UNITED THERAPEUTICS CORP
Form 10-K
February 29, 2008

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2007

OR

o **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	**52-1984749**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
1110 Spring Street, Silver Spring, MD	**20910**
(Address of Principal Executive Offices)	(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	**Name of each exchange on which registered**
Common Stock, par value $.01 per share and associated preferred stock purchase rights	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 ý No o

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 o No ý

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 ý No o

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. ý

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

Large accelerated filer ý	Accelerated filer o	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

The aggregate market value of the Common Stock held by non-affiliates of the registrant, based on the closing price on June 30, 2007, as reported by the NASDAQ National Market was approximately $1,158,300,000.

The number of shares outstanding of the issuer's common stock, par value $0.01 per share, as of February 22, 2008, was 22,343,955

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for the registrant's 2008 annual meeting of shareholders are incorporated by reference in Part III of this Form 10-K.

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PART I

ITEM 1. BUSINESS

We are a biotechnology company focused on the development and commercialization of unique products to address the unmet medical needs of patients with chronic and life-threatening cardiovascular and infectious diseases and cancer.

Our key therapeutic platforms are:

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 lead prostacyclin analog is Remodulin®, a treprostinil-based compound for the treatment of cardiovascular disease. Remodulin (treprostinil sodium) Injection, has been approved by the U.S. Food and Drug Administration (FDA) for the treatment of pulmonary arterial hypertension (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 idiopathic or familial PAH. Our inhaled and oral formulations of treprostinil are in the later stages of development. We are also developing Beraprost-MR, another prostacyclin analog, for the treatment of cardiovascular disease;

Glycobiology Antiviral Agents, which are a class of small molecules that have shown promise against a broad range of viruses, such as hepatitis C; and

Monoclonal Antibodies, which are antibodies that activate patients' immune systems to treat cancer. This platform includes the 3F8 and 8H9 murine antibodies, which are being developed for the treatment of neuroblastoma and metastatic brain cancer, respectively.

We devote most of our resources to developing products within these three therapeutic platforms. We also devote resources to the commercialization and further development of telemedicine products and services, principally for the detection of cardiac arrhythmias.

We generate revenues from sales of Remodulin, telemedicine products and services and, until September 2007, from the sale of arginine products. 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 specialty pharmaceutical distributors.

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

United Therapeutics' Products

Our Products

Our product portfolio includes the following as of December 31, 2007:

Product	Mode of Delivery	Indication/Market	Current Status	Our Territory
Remodulin	Continuous subcutaneous	Pulmonary arterial hypertension	Commercial in the U.S., most of the European Union, Canada, Israel, Australia, Mexico, Argentina and Peru*	Worldwide
Remodulin	Continuous intravenous	Pulmonary arterial hypertension	Commercial in the U.S., Canada, Israel, Mexico, Argentina and Peru. European reviews are ongoing	Worldwide
CardioPAL® SAVI and Decipher Cardiac Monitors	Telemedicine	Cardiac arrhythmias and ischemic heart disease	Commercial	Worldwide
Inhaled Treprostinil	Inhaled	Pulmonary arterial hypertension	Phase III	Worldwide
Oral Treprostinil	Oral	Pulmonary arterial hypertension	Phase III	Worldwide
Remodulin	Intravenous	Improved transplant outcome	Phase III	Worldwide
Beraprost MR	Oral	Pulmonary arterial hypertension	Phase II	North America/Europe
3F8 MAb	Intravenous	Neuroblastoma	Phase II	Worldwide
Oral Treprostinil	Oral	Peripheral vascular disease	Phase II	Worldwide
CardioPAL SAVI Wireless Cardiac Event Monitors	Telemedicine	Cardiac arrhythmias and ischemic heart disease	Phase II	Worldwide
Miglustat	Oral	Hepatitis C	Phase I	Worldwide
Inhaled Treprostinil	Inhaled	Idiopathic pulmonary fibrosis	Phase I	Worldwide
Inhaled Treprostinil with AERx Essence®	Inhaled	Pulmonary arterial hypertension	Phase I	Worldwide
8H9 MAb	Intravenous	Metastatic brain cancer	Phase I	Worldwide
Glycobiology Antiviral Agents	Oral	Hepatitis C and other infectious diseases	Pre-Clinical	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.

Products to Treat Cardiovascular Disease

Remodulin

Our lead product for treating PAH is Remodulin (treprostinil sodium) Injection, the main ingredient of which is treprostinil sodium, a prostacyclin analog. 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 $200.9 million, $152.5 million and $109.2 million of revenues, representing 95%, 96% and 94% of our total revenues from sales of Remodulin in 2007, 2006 and 2005, respectively. We obtained worldwide rights for all indications to Remodulin from GlaxoSmithKline PLC (formerly Glaxo Wellcome, Inc.) in January 1997 and from Pfizer, Inc. (formerly Pharmacia & Upjohn Company) in December 1996. In May 2002, Remodulin was approved by the FDA as a continuous subcutaneous (under the skin) infusion for the treatment of PAH in patients with NYHA Class II-IV (moderate to severe) symptoms. 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 further expanded to allow patients to transition to Remodulin from Flolan® (epoprostenol), the first FDA-approved prostacyclin for PAH. Remodulin is also approved as a continuous subcutaneous infusion treatment for various forms of PAH in 33 countries throughout the world, and as a continuous intravenous infusion treatment for various forms of PAH 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 to work on expanding commercialization to new territories such as Japan and South Korea.

PAH is a life-threatening vascular disease that affects the blood vessels in the lungs, known as the pulmonary blood vessels, which increases blood pressure in the artery between the heart and the lungs known as the pulmonary artery. 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 increases strain on the right side of the heart as it tries to pump blood to the lungs. It is estimated that PAH affects between 100,000 and 200,000 individuals worldwide. In recent years, as awareness of PAH has grown, we have seen an increase in the number of people diagnosed with the disease. However, because of the rareness of PAH and the complexities of diagnosing it, only a small fraction of these people are being treated. Many organizations are conducting research to develop easier, less invasive methods to diagnose PAH. If this research is successful, more patients could be diagnosed at an earlier stage.

