plans under the recognition and measurement provisions of APB 25, *Accounting for Stock Issued to Employees*, and related interpretations, as permitted by SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS 123). Effective January 1, 2006, United Therapeutics adopted the provisions of SFAS No. 123 (revised 2004), *Share-Based Payment*, (SFAS 123(R)) and interpretative literature within SEC Staff Accounting Bulletin No. 107, *Share-Based Payment*, (SAB 107), using the modified prospective transition method. Under the modified prospective transition method, compensation cost recognized in 2006 includes compensation cost for all equity-based payments granted prior to but not yet vested as of January 1, 2006. Such payments are based on the original grant date fair value estimated in accordance with the provisions of SFAS 123 and compensation cost for all equity-based payments granted subsequent to January 1, 2006, which are based on the grant date fair value estimated in accordance with the provisions of SFAS 123(R). Results for prior periods have not been restated.

United Therapeutics utilizes the Black-Scholes-Merton valuation model for estimating the fair value of its granted stock options. Option valuation models, including Black-Scholes-Merton, require the input of highly subjective assumptions. Changes in the assumptions used can materially affect the grant date fair value of an award. These assumptions include the risk-free interest rate, expected dividend yield, expected volatility, expected forfeiture rate and the expected term of options.

*Expected Volatility* —Volatility is a measure of the amount by which a financial variable such as a share price has fluctuated (historical volatility) or is expected to fluctuate (expected volatility) during a period. United Therapeutics uses the historical volatility based on the weekly price observations of its common

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

stock during the period immediately preceding the share-based award grant that is equal in length to the award's expected term (up to a maximum of five years). United Therapeutics believes that historical volatility within the last five years represents the best estimate of future long term volatility. Since 2001, United Therapeutics' annual volatility has ranged from 76.75% in 2001, to 42.60% in 2006 with an average of 48.84% during the five year period.

*Risk-Free Interest Rate*—This is the average interest rate consistent with the yield available on a U.S. Treasury note (with a term equal to the expected term of the underlying grants) at the date the option was granted.

*Expected Term of Options*— This is the period of time that the options granted are expected to remain outstanding. United Therapeutics adopted SAB 107's simplified method for estimating the expected term of share-based awards granted during the year ended December 31, 2006.

*Expected Dividend Yield*— United Therapeutics has never declared or paid dividends on its common stock and does not anticipate paying any dividends in the foreseeable future. As such, the dividend yield percentage is assumed to be zero.

*Expected Forfeiture Rate*—This is the estimated percentage of options granted that are expected to be forfeited or cancelled on an annual basis before becoming fully vested. United Therapeutics estimates the forfeiture rate based on historical forfeiture experience for similar levels of employees to whom options were granted.

Following are the weighted-average assumptions used in valuing the stock options granted to employees during the years ended on December 31, 2006, 2005 and 2004:

	Years ended December 31,		
	2006	2005	2004
Dividend yield	0%	0%	0%
Expected volatility	42.60%	43.56%	63.68%
Risk-free interest rate	4.83%	3.69%	3.16%
Expected lives	5.95 years	2.40 years	3.77 years

A summary of outstanding at December 31, 2006 is as follows:

<u>All Employee Options</u>	<u>Number of Shares</u>	<u>Weighted Average Exercise Price Per Share</u>	<u>Weighted Average Remaining Contractual Term (in years)</u>	<u>Aggregate Intrinsic Value (\$ in 000s)</u>
Outstanding at December 31, 2006	5,503,765	\$ 43.83	7.1	\$ 241,235
Expected to vest at December 31, 2006	1,517,060	\$ 55.93	9.1	\$ 84,845
Exercisable at December 31, 2006	3,804,929	\$ 38.43	6.1	\$ 146,224

The total intrinsic value of options exercised during the years ended December 31, 2006, 2005 and 2004, was approximately \$30.5 million, \$36.8 million and \$8.9 million, respectively.

As of December 31, 2006, there was approximately \$33.6 million of total unrecognized compensation cost related to nonvested employee stock options. That cost is expected to be recognized over a weighted-average period of 2.4 years. The total fair value of shares vested during the years ended December 31, 2006, 2005 and 2004, was approximately \$20.5 million, \$19.8 million and \$7.8 million, respectively.

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

Approximately \$14.4 million, \$15.0 million and \$7.1 million in cash was received from option exercises under all the share-based payment arrangements for each of the years ended December 31, 2006, 2005 and 2004, respectively.

A summary of the status of United Therapeutics' employee stock options as of December 31, 2006, 2005 and 2004 and changes during the years then ended is presented below:

	<u>2006</u>		<u>2005</u>		<u>2004</u>	
		<u>Weighted-Average Exercise</u>		<u>Weighted-Average Exercise</u>		<u>Weighted-Average Exercise</u>
	<u>Shares</u>	<u>Price</u>	<u>Shares</u>	<u>Price</u>	<u>Shares</u>	<u>Price</u>
Outstanding at beginning of period	5,398,859	\$ 38.16	3,717,368	\$ 21.54	4,313,222	\$ 26.81
Granted	988,061	56.18	2,564,303	55.35	672,192	34.53
Exercised	(771,688 )	18.49	(831,640 )	17.02	(485,687 )	13.42
Forfeited	(111,467 )	54.82	(51,172 )	35.33	(50,427 )	18.79
Canceled	—	—	—	—	(731,932 )	66.79
Outstanding at end of period	<u>5,503,765</u>	<u>\$ 43.83</u>	<u>5,398,859</u>	<u>\$ 38.16</u>	<u>3,717,368</u>	<u>\$ 21.54</u>
Options exercisable at end of period	<u>3,804,929</u>	<u>\$ 38.43</u>	<u>3,476,850</u>	<u>\$ 31.74</u>	<u>2,445,493</u>	<u>\$ 18.68</u>
Weighted-average fair value of options granted during the period	<u>\$ 27.27</u>		<u>\$ 15.92</u>		<u>\$ 17.12</u>	

Total employee share-based compensation expense recognized for the year ended December 31, 2006, are as follows (in thousands, except per share data):

	<u>Year Ended December 31, 2006</u>
Cost of service sales	\$ 117
Research and development	6,679
Selling, general and administrative	<u>14,156</u>
Share-based compensation expense before taxes	20,952
Related income tax benefits	<u>(8,278)</u>
Share-based compensation expense, net of taxes	<u>\$ 12,674</u>

Equity-based compensation cost capitalized as part of inventory during year ended December 31, 2006, was approximately \$505,000. United Therapeutics recorded approximately \$5.2 million in share-based compensation expense during the year ended December 31, 2006, related to the grant of options to purchase 988,061 shares of common stock to employees.

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

The following table (in thousands, except per share amounts) illustrates the effect on net income and net income per share if United Therapeutics had applied the fair value recognition provisions of SFAS 123(R) to equity-based compensation for the years ended December 31, 2006, 2005 and 2004. Information for the years ended December 31, 2006, 2005 and 2004, is presented for comparative purposes only and is consistent with the presented statement of operations.

	<b>Years ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
Net income, as reported	\$ 73,965	\$ 65,016	\$ 15,449
Less total stock-based employee compensation expense determined under fair value based method for all awards	—	(23,097)	(8,072)
Pro forma net income	<u>\$ 73,965</u>	<u>\$ 41,919</u>	<u>\$ 7,377</u>
Basic net income per common share:			
As reported	<u>\$ 3.21</u>	<u>\$ 2.85</u>	<u>\$ 0.71</u>
Pro forma	<u>\$ 3.21</u>	<u>\$ 1.84</u>	<u>\$ 0.34</u>
Diluted net income per common share:			
As reported	<u>\$ 3.06</u>	<u>\$ 2.58</u>	<u>\$ 0.66</u>
Pro forma	<u>\$ 3.06</u>	<u>\$ 1.66</u>	<u>\$ 0.32</u>

For the years ended December 31, 2006, 2005 and 2004, options granted to both employees and non-employees to purchase 787,149 shares, 889,875 shares, and 526,955 shares, respectively, were exercised.

As of December 31, 2006, there were 8,014,934 shares available for grant under the plan.

Options granted under this Plan were as follows:

	<b>Number of</b>	<b>Weighted Average</b>
	<b>Options Granted</b>	<b>Grant Price</b>
For the years ended December 31,		
2006	988,061	\$ 56.18
2005	2,564,303	\$ 55.35
2004	654,692	\$ 34.82

Prior to 2005, options were also granted outside of the Plan described above (non-Plan grants) 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.

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

Non-Plan options were awarded as follows:

	Number of Options Granted	Weighted Average Grant Price
During the years ended December 31,		
2006	—	—
2005	—	—
2004	17,500	\$ 23.89

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 and exercisable at December 31, 2006:

Exercise Prices	Options Outstanding			Options Exercisable	
	Number	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Number	Weighted-Average Exercise Price
\$ 3.00 – \$ 10.00	25,864	4.4	\$ 9.25	25,864	\$ 9.25
10.01 – 20.00	933,495	4.3	15.20	933,495	15.20
20.01 – 30.00	680,888	6.1	23.55	612,503	23.57
30.01 – 40.00	8,750	5.0	33.91	8,750	33.91
40.01 – 50.00	1,879,286	6.6	45.26	1,491,210	44.62
50.01 – 60.00	948,389	9.5	56.02	75,295	56.68
60.01 – 70.00	425,007	9.0	68.63	375,175	69.09
70.01 – 80.00	591,760	8.9	71.31	272,311	71.31
80.01 – 90.00	7,126	3.5	84.81	7,126	84.81
90.01 – 116.38	3,200	3.2	99.68	3,200	99.68
<u>\$ 3.00 – \$116.38</u>	<u>5,503,765</u>	<u>7.1</u>	<u>\$ 43.83</u>	<u>3,804,929</u>	<u>\$ 38.43</u>

During the years ended December 31, 2006, 2005 and 2004, options to purchase a total of 771,688, 831,640 and 485,687 shares of common stock, respectively, were exercised. The proceeds from these exercises totaled approximately \$14.3 million, \$14.2 million and \$6.5 million, respectively.

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

***Options Issued in Exchange for Services***

United Therapeutics issued options under the plan to consultants for services during 2006, 2005 and 2004. 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,		
2006	49,437	\$ 66.70
2005	31,417	\$ 48.02
2004	14,334	\$ 29.77

***Stock Repurchases***

In July 2006, in a privately negotiated transaction, United Therapeutics repurchased 766,666 shares of its common stock, par value \$0.01 per share, from Toray Industries for a cash purchase price of approximately \$42.2 million (or \$55.08 per share) pursuant to a stock purchase agreement between United Therapeutics and Toray Industries. The purchase price was the average of the closing prices of United Therapeutics' common stock for the 30 consecutive trading days ending on July 26, 2006. Toray Industries retains ownership of 100,000 shares of United Therapeutics common stock.

United Therapeutics' Board of Directors approved a stock repurchase program to repurchase up to 4.0 million shares of United Therapeutics' common stock over a two year period on October 17, 2006. As of December 31, 2006, a total of approximately 1.9 million shares had been repurchased at a cost of approximately \$112.4 million in the stock repurchase program. Approximately 1.8 million shares of United Therapeutics' stock were repurchased using approximately \$112.4 million of the net proceeds from the issuance of the Convertible Senior Notes, based on the closing price of the common stock on October 24, 2006, of \$62.17. The additional 55,000 shares were purchased on various dates in the open market during the month of December 2006 at a weighted-average purchase price of \$54.54 per share.

***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 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% or more of United Therapeutics' common stock or announces a tender offer which would result in ownership of 15% 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.



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

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.

***Call Spread Option***

Concurrent with the issuance of the 0.50% Convertible Senior Notes (see Note 8), United Therapeutics purchased call options on its common stock in a private transaction with Deutsche Bank London, Ltd. The call options allow United Therapeutics to receive up to approximately 3.3 million shares of its common stock at \$75.2257 from Deutsche Bank London, equal to the amount of common stock related to the excess conversion value that United Therapeutics would pay to the holders of the Convertible Senior Notes upon conversion. The Convertible Senior Notes are generally convertible once United Therapeutics' stock price exceeds \$75.2257. These call options will terminate upon the earlier of the maturity dates of the related Convertible Senior Notes or the first day all of the related Convertible Senior Notes are no longer outstanding due to conversion or otherwise. The call options, which cost approximately \$80.8 million, was recorded as a reduction to additional paid-in-capital.