The complexity of diagnosing PAH is due in part to the current uncertainties surrounding the etiology and pathophysiology of the condition. Currently, treatment of PAH focuses on three distinct molecular pathways that have been implicated in the disease process. These are the endothelin pathway, the nitric oxide pathway, and the prostacyclin pathway. Patients with PAH have been shown to have elevated levels of endothelin, a naturally occurring substance in the body that causes constriction of the pulmonary blood vessels. Therefore, one established therapeutic approach has been to block the action of endothelin with drugs that are known as endothelin receptor antagonists. Patients with PAH have also been shown to have reduced levels of the enzyme responsible for producing nitric oxide (NO), a naturally occurring substance in the body that has the effect of relaxing pulmonary blood vessels. NO produces this effect by increasing intracellular levels of an intermediary known as cGMP in cells. Therefore, another established therapeutic approach has been to inhibit the degradation of cGMP, using drugs that are termed phosphodiesterase 5 (PDE5) inhibitors. Finally, patients with PAH have been shown to have reduced levels of prostacyclin, a naturally occurring substance that has the effect of relaxing the pulmonary blood vessels, preventing platelet aggregation, and inhibiting the proliferation of smooth muscle cells in pulmonary vessels. Therefore, drugs that mimic the action of prostacyclin, termed prostacyclin analogs, are also established PAH treatments. Because any or all of these three

pathways may be operative in a patient, these three classes of drugs are used alone or in combination to treat patients with PAH.

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 (730 patients). In patients with idiopathic PAH for whom baseline hemodynamics were available (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.

Flolan, the first FDA-approved synthetic prostacyclin for PAH, is 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 lasts significantly longer 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 presence 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 mix 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 patient to continuously keep the drug cool even during infusion. This eliminates the need for cooling packs or refrigeration to keep it stable, as is required with Flolan due to Flolan's chemical instability at room temperature.

There are noteworthy adverse events associated with Remodulin infusion. When infused subcutaneously, Remodulin causes infusion site pain and 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 the risk of a bloodstream infection known as sepsis, 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.

FDA Review of 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. In May 2002, the FDA approved Remodulin, under Subpart H regulations, 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 types of PAH and is the only PAH treatment approved for NYHA class II, III and IV patients.

FDA Review of 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 that there were no additional safety concerns associated with chronic intravenous 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.

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 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. 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 subcutaneous Remodulin. Many patients are unsuccessful in managing such infusion site pain even when 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, Remodulin remains active for a few hours, whereas 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. Intravenous Remodulin can be infused continuously for up to 48 hours while Flolan can only be infused for 24 hours. This allows patients to mix 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 pumps, is available to patients.

In February 2007, the Scientific Leadership Committee (SLC) of the Pulmonary Hypertension Association announced new guidance related 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 were subsequently published in the March 2, 2007, issue of the CDC's *Morbidity and Mortality Weekly Report*. The slides and report were prepared in connection with a CDC retrospective inquiry at seven centers into a report of increased blood stream infections (sepsis), 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. The risk of sepsis is already noted in the Remodulin package insert. In February 2008, the FDA revised the Remodulin package insert to more fully describe the associated infection risk and appropriate techniques to be practiced when preparing and administering Remodulin intravenously.

International Regulatory Review of Subcutaneous and Intravenous Remodulin

Remodulin for subcutaneous use is approved in countries throughout the world. We used the mutual recognition process to obtain approval of subcutaneous Remodulin from European Union member countries. The mutual recognition process is described in detail in the section entitled *Government Regulation* below. The mutual recognition process for subcutaneous Remodulin was completed in August 2005, with positive decisions received from most European Union countries. We withdrew our applications in Ireland, Spain and the United Kingdom following a request for additional documentation from these countries. We anticipate resubmitting these applications following intravenous Remodulin approval in Europe. Licenses and pricing approvals have been received in most European Union countries. In addition, we have submitted a variation of the license for approval of intravenous Remodulin in the European Union through the mutual recognition process, as we are required to follow the same approval process used for the approval of subcutaneous Remodulin. The license variation for intravenous Remodulin is currently under review by the host nation, France, which has notified us that it is not satisfied with the filing we have made. We will work to address these concerns and believe that we will eventually receive commercial approval for intravenous Remodulin in at least some European countries. In the meantime, we will continue to sell (but not market) Remodulin in European Union countries where we are not approved under the named-patient system, which allows us to import Remodulin into European Union countries for sale to hospitals for use in treating specifically identified patients.

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 sales and marketing team consisted of approximately 65 employees as of December 31, 2007, up from approximately 20 employees as of December 31, 2006, with further growth expected in 2008. Our marketing team is divided into two approximately equal groups. The first group is primarily responsible for national and large regional medical practice accounts currently prescribing Remodulin. The second group is primarily responsible for the smaller, local, community-oriented medical practices not currently prescribing Remodulin. Additionally, we rely on specialty pharmacy distributors to handle physician and patient requests for Remodulin on a non-exclusive basis in the United States. For additional information, see the section entitled *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., through a national specialty pharmaceutical wholesaler. We are working with our current distributors to expand Remodulin sales into other countries in which they have distribution rights.

Domestic Distribution of Remodulin

To provide for marketing, promotion and distribution of subcutaneous and intravenous Remodulin in the United States, we entered into non-exclusive distribution agreements with CuraScript, Inc. (a

wholly-owned subsidiary of Express Scripts, Inc., formerly Priority Healthcare Corporation), Accredo Therapeutics, Inc. (a wholly-owned subsidiary of Medco Health Solutions, Inc.), and Caremark, Inc. (a wholly-owned subsidiary of CVS Corporation). Effective January 1, 2007, Accredo also became the exclusive U.S. distributor for Flolan. Our distributors are responsible for assisting patients with obtaining reimbursement for the cost of Remodulin therapy and providing other support services. Under our distribution agreements, we sell Remodulin to our distributors at a discount from an average wholesale price recommended by us. These agreements provide for automatic renewal for additional two-year periods, in the case of CuraScript, and one-year periods in the case of Accredo and Caremark, unless either party to the agreements provides notice of termination. Due to changes in the regulatory environment, i.e., changes in the regulatory requirements, from time to time we update the contracts with our distributors. None of the changes have had or are expected to have a significant impact on our operations or relationships with these distributors, as these changes tend to be in the ordinary course of business. In addition, none of our current agreements contain the distribution rights for inhaled or oral treprostinil in the United States. If these distributor agreements expire or terminate, we may, under certain circumstances, be required to repurchase unsold Remodulin inventory held by the distributors. We have also established a patient assistance program in the United States, which provides qualified uninsured or underinsured patients with Remodulin at no charge.