In a separate transaction with the issuance of the Convertible Senior Notes, United Therapeutics sold warrants to Deutsche Bank London to issue shares of its common stock at an exercise price of \$105.689 per share. Pursuant to this transaction, warrants for approximately 3.3 million shares of United Therapeutics' common stock were issued. Proceeds received from the issuance of the warrants totaled approximately \$45.4 million and were recorded as an increase to additional paid-in-capital.

The combination of the call options and warrants, effectively reduces the dilutive effect of the conversion the Convertible Senior Notes. Deutsche Bank London is responsible for providing 100% of the necessary shares of United Therapeutics common stock upon conversion for the value of United Therapeutics' stock between the conversion price, \$75.2257 and the warrant exercise price of \$105.689. As United Therapeutics' stock increases beyond the warrant exercise price, United Therapeutics is responsible for issuing more shares upon conversion and Deutsche Bank London fewer shares. The shares of common stock that Deutsche Bank London needs to supply will come from existing shareholders.

**7. Income Taxes**

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

	<b>Years Ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
Current:			
Federal	\$ —	\$ —	\$ —
State	868	953	—
Total current	868	953	—
Deferred			
Federal	(32,807)	(18,706)	—
State	(2,118)	259	—
Total deferred	(34,925)	(18,447)	—
Total provision for (benefit from) income taxes	<u>\$ (34,057)</u>	<u>\$ (17,494)</u>	<u>\$ —</u>

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

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

	<b>Years Ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
Federal tax provision computed at 35% in 2006 and 2005 and 34% in 2004	\$ 13,877	\$ 16,804	\$ 5,197
State tax provision, net of federal tax provision	1,908	1,212	807
Change in the valuation allowance for deferred tax assets allocated to tax expenses	(45,662)	(36,934)	(6,858)
General business credits	(4,358)	—	—
ISO stock option expense	1,771	—	—
Change in rate of deferred tax assets	(1,402)	—	—
Nondeductible expenses	(191)	1,424	854
Total income tax expense (benefit)	<u>\$ (34,057)</u>	<u>\$ (17,494)</u>	<u>\$ —</u>

As a result of positive earnings trend and projected future taxable income for future years, United Therapeutics reversed the majority of its valuation allowance. United Therapeutics recognized an income tax benefit of approximately \$34.1 million for the year ended December 31, 2006, primarily due to the recording of a reduction in the deferred tax asset valuation allowance of approximately \$45.7 million representing the anticipated utilization of a portion of its deferred tax assets in subsequent years.

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, 2006 and 2005, respectively, are approximately as follows (in thousands):

	<b>Years Ended December 31,</b>	
	<b>2006</b>	<b>2005</b>
<b>Deferred tax assets:</b>		
Net operating loss carryforwards	\$ 866	\$ 16,903
General business credits	46,355	30,819
Impairment losses on investments	3,279	3,069
Realized losses on marketable investments	2,286	2,518
License fees capitalized for tax purposes	5,513	6,091
Nonqualified stock option	8,279	—
In-process research and development capitalized for tax purposes	3,368	3,721
Other	6,386	3,917
Total deferred tax assets	76,332	67,038
<b>Deferred tax liabilities:</b>		
Furniture and equipment principally due to differences in depreciation	(1,579)	(401)
Total deferred tax liabilities	(1,579)	(401)
Net deferred tax asset before valuation allowance	74,753	66,637
Valuation allowance	(6,754)	(46,926)
Net deferred tax asset	<u>\$ 67,999</u>	<u>\$ 19,711</u>

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

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 a majority 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 \$45.7 million reduction in the valuation allowance, net of current year activity, related to the anticipated utilization of its general business credits of approximately \$46.4 million and other deferred tax assets of \$11.4 million. Approximately \$17.5 million tax benefit of net operating losses attributable to the exercises of stock options, and its related valuation allowance of the same amount, has been removed from both 2005 and 2006 in the detail of deferred tax assets, liabilities and valuation allowance above. This benefit will be recorded as additional paid-in-capital when the loss carryover reduces taxes payable.

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 if the valuation allowance is decreased.

United Therapeutics also recognized approximately \$888,000 related to the tax benefit realized from the amortization of the call hedge purchased by United Therapeutics in connection with the issuance of the Senior Convertible Notes as of December 31, 2006.

At December 31, 2006, United Therapeutics had for federal income tax purposes net operating loss carryforwards of approximately \$52.2 million and business tax credit carryforwards of approximately \$46.4 million, which expire at various dates from 2012 through 2024. Approximately \$51.4 million of the net operating loss carryforwards is attributable to net operating losses from the exercise of stock options, the benefit of which, when realized by a reduction in taxes payable, increases additional paid-in-capital. Business tax credits 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 existing 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.

## **8. Notes Payable**

### ***Convertible Senior Notes***

On October 30, 2006, United Therapeutics issued \$250.0 million of 0.50% Convertible Senior Notes due October 2011 (the Convertible Senior Notes). In connection with the issuance of the Convertible Senior Notes, United Therapeutics also entered into a call spread option (See Note 6). The Convertible Senior Notes were issued at par value and pay interest in cash semi-annually in arrears on April 15 and October 15 of each year, beginning on April 15, 2007. The Convertible Senior Notes are unsecured unsubordinated obligations and rank equally with all other unsecured and unsubordinated indebtedness. The Convertible Senior Notes have an initial conversion price of \$75.2257 per share. The Convertible

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

Senior Notes may only be converted: (i) anytime after July 15, 2011; (ii) during any calendar quarter commencing after the date of original issuance of the notes, if the closing sale price of United Therapeutics' common stock for at least 20 trading days in the period of 30 consecutive trading days ending on the last trading day of the calendar quarter preceding the quarter in which the conversion occurs is more than 120% of the conversion price of the notes in effect on that last trading day; (iii) during the ten consecutive trading-day period following any five consecutive trading-day period in which the trading price for the notes for each such trading day was less than 95% of the closing sale price of United Therapeutics' common stock on such date multiplied by the then current conversion rate; or (iv) if specified significant distributions to holders of United Therapeutics' common stock are made, specified corporate transactions occur, or United Therapeutics' common stock ceases to be approved for listing on The NASDAQ Global Select Market and is not listed for trading on another U.S. national or regional securities exchange. Upon conversion, a holder will receive: (i) cash equal to the lesser of the principal amount of the note or the conversion value; and (ii) to the extent the conversion value exceeds the principal amount of the note, shares of United Therapeutics' common stock. In addition, upon a change in control, as defined in the indenture under which the Convertible Senior Notes have been issued, the holders may require United Therapeutics to purchase all or a portion of their Convertible Senior Notes for 100% of the principal amount plus accrued and unpaid interest, if any, plus a number of additional shares of United Therapeutics' common stock. As of December 31, 2006, the fair value of the \$250.0 million Convertible Senior Notes outstanding was approximately \$237.2 million, based on the quoted market price.

**9. Commitments and Contingencies**

***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. Under these agreements, Wachovia funded \$32.0 million towards the construction of the laboratory facility on ground owned by United Therapeutics. The construction phase commenced in 2004 and was completed in May 2006. Following construction, Wachovia leased 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.

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

In addition, United Therapeutics pledged, as collateral, a portion of its marketable investments to secure its lease obligations. At December 31, 2006, approximately \$39.0 million of marketable investments and cash were pledged as collateral and are reported as restricted marketable investments and cash in the consolidated balance sheet.

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

This arrangement enabled United Therapeutics to construct its laboratory facility without using its own working capital. There will not be any depreciation expense associated with the laboratory facility, since these improvements are owned by Wachovia. The amount of rent to be paid to Wachovia during the term of the laboratory lease 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.

Upon the completion of the building in May 2006, Wachovia advanced to United Therapeutics the remaining funds available for construction due to the lengthy process involved in finalizing construction costs. When the final construction costs have been agreed upon, any remaining funds that were advanced will be returned to Wachovia. It is anticipated that the finalization of construction costs will be completed in early 2007. Until then, the rent payments will be based on the full \$32.0 million lease facility. Upon the return of unspent funds, the remaining rent payments will be based on the actual funded costs of the building. At December 31, 2006, the remaining construction advance totaled approximately \$882,000 and is classified as other current liability in the consolidated balance sheets.

Based on construction costs of approximately \$32.0 million and the current effective rate of approximately 5.9% (equivalent to the current 30-day LIBOR rate plus approximately 55 basis points at December 31, 2006), the rents to be paid approximate \$1.9 million annually. In addition, Wachovia paid United Therapeutics ground rent in June 2004 covering the period through May 2011 and totaling an aggregate of approximately \$307,000. This amount is being recognized as income ratably through May 2011.

United Therapeutics guaranteed a minimum residual value of the laboratory facility. This guaranteed residual is generally equal to 86% of the amount funded by Wachovia towards construction. If, at the end of the lease term, United Therapeutics does not renew the lease or purchase the improvements, then the building will be sold to a third party. In that event, United Therapeutics has guaranteed that Wachovia will receive at least this residual value amount. The maximum potential amount of this guarantee is approximately \$27.5 million, equivalent to 86% of expected total construction costs of \$32.0 million. United Therapeutics has reported this guarantee as a non-current asset (prepaid rent) and non-current liability (other liability). United Therapeutics has recorded a guarantee liability and corresponding asset of approximately \$734,000, net of accumulated amortization at December 31, 2006.

In October 2006, United Therapeutics and Wachovia amended the laboratory lease to eliminate a covenant that United Therapeutics maintain a consolidated current debt ratio of not less than 1.2:1.0. The laboratory lease and other agreements continue to require, among other things, that United Therapeutics maintain a consolidated net worth of at least \$70.0 million. The agreements contain other covenants and conditions with which United Therapeutics must comply throughout the lease periods and upon termination of the lease. If United Therapeutics 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 United Therapeutics' acquisition of the improvements from Wachovia or the loss of its liquid collateral.

***Capital Leases***

United Therapeutics also leased certain equipment under capital leases with average interest rates of approximately 8.1% and terms up to 3 years.

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

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

<u>Years ending December 31,</u>	<u>Capital Leases</u>
2007	\$ 23
2008	19
2009	3
2010 and thereafter	—
	<u>45</u>
Less amounts representing interest	(20)
Less current portion	<u>(10)</u>
	<u>\$ 15</u>

At December 31, 2006 and 2005, the carrying value of equipment under capital leases was approximately \$33,000 and \$91,000, respectively, and accumulated depreciation was approximately \$8,000 and \$70,000, respectively. Amortization of equipment under capital leases is included within depreciation expense.

***Other Operating Leases***

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

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

<u>Years ending December 31,</u>	
2007	\$ 3,230
2008	3,006
2009	2,822
2010	2,453
2011	811

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, 2006. Total rent expense was approximately \$2.7 million for December 31, 2006, and approximately \$1.4 million for each of the years ended December 31, 2005 and 2004. The increase in 2006 represents amounts paid to Wachovia Development Corporation in accordance with the terms of the operating lease agreement.

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

**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, 2006, 2005 and 2004 (in thousands):

	Years ended December 31,		
	2006	2005	2004
Net income	\$ 73,965	\$ 65,016	\$ 15,449
Other comprehensive income:			
Foreign currency translation gain (loss) adjustments	336	(220)	48
Unrealized gain (loss) on available-for-sale securities	(2,453)	1,136	955
Comprehensive income	<u>\$ 71,848</u>	<u>\$ 65,932</u>	<u>\$ 16,452</u>

**11. Marketable Investments**

*Held-to-maturity investments*

At December 31, 2006 and 2005, a portion of United Therapeutics' investments consisted of federally-sponsored and corporate 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, 2006 and 2005. 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.