International Distribution of Remodulin

We currently sell Remodulin to six distributors who have distribution rights for subcutaneous and intravenous Remodulin in European Union countries, other non-European Union countries, South America, and Israel. In the European markets where we are not licensed, we sell (but do not market) Remodulin under the named-patient system in which patients typically are approved for therapy on a case by case review by a national medical review board. We are working on expanding our sales of subcutaneous and intravenous Remodulin into new territories outside of the United States through our existing distributors and new distributors. In March 2007, we entered into a distributor agreement with Mochida Pharmaceutical Co., Ltd. (Mochida) to exclusively distribute subcutaneous and intravenous Remodulin in Japan. In addition, Grupo Ferrer Internacional, S.A. (Grupo Ferrer) has been actively working toward commencing commercial sales of Remodulin in Taiwan and South Korea, territories to which Grupo Ferrer was granted distribution rights. However, certain countries, like Japan, may require that new clinical trials, called bridging trials, be conducted in order to show the efficacy and safety of a drug in their patient population. Commercial sales in such countries could therefore be several years from realization.

Inhaled Treprostinil

We are working to develop an inhaled formulation of treprostinil for the treatment of PAH. 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 orphan designation for inhaled treprostinil for the treatment of both PAH and chronic thromboembolic pulmonary hypertension. If inhaled treprostinil is approved by the FDA for the treatment of PAH, it will most likely be covered in the United States under the remaining orphan drug exclusivity applicable to Remodulin. This period of orphan drug exclusivity expires on May 21, 2009. If we obtain a separate orphan drug designation for inhaled treprostinil for the treatment of PAH and we demonstrate that inhaled treprostinil is clinically superior to Remodulin, then we may obtain a seven-year period of orphan drug exclusivity for inhaled treprostinil that will begin upon the approval of our New Drug Application.

In June 2005, our wholly-owned subsidiary, Lung Rx, Inc., commenced a 12-week, randomized, double-blind, placebo-controlled Phase III trial of inhaled treprostinil in patients with PAH who are also being treated and were optimized with Tracleer®, an oral endothelin antagonist marketed by Actelion Ltd. During the 12-week trial, patients were administered inhaled treprostinil or placebo in four daily inhalation sessions with a maximum dose of approximately 45 micrograms per session. The primary endpoint of the trial was the peak six minute walk (6MW) distance improvement test, which is a typical benchmark test of cardiovascular health. This trial, TRIUMPH-1 (**TR**eprostinil Sodium **I**nhalation **U**sed in the **M**anagement of **P**ulmonary Arterial **H**ypertension), was conducted at approximately 36 centers in the United States and Europe. In May 2006, the FDA agreed to also permit the inclusion in the trial of PAH patients who were also being treated with and optimized on Revatio®, an oral PDE-5 inhibitor marketed by Pfizer, Inc. The FDA also agreed to expand the trial size to at least 200 patients, and to permit an interim efficacy assessment after 150 patients had completed the trial. We did not conduct the interim efficacy assessment.

In November 2007, we announced the completion of our TRIUMPH-1 trial. The study population consisted of 235 patients. The majority of patients were classified as New York Heart Association (NYHA) Class III (98%). Patients in the trial were affected by PAH of varied etiologies, including idiopathic or familial PAH (~55%), collagen vascular disease associated PAH (~35%), and PAH associated with HIV, anorexigens (appetite suppressants) or other associated conditions (~10%). Mean baseline walk distance was approximately 350 meters.

The primary efficacy endpoint of the trial was the 6MW distance at 12 weeks measured at peak exposure, defined by the trial protocol as 10-60 minutes after inhalation of treprostinil, relative to baseline. Preliminary analysis of the TRIUMPH-1 results demonstrated an improvement in median 6MW distance by approximately 20 meters ($p<0.0006$, using the Hodges-Lehmann estimate and non-parametric analysis of covariance in accordance with the trial's pre-specified statistical analysis plan), in patients receiving treprostinil as compared to patients receiving placebo.

At trough exposure, which was defined by the trial protocol as a minimum of four hours after inhalation of treprostinil, the treatment-related change in 6MW distance at week 12 relative to baseline was also significantly improved, with an increase in median 6MW distance of approximately 14 meters ($p<0.01$). Additionally, the 6MW distance at week 6 relative to baseline was significantly improved, with an increase in median 6MW distance of approximately 18 meters ($p<0.0005$).

Preliminary analysis of other secondary endpoints, including change in Borg Dyspnea Scale rating (shortness of breath test), NYHA functional class, time to clinical worsening (as defined by death, transplant, the need for atrial septostomy (surgical opening of the septum), hospitalization due to PAH, or initiation of another approved PAH therapy), and the 6MW distance at treatment day one, did not differ significantly between the inhaled treprostinil and placebo groups ($p>0.05$). Analysis of two remaining secondary endpoints, quality of life and signs and symptoms of disease (composite measure), is ongoing.

Inhaled treprostinil was generally well-tolerated in the trial and adverse events appeared to be similar to those previously reported for treprostinil or due to administration by inhalation. The most common adverse events seen in the trial were transient cough, headache, nausea, dizziness and flushing. Detailed analysis of the reported adverse events is ongoing. All patients in the trial had the option to continue receiving inhaled treprostinil in an open-label continuation study after completion of the 12-week study period. Of the 212 patients who completed the 12-week study period, approximately 200 patients entered the open-label continuation study. Approximately 160 patients are currently being treated with inhaled treprostinil, with the longest duration of treatment exceeding two years. Further review and analysis of the TRIUMPH-1 results are ongoing. Full data from TRIUMPH-1 is expected to be presented at the American Thoracic Society meeting in May 2008 and is also expected to be available through the publication of peer-reviewed journal articles.

FDA approval for inhaled treprostinil will be sought by filing a New Drug Application (NDA). The Optineb® inhalation device will also be submitted for approval as part of this filing. Optineb is the ultra-sonic nebulizer that was used for administration of inhaled treprostinil in the TRIUMPH-1 trial. Optineb is manufactured by NEBU-TEC International Med Products Eike Kern GmbH. (NEBU-TEC), a German company. Optineb is approved in Germany and in other European countries, but is not yet approved in the United States.