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, 2006	\$ 90,572	\$ 1	\$ (1,894)	\$ 88,679
Corporate notes and bonds at December 31, 2006	71,508	—	(82)	71,426
Total	<u>\$ 162,080</u>	<u>\$ 1</u>	<u>\$ (1,976)</u>	<u>\$ 160,105</u>
Reported as				
Current marketable securities	\$ 90,382			
Noncurrent marketable securities	71,698			
	<u>\$ 162,080</u>			

  

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Agency notes at December 31, 2005	<u>\$ 72,788</u>	<u>\$ —</u>	<u>\$ (2,154)</u>	<u>\$ 70,634</u>

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

The unrealized losses at December 31, 2006 and 2005 on the corporate and 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, 2006 and 2005 (in thousands):

	<b>December 31, 2006</b>		<b>December 31, 2005</b>	
	<b>Amortized Cost</b>	<b>Fair Value</b>	<b>Amortized Cost</b>	<b>Fair Value</b>
Less than one year	\$ 90,382	\$ 90,275	\$ 7,954	\$ 7,886
Due in one to two years	28,305	27,994	11,498	11,400
Due in three to five years	33,393	32,324	33,443	32,231
Due after five years	10,000	9,512	19,893	19,117
<b>Total</b>	<b>\$ 162,080</b>	<b>\$ 160,105</b>	<b>\$ 72,788</b>	<b>\$ 70,634</b>

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

	<b>Years Ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
Gross proceeds	\$ 32,360	\$ 200	\$ 30,000
Realized gains	\$ —	\$ —	\$ —
Realized losses	\$ —	\$ —	\$ —

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

At December 31, 2006, 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.

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

	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Value</b>
Agency notes at December 31, 2006	\$ 46,300	\$ —	\$ —	\$ 46,300
Agency notes at December 31, 2005	\$ 48,350	\$ —	\$ —	\$ 48,350



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

The following table summarizes maturities of United Therapeutics' available-for-sale investment securities at December 31, 2006 and 2005 (in thousands):

	<b>December 31, 2006</b>		<b>December 31, 2005</b>	
	<b>Amortized Cost</b>	<b>Fair Value</b>	<b>Amortized Cost</b>	<b>Fair Value</b>
Less than one year	\$ —	\$ —	\$ —	\$ —
Due in one to two years	—	—	—	—
Due in three to five years	—	—	—	—
Due after five years	46,300	46,300	48,350	48,350
Total	<u>\$ 46,300</u>	<u>\$ 46,300</u>	<u>\$ 48,350</u>	<u>\$ 48,350</u>

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

	<b>Years Ended December 31,</b>		
	<b>2006</b>	<b>2005</b>	<b>2004</b>
Gross proceeds	\$ 86,400	\$ 12,700	\$ —
Realized gains	\$ —	\$ —	\$ —
Realized losses	\$ —	\$ —	\$ —

## 12. Investments in Affiliates

### *Northern Therapeutics, Inc.*

In December 2000, Lung Rx, Inc. formed a new company in Canada, Northern Therapeutics, Inc., with the inventor of a new form of autologous (meaning derived from a patient's own body and not from foreign materials such as viruses) gene therapy for PAH and other diseases. The purpose of Northern Therapeutics was to develop the gene therapy and also to distribute Remodulin and other United Therapeutics products in Canada. Lung Rx received approximately 59% 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%.

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, 2006, Lung Rx's investment in Northern Therapeutics was reported at approximately \$1.6 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

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

underlying net assets was approximately \$1.0 million at December 31, 2006. 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,		
	2006	2005	2004
Total assets	\$ 1,576	\$ 1,883	\$ 2,874
Total liabilities	\$ 111	\$ 206	\$ 140
Total revenues	\$ 1,434	\$ 1,497	\$ 527
Net loss	\$ (718)	\$ (1,102)	\$ (1,148)

In October 2006, Northern Therapeutics agreed to grant a license to United Therapeutics to develop and commercialize the gene therapy in the United States for PAH. The license will require United Therapeutics to make incremental payments totaling \$1.5 million to Northern Therapeutics upon achieving certain milestones in increments during and upon completion of the Phase I trial in March 2006. After successful completion of the Phase I trial, United Therapeutics will assume the development program and related costs for the United States. As of December 31, 2006, United Therapeutics has paid approximately \$500,000 in milestone payments to Northern Therapeutics under the license agreement. In anticipation of this agreement, United Therapeutics and Northern Therapeutics terminated the Remodulin distribution agreement for Canada. United Therapeutics now distributes Remodulin directly in Canada through the management of its Canadian wholly-owned subsidiary, Unither Biotech Inc.

### **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%, subject to certain limitations. For the years ended December 31, 2006, 2005 and 2004, United Therapeutics contributed and expensed \$295,000, \$223,000 and \$207,000, respectively, to the plan as a result of this matching.

### **14. Supplemental Executive Retirement Plan**

In May 2006, the Compensation Committee approved the United Therapeutics Corporation Supplemental Executive Retirement Plan (the SERP). The SERP is administered by the Compensation Committee. Only a member of a "select group of management or highly compensated employees" within the meaning of ERISA section 201(2) may be eligible to participate in the SERP. If a participant terminates employment with United Therapeutics for any reason prior to age 60, no benefit will be earned. United Therapeutics' Chief Executive Officer (CEO), three other executive officers and three other officers have been designated as eligible to participate in the SERP. Each of these participants, who may retire at the age of 60, is eligible to receive monthly payments equal to the monthly average of the total gross base salary received by the participant over his or her last 36 months of active employment (the Final Average Compensation), reduced by the participant's Social Security benefit (determined as provided

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

under the SERP), for the remainder of the participant's life (the aggregate amount of such payments, the Normal Retirement Benefit), commencing on the first day of the sixth month after retirement. The participant may elect to receive a lump sum distribution equal to the present value of payments that he or she would be expected to receive upon retirement under the calculation noted.

Future SE RP participants will become eligible upon recommendation by the CEO and confirmation by the Compensation Committee. Eligibility commences on the first day of the month following Compensation Committee approval. If Compensation Committee approval occurs on the first day of the month, eligibility commences immediately. Upon retirement after the age of 60, such participants will be eligible to receive a Normal Retirement Benefit, made in monthly payments equal to (1) the participant's Final Average Compensation, reduced by the participant's Social Security benefit (determined as provided under the SERP), multiplied by (2) a fraction (no greater than one), made up of a numerator equal to the participant's years of service at United Therapeutics and a denominator of 15. This benefit will run for the remainder of the participant's life (unless the participant elects to receive a lump sum payment), commencing on the first day of the sixth month of retirement. In the event that a participant's employment ceases due to disability or death prior to the age of 60 or retirement if older than 60, a participant or the participant's designated beneficiary will be entitled to a Disability Retirement Benefit. Such benefit would be equal to a percentage of the participant's anticipated Normal Retirement Benefit under the SERP. This benefit would still commence on the first day of the sixth month after cessation of employment due to death or disability. Should a SERP participant die after the program commences, his or her designated beneficiary will continue to receive a percentage of the SERP benefit for the remainder of what would have been the participant's years of eligibility. The Compensation Committee expects the number of participants to remain small during the life of this program.

In the event of a transfer of control of United Therapeutics by acquisition, merger, hostile takeover or for any other reason whatsoever which also qualifies as a "change in the ownership or effective control of the corporation, or in the ownership of a substantial portion of the assets of the corporation" under Internal Revenue Code section 409A(a)(2)(A)(v) (Change in Control), a participant who is actively employed on the date of the Change in Control will be entitled to a lump sum payment equal to the actuarial equivalent present value of a monthly single life annuity equal to (1) the participant's Final Average Compensation, reduced by the participant's estimated future Social Security benefit (determined as provided under the SERP), multiplied by (2) a fraction (no greater than one) made up of a numerator equal to the participant's years of service at United Therapeutics and a denominator of 15, to be paid as soon as administratively practicable following the Change in Control. In the event that a participant is entitled to a Normal Retirement Benefit or Disability Retirement Benefit at the time of a Change in Control, all such payments (or any remaining payments, with respect to any participant who is receiving payments under the SERP at the time of the Change in Control) will be made in a lump sum as soon as administratively practicable following such Change in Control (without regard to whether the participant otherwise is in pay status at the time of the Change in Control).

Participants in the SERP will be prohibited from competing with United Therapeutics or soliciting United Therapeutics' employees for a period of twelve months following their termination of employment (or, if earlier, upon attainment of age 65). Violation of this covenant will result in the forfeiture of all benefits under the SERP.

The SERP is entirely unfunded. No assets of United Therapeutics have been designated to secure benefits under the plan. Benefits will be funded as they are paid to participants upon or after retirement.

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

death or disability. United Therapeutics accounts for the SERP in accordance with SFAS No. 87, *Employers Accounting for Pensions* (SFAS 87), and related standards and interpretations. In accordance with SFAS 87, a material change in the plan, such as adding a participant which occurred in August 2006, requires a remeasurement of the Plan. For the year ended December 31, 2006, United Therapeutics recorded approximately \$1.6 million of expense related to the SERP, which was reported in selling, general and administrative and research and development expenses in the accompanying consolidated statements of operations. The expense is based on an expected service cost of approximately \$1.6 million through December 31, 2006 using a discount rate of 6.2% on the expected future benefits. The original expected service cost through December 31, 2006 and original discount rate were \$1.4 million and 6.4%, respectively. Since there are no plan assets, no interest on assets is assumed earned. With the addition of a participant and the change in discount rate, there is an Unrecognized Prior Service Cost of approximately \$772,000 which will be amortized over the next 13 years, the average expected future service period of all the plan participants. In addition, there is unrealized loss of approximately \$22,000 which will be amortized as an expense only when the cumulative unrecognized losses exceed 10% of Projected Benefit Obligations. Benefit payments are not expected to be paid over the next five years since no current participants will reach the age of 60 within this time period.

**15. Relocation Costs**

United Therapeutics has constructed a laboratory facility adjacent to its headquarters in Silver Spring, Maryland to replace its current laboratory in Chicago, Illinois. Certain Chicago-based employees are being 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. As of December 31, 2006, total relocation costs incurred to date were approximately \$288,000.

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 agreement was reached with employees in October 2005 to the date of payment in 2007. As of December 31, 2006, approximately \$141,000 has been accrued for these bonuses and they are classified in selling, general and administrative expenses.

**16. Accrued Expenses**

Accrued expenses consisted of the following (in thousands):

	<b>December 31,</b>	
	<b>2006</b>	<b>2005</b>
Professional fees	\$ 230	\$ 64
Research related	2,293	1,778
Payroll related	3,853	2,902
Royalties and rebates	6,382	4,148
Contracted services	305	382
Other	2,202	1,120
Total	<u>\$ 15,265</u>	<u>\$ 10,394</u>

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

**17. Segment Information**

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

Segment information as of and for the year ended December 31, 2006, was as follows (in thousands):

	<u>Pharmaceutical</u>	<u>Telemedicine</u>	<u>Consolidated Totals</u>
Revenues from external customers	\$ 153,035	\$ 6,597	\$ 159,632
Net income (losses)	74,438	(473)	73,965
Interest income	10,679	21	10,700
Interest expense	(482)	—	(482)
Income tax benefit	34,057	—	34,057
Depreciation and amortization	(2,273)	(440)	(2,713)
Equity loss in affiliate	(491)	—	(491)
Total investments in equity method investees	1,568	—	1,568
Expenditures for long-lived assets	(15,170)	(464)	(15,634)
Goodwill, net	1,287	6,178	7,465
Total assets	466,493	12,057	478,550

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

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

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 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

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.

## **18. Recent Accounting Pronouncements**

### ***Fair Value Measurements***

In September 2006, the FASB issued SFAS 157, *Fair Value Measurements*. SFAS 157 defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. United Therapeutics is currently evaluating the impact the adoption of this statement could have on its financial condition, results of operations or cash flows.

### ***Uncertain Tax Positions***

In July 2006, the FASB issued FIN 48, *Accounting for Uncertainty in Income Taxes*, an interpretation of Statement of Financial Accounting Standards No. 109, *Accounting for Income Taxes*. FIN 48 clarifies the accounting for income taxes by prescribing the minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. FIN 48 also provides guidance on derecognition, measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition. The interpretation applies to all tax positions related to income taxes subject to SFAS 109. FIN 48 is effective for fiscal years beginning after December 15, 2006. United Therapeutics is currently evaluating the impact the adoption of this interpretation, but believes that the adoption will not have a significant impact on its financial condition, results of operations or cash flows.