This is the first time we have submitted an inhalation device for FDA approval. Since we do not manufacture the Optineb device, we rely on NEBU-TEC for certain design, mechanical, operational and study information needed for the filing. We are actively working with NEBU-TEC to obtain information necessary to complete the application. We expect to file the NDA and the application for approval of the Optineb device by mid-2008. FDA review of the NDA generally takes 10 months. We plan on filing for approval in the European Union using the centralized filing process by the end of 2008. See the section entitled *Government Regulation* below for further details.

Currently, the only FDA approved inhaled prostacyclin analog is Ventavis®. 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 administered six to nine times per day using a nebulizer. Each session on the nebulizer requires continuous inhalation of the drug for 4 to 10 minutes. Due to the longer half-life of treprostinil and its greater selectivity to the lungs, treprostinil can be inhaled with a nebulizer for about one minute, taking six to nine breaths per session, four times a day.

The inhalation device market is ever-changing, with smaller devices being developed concurrently with the discovery of new technologies. We are interested in new technologies that would enable a more efficient and convenient means of administering inhaled treprostinil to patients. For this reason, in August 2007, our wholly-owned subsidiary, Lung Rx Inc., entered into an exclusive license, development and commercialization agreement with Aradigm Corporation (Aradigm) for the rights to manufacture, develop and commercialize its AERx Essence® device, a pulmonary drug delivery system, for use as a next-generation metered-dose inhaler with inhaled treprostinil.

UT-15C Sustained Release (Oral Treprostinil)

We are developing an oral formulation of treprostinil, treprostinil diethanolamine, which is 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 in tablets. The coating technology, which is resistant to being broken down by the body's digestive system, allows for treprostinil to be released into the body through an extremely small hole that is laser-drilled into the coating of each tablet. This technology releases the treprostinil at a relatively even rate over a controllable period of time. In 2005, a Phase I study of normal volunteers demonstrated that the formulation and coating provided sustained blood concentrations of treprostinil for 8 to 10 hours following a single oral dose. This duration may allow for twice daily dosing. In July 2005, the European Medicines Agency announced that oral treprostinil had been granted orphan product status in the European Union. If we obtain a separate orphan drug designation for oral treprostinil for the treatment of PAH and we demonstrate that oral treprostinil is clinically superior to Remodulin, then we may obtain a seven-year period of orphan drug exclusivity for oral treprostinil that will begin upon the approval of our New Drug Application. Drugs with orphan status generally receive accelerated review of approval applications and may receive longer periods of protection against competition from generic drugs.

Two multi-national, placebo-controlled clinical trials of oral treprostinil in patients with PAH commenced in October 2006. These are Phase III trials in which both dosing and efficacy are being studied. The FREEDOM-C trial is a 16-week study of up to 300 patients currently on approved background therapy using a PDE5 inhibitor, such as Revatio, or an endothelin antagonist, such as Tracleer, or a combination of both, with a possible interim assessment at 150 patients. The FREEDOM-M trial is a 12-week study of up to 150 patients, who are not on any background therapy, with a possible interim assessment at 90 patients. We do not expect to conduct the interim efficacy assessment available in either trial. Both trials are being conducted at approximately 60 centers throughout the United States and the rest of the world. During these trials, patients are administered oral treprostinil or placebo twice a day. The dosage begins at 1 mg twice daily for both trials, the maximum dose is set at 16 mg twice daily for the FREEDOM-C trial and 12 mg twice daily for the FREEDOM-M trial, based on symptomatic benefit and tolerability. The primary endpoint of the trial is the 6MW test in which the distance a patient walks in six minutes on a treadmill is measured at the start of the trial and at additional pre-specified points in time during the trial in order to detect any improvement in the distance the patient is able to walk over the course of the trial.

We commenced the trials using a 1 mg tablet, but during the open-label extension trial discovered that the absorption rate of treprostinil was higher in diseased patients than in healthy individuals. The difference in absorption rate led to a number of discontinuations from the trials due to patients suffering from tolerability-related side effects, including nausea, jaw-pain and headaches as the dose was increased. As a result, we introduced a 0.5 mg tablet in July 2007 to enable more gradual dose titration (increase). A 0.25 mg tablet is also being manufactured for use in the trials and will be available once all appropriate quality and release testing has been completed. We are also developing a 0.125 mg tablet and a 2.5 mg tablet. Since the introduction of the 0.5 mg tablet, discontinuations have greatly diminished. As of December 31, 2007, there were approximately 200 and 90 patients enrolled in the FREEDOM-C and FREEDOM-M trials, respectively. As of February 18, 2008, there were approximately 240 and 100 patients enrolled in the FREEDOM-C and FREEDOM-M trials, respectively.

There are currently no approved oral prostacyclin therapies available to patients in the United States or Europe. If we are successful in developing oral treprostinil, patients and physicians may be encouraged to use prostacyclin earlier in the PAH disease cycle and in the treatment of other diseases.

Beraprost-MR

In June 2000, we entered into an agreement with Toray Industries, Inc. (Toray), for 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 cardiovascular indications. Beraprost is a chemically stable orally bioavailable prostacyclin analog. 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.

In March 2007, Lung Rx, Inc. (Lung Rx), entered into an amended agreement with Toray to assume and amend the rights and obligations of the June 2000 agreement entered into between Toray and us concerning the commercialization of a modified release formulation of beraprost (beraprost-MR). The amended agreement grants us additional exclusive rights to commercialize beraprost-MR in Europe and broadens the indication to vascular disease (excluding renal disease), among other revisions. An earlier clinical trial which examined an immediate release form of beraprost as monotherapy in PAH had demonstrated 6MW distance improvement at 12 weeks but not at 36 weeks. However, because a number of patients did respond positively to the drug, we feel that the development of beraprost-MR as combination therapy presents a promising clinical opportunity. Since individual PAH patients may respond to the same class of molecules in different ways, we believe that the development of other molecules within the same family is desirable. In addition, we are in the early

stages of exploring the use of beraprost-MR for the treatment of other cardiovascular and cardiopulmonary conditions.

On October 19, 2007, Toray announced that beraprost-MR received regulatory approval in Japan for use in the treatment of PAH.