### ***Hybrid Financial Instruments***

In February 2006, the FASB issued SFAS 155, *Accounting for Certain Hybrid Financial Instruments* which amends SFAS 133, *Accounting for Derivative Instruments and Hedging Activities* and SFAS 140,

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

Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities. SFAS 155 simplifies the accounting for certain derivatives embedded in other financial instruments by allowing them to be accounted for as a whole if the holder elects to account for the whole instrument on a fair value basis. SFAS 155 also clarifies and amends certain other provisions of SFAS 133 and SFAS 140. SFAS 155 is effective for all financial instruments acquired, issued or subject to a remeasurement event occurring in fiscal years beginning after September 15, 2006. United Therapeutics does not believe the adoption of this statement will have a material impact on its financial condition, results of operations or cash flows.

***Accounting for Changes and Error Corrections***

In May 2005, the FASB issued SFAS 154, Accounting Changes and Error Corrections which supersedes APB Opinion No. 20, Accounting Changes and SFAS 3, Reporting Accounting Changes in Interim Financial Statements. SFAS 154 changes the requirements for the accounting for and reporting of a change in accounting principle. SFAS 154 also carries forward without change the guidance contained in APB 20 for reporting the correction of an error in previously issued financial statements and a change in accounting estimate. SFAS 154 requires retrospective application to prior periods' financial statements of changes in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. The correction of an error in previously issued financial statements is not a change in accounting principle. However, the reporting of an error correction involves adjustments to previously issued financial statements similar to those generally applicable to reporting an accounting change retroactively. Therefore, the reporting of a correction of an error by restating previously issued financial statements is also addressed by SFAS 154. SFAS 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. United Therapeutics does not believe that the adoption of this statement will have a material impact on its financial condition, results of operations or cash flows.

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

The following presents certain quarterly financial information for each of the years ended December 31, 2006 and 2005 (in thousands, except per share amounts):

	<b>Quarters Ending During 2006</b>			
	<b>December 31,</b>	<b>September 30,</b>	<b>June 30,</b>	<b>March 31,</b>
	<b>2006</b>	<b>2006</b>	<b>2006</b>	<b>2006</b>
Net sales	\$ 45,826	\$ 40,397	\$ 40,245	\$ 33,164
Gross profit	41,073	36,243	36,001	29,287
Net income	55,508	8,478	7,673	2,307
Income per share—basic	\$ 2.54	\$ 0.37	\$ 0.33	\$ 0.10
Income per share—diluted	\$ 2.42	\$ 0.34	\$ 0.30	\$ 0.09

  

	<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

**United Therapeutics Corporation**  
**Schedule II—Valuation and Qualifying Accounts**  
**Years Ended December 31, 2006, 2005, and 2004**  
(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, 2006	\$ 15	\$ 1	\$ (15)	\$ 1
Year ended December 31, 2005	\$ 23	\$ 9	\$ (17)	\$ 15
Year ended December 31, 2004	\$ 119	\$ 24	\$ (120)	\$ 23

	<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, 2006	\$ 570	\$ 472	\$ (602)	\$ 440
Year ended December 31, 2005	\$ 447	\$ 315	\$ (192)	\$ 570
Year ended December 31, 2004	\$ 321	\$ 316	\$ (190)	\$ 447

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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, 2006. 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, 2006.

### ***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, 2006, 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, 2006, 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, 2006 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, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information required by Item 10 regarding nominees and directors appearing under *Election of Directors* in our definitive proxy statement for our 2007 annual shareholders meeting (the 2007 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 and the Audit Committee's financial expert appearing under *Board Meetings and Committees—Audit Committee* in the 2007 Proxy Statement is hereby incorporated herein by this reference.

Information appearing under *Section 16(a) Beneficial Ownership Reporting Compliance* in the 2007 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 <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 Senior 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 *Compensation Disclosure and Analysis* in the 2007 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 2007 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, 2006 regarding our securities authorized for issuance under equity compensation plans:

Plan category	Number of securities to be	Weighted average exercise price of outstanding options	Number of securities remaining
	issued upon exercise of outstanding options (a)		available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plan approved by security holders	4,997,222	\$ 47.14	8,014,934
Equity compensation plans not approved by security holders	711,698	\$ 20.23	None
Total	<u>5,708,920</u>	<u>\$ 43.78</u>	<u>8,014,934</u>

We have one equity compensation plan approved by security holders. In addition, prior to 2005, 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 6 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 10.22 and 10.38.

#### **ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

Information concerning related party transactions and director independence required by Item 13 appears under *Certain Relationships and Related Transactions Director Independence and Board Committees* in the 2007 Proxy Statement and is hereby incorporated herein by this reference.

#### **ITEM 14. PRINCIPAL ACCOUNTING 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 2007 Proxy Statement and is hereby incorporated by reference.

**PART IV**

**ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES**

- (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 A 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 18, 2000.
4.7	Indenture, dated October 30, 2006, between Registrant and The Bank of New York, as trustee (including form of 0.50% Convertible Senior Note due October 15, 2011), incorporated by reference to Exhibit 4.1 of Registrant's Current Report on Form 8-K filed October 30, 2006.
4.8	Resale Registration Rights Agreement, dated October 30, 2006, between Registrant and Deutsche Bank Securities Inc., as the initial purchaser, incorporated by reference to Exhibit 4.2 of Registrant's Current Report on Form 8-K filed October 30, 2006.
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**	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).
10.3**	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.

- 10.4\*\* 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.
- 10.5\*\* 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.
- 10.6\* 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).
- 10.7\* 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).
- 10.8\* 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).
- 10.9\* 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).
- 10.10\*\* 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.
- 10.11\*\* 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.
- 10.12\* 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).
- 10.13\*\* 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.
- 10.14 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).
- 10.15\* 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).
- 10.16 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).
- 10.17 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 February 1, 2001.
- 10.18 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 February 1, 2001.

- 10.19 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.
- 10.20 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.
- 10.21\*\*\* 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.
- 10.22\*\* Standard Non-plan Option Award Agreement used by Registrant, incorporated by reference to Exhibit 10.39 to Registrant's Form 10-K for the year ended December 31, 2002.
- 10.23\*\* 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.
- 10.24\*\* 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.
- 10.25\*\* 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.
- 10.26 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.
- 10.27\*\* 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.
- 10.28 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.
- 10.29 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.
- 10.30 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.
- 10.31 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.
- 10.32 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.
- 10.33\*\* 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.

10.34**	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.
10.35**	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.
10.36**	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.
10.37**	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.
10.38**	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.
10.39	Turner Construction Contract, incorporated by reference to Exhibits 99.1 and 99.2 of Registrant's Current Report on Form 8-K filed March 17, 2005.
10.40**	United Therapeutics Corporation Supplemental Executive Retirement Plan, incorporated by reference to Exhibit 10.1 of Registrant's Current Report on Form 8-K filed May 4, 2006.
10.41**	Description of Registrant's modified cash bonus target criteria for 2006, incorporated by reference to Registrant's Current Report on Form 8-K filed June 26, 2006.
10.42	Stock Purchase Agreement, dated as of July 27, 2006, between Registrant and Toray Industries, Inc., incorporated by reference to Exhibit 10.1 of Registrant's Current Report on Form 8-K filed July 27, 2006.
10.43**	Employment Agreement, dated August 2, 2006, between John Ferrari and Registrant, incorporated by reference to Exhibit 10.1 of Registrant's Current Report on Form 8-K filed August 4, 2006.
10.44**	Amendment, dated July 31, 2006, to amended Employment Agreement, dated November 29, 2000, between Roger Jeffs, Ph.D. and Registrant, incorporated by reference to Exhibit 10.2 of Registrant's Current Report on Form 8-K filed August 4, 2006.
10.45**	Amendment, dated July 31, 2006, to amended Employment Agreement, dated June 16, 2001, between Paul A. Mahon and Registrant, incorporated by reference to Exhibit 10.3 of Registrant's Current Report on Form 8-K filed August 4, 2006.
10.46	First Amendment to Certain Operative Agreements, dated May 16, 2006, between Wachovia Development Corporation and Registrant, incorporated by reference to Exhibit 10.1 of Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2006.
10.47	Confirmation, dated October 24, 2006, between Deutsche Bank AG London and Registrant, incorporated by reference to Exhibit 10.1 of Registrant's Current Report on Form 8-K filed October 30, 2006.
10.48	Confirmation, dated October 24, 2006, between Deutsche Bank AG London and Registrant, incorporated by reference to Exhibit 10.2 of Registrant's Current Report on Form 8-K filed October 30, 2006.
10.49**	Amendment, dated December 28, 2006, to Employment Agreement, dated August 2, 2006, between John Ferrari and Registrant, incorporated by reference to Exhibit 10.1 of Registrant's Current Report on Form 8-K filed on December 29, 2006.
12.1	Computation of Earnings to Fixed Charges.
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, 2007

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, 2007
<u>/s/ ROGER A. JEFFS</u> Roger A. Jeffs	President, Chief Operating Officer and Director	February 27, 2007
<u>/s/ JOHN M. FERRARI</u> John M. Ferrari	Chief Financial Officer and Treasurer	February 27, 2007
<u>/s/ CHRISTOPHER CAUSEY</u> Christopher Causey	Director	February 27, 2007
<u>/s/ RAYMOND DWEK</u> Raymond Dwek	Director	February 27, 2007
<u>/s/ R. PAUL GRAY</u> R. Paul Gray	Director	February 27, 2007
<u>/s/ RAYMOND KURZWEIL</u> Raymond Kurzweil	Director	February 27, 2007
<u>/s/ CHRISTOPHER PATUSKY</u> Christopher Patusky	Director	February 27, 2007
<u>/s/ LOUIS W. SULLIVAN</u> Louis W. Sullivan	Director	February 27, 2007

**United Therapeutics Corporation**  
**Ratio of Earnings to Fixed Charges**  
**(Unaudited)**

	Years Ended December 31,				
	2006	2005	2004	2003	2002
	(in thousands, except ratio)				
Earnings (losses) from continuing operations before fixed charges	\$ 28,982	\$ 42,893	\$ 13,209	\$ (11,526)	\$ (18,003)
Fixed charges					
Interest expenses, net of capitalized interest	\$ 482	\$ 29	\$ 3	\$ 112	\$ 117
Capitalized interest	—	—	—	—	—
Portion of rentals representative of interest factor	1,172	—	—	—	—
Total fixed charges	1,654	29	3	112	117
Ratio of earnings to fixed charges	17.52	1,479.07	4,403.00	—	—
Excess fixed charges over earnings	\$ —	\$ —	\$ —	\$ 11,638	\$ 18,120

NOTE: The Ratio of Earnings to Fixed Charges should be read in conjunction with the Consolidated Financial Statements and related Notes and Management's Discussion and Analysis of Financial Condition and Results of Operations in United Therapeutics Corporation's Annual Report on Form 10-K for the year ended December 31, 2006.

**SUBSIDIARIES OF THE REGISTRANT**

Lung Rx, Inc., a Delaware Corporation

Unither Telmed, Ltd. (f/k/a Unither Telemedicine Services Corporation), 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 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-8 No. 333-108169) pertaining to the United Therapeutics Corporation's Equity Incentive Plan,
- (3) Registration Statement (Form S-8 No. 333-56922) pertaining to the United Therapeutics Corporation's Equity Incentive Plan;
- (4) Registration Statement (Form S-8 No. 333-95419) pertaining to the United Therapeutics Corporation's Equity Incentive Plan;  
and
- (5) Registration Statement (Form S-3 No. 333-139631) of United Therapeutics Corporation.

of our reports dated February 27, 2007, with respect to the consolidated financial statements and schedule of United Therapeutics Corporation, 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 this 2006 Annual Report (Form 10-K) of United Therapeutics Corporation.

/s/ Ernst & Young LLP

McLean, Virginia  
February 27, 2007

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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, 2007

/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, John M. Ferrari, 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, 2007

/s/ JOHN M. FERRARI

By: John M. Ferrari

Title: *Chief Financial Officer and Treasurer*

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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, 2006 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, 2007

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, 2006 as filed with the Securities and Exchange Commission (the "Report"), I, John M. Ferrari, 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/ JOHN M. FERRARI

John M. Ferrari

*Chief Financial Officer and Treasurer*

United Therapeutics Corporation

February 27, 2007

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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