Products to Treat Peripheral Vascular Disease/Critical Limb Ischemia

UT-15C Sustained Release (Oral Treprostinil)

We are also developing oral treprostinil for late-stage peripheral vascular disease known as critical limb ischemia. Peripheral vascular disease 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 assessing the safety and blood flow effects of intravenous Remodulin on patients with critical limb ischemia. The study demonstrated that Remodulin can be administered safely to patients with critical limb ischemia and that Remodulin substantially increases 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 ended before becoming fully enrolled due to difficulties in patient recruitment. We believe that more convenient formulations of treprostinil, such as the oral form, may be more appropriate for patients with peripheral vascular disease. Accordingly, we have commenced safety and tolerability studies with oral treprostinil in patients with critical limb ischemia.

Products to Treat other Medical Conditions

We are currently studying the use of intravenous Remodulin in connection with liver transplants. Independent studies indicate that patients who received prostacyclin after a liver transplant tended to have a lower rate of tissue rejection and increased liver function which resulted in shorter hospital stays and improved transplant outcomes. We are currently conducting a Phase III study to demonstrate the safety and efficacy of intravenous Remodulin when administered during and after liver transplant.

Products to Treat Infectious Diseases 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 and other infectious diseases. Currently, many of these agents are undergoing laboratory testing, and new agents are also being synthesized.

We are in the planning stages of conducting a Phase II clinical trial with miglustat, a glycobiology compound which inhibits alpha-glucosidase enzymes, to initially evaluate efficacy in patients with hepatitis C. Miglustat is approved and is currently marketed in the United States and Europe by Actelion Ltd for the treatment of Gaucher's disease, a glycolipid storage disorder. Patent protection for manufacturing the compound has expired. As a result of our research agreement with the University of Oxford, we have the exclusive right to commercialize miglustat as an anti-viral agent for the treatment of hepatitis C.

Products to Treat Cancer

OvaRex

In April 2002, we entered into an agreement with AltaRex Corp. (which later became AltaRex Medical Corp., a wholly-owned subsidiary of ViRexx Medical Corp.) (AltaRex) to exclusively license certain rights to a platform of five investigational 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® MAb for the treatment of advanced ovarian cancer, had completed Phase II studies.

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 December 2007, we announced the completion of our two pivotal trials of OvaRex. Analysis of the results demonstrated that the studies failed to reach statistical significance.

The identical studies, known as IMPACT I and II (**IM**munotherapy **P**ivotal ov**A**rian **C**ancer **T**rial), were randomized, double-blind, placebo-controlled trials conducted at over 60 centers across the United States. The studies enrolled 367 ovarian cancer patients and assessed the efficacy of OvaRex mono-immunotherapy during the so-called "watchful waiting" period following front-line carboplatin-paclitaxel based chemotherapy. The program sought to confirm data observed in a subset analysis of a prior randomized Phase II study, which suggested the potential of OvaRex to extend the time to disease relapse among patients who had successfully completed front-line therapy. The studies were well balanced in terms of patient demographics and the safety profile and quality of life were similar between active and control populations. The studies demonstrated no difference between active (standard of care followed by OvaRex) and control (standard of care followed by placebo) populations. The results of IMPACT I and II were consistent with each other.

The full data from the IMPACT I and II trials is expected to be presented at an upcoming medical meeting and published in a peer-reviewed journal.

Based on the results from the IMPACT I and II trials, we decided to terminate our license agreement with AltaRex and to cease further development of the entire platform of antibodies licensed thereunder. We expect to incur approximately $1.1 million in total close-out costs for this program, of which we had incurred approximately $533,000 as of December 31, 2007.

3F8 and 8H9 Antibodies

In December 2007, we entered into two agreements with Memorial Sloan-Kettering Cancer Center (MSKCC) to exclusively license certain rights to two investigational monoclonal antibodies, 3F8 and 8H9, for the treatment of neuroblastoma and metastatic brain cancer. The monoclonal antibody 3F8 is a mouse IgG3 MAb, which is currently used in an investigational setting for the treatment of neuroblastoma, a rare cancer of the sympathetic nervous system mainly affecting children. It is the most common extracranial solid cancer in children and the most common cancer in infants. More than

400 patients have been treated with the 3F8 antibody since 1986 under investigator-initiated Investigational New Drug applications. There are fewer than 1,000 new cases of neuroblastoma diagnosed each year.

The monoclonal antibody 8H9 is an IgG1 antibody that is also a mouse antibody. The 8H9 antibody is highly reactive with a range of human solid tumors, including human brain cancers. The 8H9 antibody is in early investigational development for metastases which develop in the brain from the spread of cancers from other tissues in the body. Metastatic brain cancers are ten times more common than cancers that originate in the brain, and prognosis is very poor. In the United States, more than 100,000 cases of metastatic brain cancer are diagnosed each year.

Products to Provide Telemedicine Services for Cardiac Arrhythmias and Ischemic Heart Disease

CardioPAL and Decipher Recorders

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), 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 $7.7 million, $6.6 million and $5.8 million from the sales of telemedicine products and services were earned in 2007, 2006 and 2005, respectively.

Arginine Products for Vascular Function

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® line of arginine-enriched products, which operated 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.

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.

In September 2007, we discontinued all sales of our arginine products and we reevaluated our assumptions used in determining the value of our arginine patents, based on a then recent publication discounting the benefits of arginine supplementation and a June 2007 Supreme Court decision concerning the enforceability of patents. This decision has no effect on our current licenses with companies selling arginine products.

Approximately $123,000, $100,000 and $293,000 of revenues were earned from the sales and royalties of arginine related products in 2007, 2006 and 2005, respectively.

Strategic Licenses and Relationships

Northern Therapeutics, Inc.

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

In October 2006, Northern agreed to grant us an exclusive 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 depending on patient enrollment to Northern totaling $1.5 million if the planned 18 patient Phase I trial is successfully enrolled. For the twelve months ended December 31, 2007 and 2006, we incurred approximately $150,000 and $500,000, respectively, in expense to Northern. If the Phase I trial is successfully completed, we will assume the development program and related costs for the United States market. Northern will receive royalty payments following commercialization. As part of this agreement, we terminated the Remodulin distribution agreement with Northern for Canada. We are distributing Remodulin directly in Canada under the management of our Canadian wholly-owned subsidiary, Unither Biotech Inc.

Due to our $5.0 million investment, we currently own approximately 68% of Northern, but only 49% of the voting stock. Although we own approximately 68% of Northern, 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 and consolidating the company's financial statements with our own.

NEBU-TEC Supply Agreement

In June 2004 and September 2006, we entered into Clinical and Commercial Supply Agreements with NEBU-TEC to provide for the availability of Optineb nebulizer devices and related supplies for use in our TRIUMPH-1 clinical trial of inhaled treprostinil and for commercial use following regulatory approval. The non-exclusive agreements provide for NEBU-TEC to sell us Optineb devices and supplies at specified prices and payment terms for clinical and commercial use. The agreements also specified the obligations that each party has with respect to regulatory approvals. In February 2008, we entered into an amendment to the September 2006 Clinical and Commercial Supply Agreement under which the term of the agreement was extended to the first anniversary of the first to occur of United States or European Union approval of inhaled treprostinil. We also agreed to an advance order of Optineb devices and related supplies following satisfactory completion of a testing program in support of our NDA filing. The amendment also clarified certain regulatory obligations of the parties and provided NEBU-TEC with the first opportunity to sell devices in Europe for so long as NEBU-TEC was able to meet market demand.

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 MiniMed at a discount to MiniMed list prices. The agreement commenced on September 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. Our distributors are purchasing pumps from other vendors and associated supplies from either MiniMed or directly from other vendors. Approximately $56,000, $457,000 and $397,000 of revenues were earned from the resale of MiniMed pumps and supplies in 2007, 2006 and 2005, respectively.

Aradigm Licensing Agreement

In August 2007, Lung Rx entered into an exclusive license, development and commercialization agreement with Aradigm Corporation (Aradigm) for the rights to manufacture, develop and commercialize its AERx Essence device, a pulmonary drug delivery system, for use as a next-generation metered-dose inhaler with our investigational inhaled treprostinil product in patients with PAH and other conditions. Under the terms of the agreement, we made an upfront payment of $440,000 to Aradigm and paid an additional $440,000 in January 2008. Aradigm will initiate, and is responsible for conducting and funding, a study that includes a bridging clinical trial comparing the AERx Essence technology to the Optineb nebulizer used in the TRIUMPH-1 trial. If the study is successful we will fund the costs to develop, commercialize and manufacture inhaled treprostinil for use with AERx Essence.

If the study is successful, we will purchase approximately $3.5 million of Aradigm's common stock and pay it a $650,000 licensing fee. Aradigm will receive three milestone payments over the course of the development period. The milestone payments will be made upon the first to occur of a specified event or the successive anniversaries of the effective date of our agreement with Aradigm, August 30, 2007. The first milestone payment of $2.0 million is due no later than August 30, 2008. The second and third milestone payments are due no later than each successive anniversary date and increase by $1.0 million each year. The agreement allows for the extension of these payment deadlines by the amount of time equal to the duration of any delay caused by a regulatory agency. In addition, we agreed to pay Aradigm royalty fees on a sliding scale based on net sales of the AERx Essence device.

Toray Amended License Agreement

In June 2000, we obtained from Toray Industries, Inc. (Toray) the exclusive right to develop and market beraprost, a chemically stable oral prostacyclin analog, in a sustained release formulation (beraprost-SR) in the United States and Canada for the treatment of cardiovascular indications. In March 2007, Lung Rx entered into an amended agreement with Toray to assume and amend the rights and obligations of the June 2000 agreement entered into between Toray and us in June 2000 concerning the commercialization of modified release formulations of beraprost (beraprost-MR). The amended agreement grants us additional exclusive rights to commercialize beraprost-MR in Europe and broadens the indication to vascular disease (excluding renal disease), among other revisions.

In accordance with the terms of the amended agreement, in March 2007 we issued 200,000 shares of our common stock to Toray in exchange for the cancellation of Toray's existing right to receive an option grant to purchase 500,000 shares of our common stock (the Option Grant). Under the June

2000 Agreement, Toray's right to receive the Option Grant was conditioned upon Toray's delivery to us of adequate documentation regarding the use of beraprost-SR in humans and its transfer of clinical trial material to us, neither of which had occurred as of the effective date of the amended agreement. Had the Option Grant been made, the exercise price of the options would have been set at the average closing price of our common stock for the period one month prior to the delivery date. Under the terms of the amended agreement, Toray has the right to request that we repurchase the newly issued 200,000 shares of our common stock upon 30 days prior written notice at the price of $54.41 per share, which was the average closing price of our common stock between January 11, 2007, and February 23, 2007. Based on the average closing price of our common stock for the two trading days prior to and the two trading days after March 16, 2007, the effective date of the amended agreement, we recognized a research and development expense of approximately $11.0 million relating to the issuance of the 200,000 shares, because beraprost-MR had not yet obtained regulatory approval for commercial sales. In accordance with the provision of SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, EITF 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*, and EITF Topic No. D-98, *Classification and Measurement of Redeemable Securities*, these shares of our common stock are reflected in mezzanine equity as common stock subject to repurchase valued at the repurchase price. If Toray requests that we repurchase these shares, then an amount equal to the repurchase price will be transferred to a liability account until the repurchase is completed.

The amended agreement also specifies that we make certain milestone payments to Toray during the development period and upon U.S. or European Union regulatory approval. Upon execution of the amended agreement, we made a $3.0 million payment to Toray in addition to the issuance of the 200,000 shares of our common stock discussed above. Additional annual milestone payments of $2.0 million are specified in the amended agreement and are to commence in the first quarter of 2008, increasing annually in $1.0 million increments through 2011. These payments will be expensed when incurred. These payments are contingent upon the receipt of clinical trial material and commercial drug from Toray that meet all regulatory standards and requirements, including those relating to chemistry, manufacturing and controls, and are documented to the satisfaction of U.S. and European Union regulatory authorities. In addition, if Toray elects to terminate production of beraprost-MR, no further payments would be due under the amended agreement. Conversely, if we elect to terminate development of beraprost-MR, then all remaining milestone payments would be due to Toray, unless certain regulatory standards and requirements have not been met, or if material problems have been identified with respect to manufacturing and regulatory compliance.

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).

GlaxoSmithKline Assignment

In January 1997, Glaxo Wellcome, Inc. (now GlaxoSmithKline PLC), 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.

Pfizer License

In December 1996, Pharmacia & Upjohn Company (now Pfizer, Inc.) 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.

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, we entered into an exclusive license agreement with Supernus to use certain technologies developed by them in our sustained release oral treprostinil formulation. Under the agreement, in return for the license, we 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 commercialization of other products developed using the technology granted in this license.

TransMIT License

In March 2007, TransMIT Gesellschaft fur Technologletransfer GmbH. (TransMIT), an affiliate of the University of Giessen, assigned to Lung Rx its entire interest in the patent rights to a portable ultrasonic nebulizer and related technology in order to make, have made, use and sell products based on such patent rights. As consideration for the assignment, Lung Rx paid to TransMIT approximately $779,000 and agreed to pay a 5% running royalty on net sales of nebulizers using the technology in Germany. However, no royalty payments are due to TransMIT until royalties on net sales of products in Germany exceed the original payment of approximately $779,000.

Memorial Sloan Kettering

In December 2007, we entered into two agreements with Memorial Sloan-Kettering Cancer Center (MSKCC) to exclusively license certain rights to two investigational monoclonal antibodies, 3F8 and 8H9, for the treatment of neuroblastoma and metastatic brain cancer. The monoclonal antibody 3F8 is a mouse IgG3 MAb, which is currently used in an investigational setting for the treatment of neuroblastoma, a rare cancer of the sympathetic nervous system mainly affecting children. 8H9 is also a mouse monoclonal antibody, but of the IgG1 subclass. The 8H9 antibody is highly reactive with a range of human solid tumors, including brain cancers. The 8H9 antibody is in early investigational development for metastatic brain cancer.

Under the terms of the licensing agreements, MSKCC granted us an exclusive license for the development and commercialization of the 3F8 and 8H9 antibodies for cancer throughout the universe. In exchange for these exclusive licenses, we agreed to pay a royalty fee on net sales, with an annual minimum royalty payment for each antibody. Milestone payments may also be due for the development and commercialization of these antibodies under our licenses.

Patent Term Extensions

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. Additional patents covering other products to which we have rights may also 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.

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 2007, 2006 and 2005 totaled approximately $83.4 million, $57.6 million and $36.1 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 made treprostinil, the active ingredient for Remodulin and inhaled treprostinil, and treprostinil diethanolamine, the active ingredient for oral treprostinil, at our manufacturing facility in Chicago, Illinois, until March 2007 at which time we transitioned 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 the first quarter of 2008, with regulatory agency approvals expected in the latter half of 2008. Until FDA approval, we cannot commercially use any products manufactured in the Silver Spring facility. We currently maintain an inventory of formulated Remodulin that will meet over two years of expected demand.

With the transfer of our manufacturing operations to the Silver Spring, Maryland, facility, we have also changed our internal manufacturing process. When we began, we produced treprostinil starting with basic chemicals and completed the full manufacturing process. Over the last two years, we have been modifying the process to begin treprostinil manufacturing with advanced intermediate compounds made by outside vendors. We anticipate that upon commercialization of oral treprostinil, the need for treprostinil diethanolamine will be greater than the need for treprostinil sodium used for the 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 sodium as needed. 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 from treprostinil 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 Catalent Pharma Solutions, Inc. (formerly, Cardinal Health, Inc.), for conducting stability studies on Remodulin, formulating inhaled treprostinil, formulating oral treprostinil for clinical trials, and analyzing other products we are developing.

In 2008, we anticipate commencing commercial development of the 3F8 and 8H9 antibodies licensed from MSKCC at our Silver Spring, Maryland, facility. We expect to be able to use the same equipment for 3F8 and 8H9 development as we used for the OvaRex process.

Our telemedicine products are currently manufactured by MSI of Florida. In 2008, we anticipate moving the manufacturing of our telemedicine products to Winland Electronics, Inc., due to an increase in the volume of devices needed to meet patient demand.

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 our respective products or result in increased costs. (For further discussion on this risk, see *Item 1A Risk Factors We have limited experience with production and manufacturing products.)*

Competition

Many drug companies engage in research and development to commercialize products to treat cardiovascular and infectious diseases and cancer. For the treatment of PAH, we compete with many approved products in the United States and worldwide, including the following:

Flolan. The first product approved by the FDA for treating PAH, Flolan has been marketed by GlaxoSmithKline PLC since 1996. In the second quarter of 2006, Myogen, Inc. acquired the marketing rights for Flolan in the United States. In November 2006, Myogen was acquired by Gilead Sciences, Inc. The generic exclusivity period for Flolan expired in April 2007, so it is possible that generic formulations of Flolan could become available for commercial sale.

Ventavis. Approved in December 2004 in the United States and in September 2003 in Europe, Ventavis is the only prostacyclin analog that has been approved for inhalation. Ventavis was initially marketed by CoTherix, Inc., (CoTherix) in the United States and Schering AG in Europe. In January 2007, CoTherix was acquired by Actelion Ltd, the manufacturer and distributor of Tracleer.

Tracleer. The first oral drug to be approved for PAH, Tracleer is also the first drug in its class, known as endothelin receptor antagonists. Tracleer was approved in December 2001 in the United States and in May 2002 in Europe. Tracleer is marketed by Actelion Ltd worldwide.

Revatio. 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 PDE5 inhibitors, to be approved for PAH.

Letairis . Approved in June 2007 in the United States, Letairis is an oral therapy, and is marketed by Gilead Sciences, Inc. in the United States for the treatment of PAH. Like Tracleer, Letairis is an endothelin receptor antagonist. GlaxoSmithKline is seeking approval of Letairis in Europe where it is known as Volibris®. In February 2008, GlaxoSmithKline announced that Volibris received a positive opinion for approval in the European Union.

Thelin . Approved in August 2006 in the European Union, Thelin is an oral therapy, and is marketed by Encysive Pharmaceuticals Inc. (Encysive), for the treatment of PAH. Like Tracleer and Letairis, Thelin is an endothelin receptor antagonist. In February 2008, Pfizer Inc. announced that it had reached an agreement to acquire Encysive. Thelin is not approved in the United States.

Due to their ease of use, oral therapies, such as Tracleer and Revatio, are generally considered front-line therapies for newly diagnosed patients. Flolan and Remodulin, more complex infusion therapies, are generally considered later-stage therapies for sicker patients. The use of the available oral therapies and Ventavis, either alone or in combination, will delay the need for infusion therapy for many patients. 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 treatment. (For further discussion on this risk, see *Item 1A Risk Factors We may not successfully compete with established drugs and the companies that develop and market them).*

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 have.

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 (NDA) 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 treprostinil for the treatment of PAH without regard to drug product formulation. We believe that the orphan designation of treprostinil includes all types of PAH, regardless of etiology. However, such designation does not preclude us from seeking orphan drug designation for other formulations of treprostinil or for other etiologies of PAH or medically plausible subsets of PAH, and does not preclude the FDA from granting a new seven-year period of orphan drug exclusivity upon the approval of an NDA for a new formulation of treprostinil for the designated new indication, provided we demonstrate that such new formulation is clinically superior to the older formulation of parenteral Remodulin.

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 subcutaneous use of Remodulin for PAH, we used the mutual recognition procedure. Under the rules then applicable, centralized filing was not required and we perceived the decentralized procedure to be the most effective means for approval. We 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 since these countries required additional information not required by the other European countries. We have to file for approval for intravenous use of Remodulin using the mutual recognition process since intravenous use of Remodulin is considered a variation to the original license. We have filed our application with our reference member state, France, which has notified us that it is not satisfied with the filing we have made. We will work to address these concerns and believe that we will

eventually receive commercial approval for intravenous Remodulin in at least some European countries. We have regulatory applications pending in other countries as well.

To secure European regulatory approval for inhaled treprostinil, we will use the centralized process. Regulations in Europe have changed since we made our initial filing for Remodulin and all therapies for orphan diseases must use the centralized process. We plan on filing for European approval of inhaled treprostinil in late 2008.

To secure approval of the Optineb device in the United States, applicable regulations require a quality system for the design, manufacture, packaging, labeling, storage, installation and servicing of devices intended for commercial distribution. These quality system regulations require that various specifications and controls be established for devices, devices be designed under a quality system to meet these specifications, devices be manufactured under a quality system, finished devices meet these specifications, devices be correctly installed, checked and serviced, quality data be analyzed to identify and correct quality problems, and complaints be processed. Regulatory authorities may also require additional patient data to support approval for these devices. We are also subject to inspections by regulatory agencies and ensuring that we and NEBU-TEC meet all requirements during inspections.

To continue marketing our products after approval, applicable regulations require us to maintain a positive benefit-risk profile, maintaining regulatory applications through periodic reports to regulatory authorities, fulfilling pharmacovigilance requirements, maintaining manufacturing facilities to Good Manufacturing Practices requirements, and successfully completing regulatory agency inspections, among other requirements.

Telemedicine products are manufactured at contract facilities that are regulated by the FDA under different laws and regulations that apply to medical devices. 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 2008. 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 320 employees as of February 26, 2008. We also maintain active independent contractor relationships with various individuals, most of whom have month-to-month or annual consulting contracts. We believe our employee relations are excellent.

Industry Segments and Geographic Areas

We operate two business segments: pharmaceuticals and telemedicine. We sell our products in the United States and abroad. 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 2 and 18, 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 *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). They are also available through the SEC's EDGAR portal.

EXECUTIVE OFFICERS OF THE REGISTRANT

The following is a list, as of February 21, 2008, 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.

Name	Age	Position
Martine A. Rothblatt, Ph.D., J.D., M.B.A.	53	Chairman, Chief Executive Officer and Director
Roger Jeffs, Ph.D.	46	President, Chief Operating Officer and Director
John M. Ferrari	53	Chief Financial Officer and Treasurer
Paul A. Mahon, J.D.	44	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 full-time 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.

PART II. OTHER INFORMATION

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 existence and activities of competitors;

The pricing of Remodulin;

The expected levels and timing of Remodulin sales;

The dosing and rate of patient consumption of Remodulin;

The outcome of potential future regulatory actions from the FDA and international regulatory agencies;

The adequacy of our intellectual property protections and their expiration dates;

The ability of third parties to market, distribute and sell our products;

The current and expected future value of our goodwill and recorded intangible assets;

The ability to obtain financing in the future;

The value of our common stock;

The expectation of future repurchases of those shares subject to repurchase from Toray;

The expectation of continued profits or losses;

The pace and timing of enrollment in clinical trials;

The expectation and timing of filing for regulatory approvals of inhaled treprostinil;

The timing, resubmission, completion and outcome of the applications for approval of subcutaneous Remodulin in Ireland, Spain and the United Kingdom;

The expectation, outcome and timing of marketing approvals in European Union countries for intravenous Remodulin;

The expected timing of milestone payments from Mochida and commercial activities in Japan;

The expected timing of payments to third parties under licensing agreements;

The potential impacts of new accounting rules;

The outcome of any litigation in which we are or become involved;

Any statements preceded by, followed by or that include any form of the words "believe," "expect," "predict," "anticipate," "intend," "estimate," "should," "may," "will," 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 the section entitled *Item 2 Management's Discussion and Analysis of Financial Condition and Results of Operations* above 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

We have a history of losses and may not continue to be profitable

Although we have been profitable for each calendar year since 2004, we have had quarters in which we experienced a loss. At December 31, 2007, our accumulated deficit was approximately $21.5 million. Although we set our annual operating budgets to be less than our estimated revenues, numerous factors, some of which are beyond our control, could affect consolidated revenues and profitability and cause our quarterly and annual operating results to fluctuate.

We rely heavily on sales of Remodulin to produce revenues.

We rely heavily on sales of Remodulin. During the year ended December 31, 2007, our Remodulin sales accounted for 95% of our total revenues. A wide variety of events, many of which are described in other risk factors below, could cause Remodulin sales to decline. For example, if regulatory approvals for Remodulin are withdrawn, we will be unable to sell that product and our revenues will suffer. 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. 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. In addition, we rely on third parties to produce, market, distribute and sell Remodulin. The loss of third parties to perform these functions, or the failure of these parties to do so successfully, also could cause our revenues to suffer. Because we are so dependent on sales of Remodulin, any reduction in the sale of Remodulin would cause our results of operations to suffer.

Most of our pharmaceutical products are in clinical development and may never generate profits.

Our only pharmaceutical product currently in commercial distribution is Remodulin. Most of our pharmaceutical products are in clinical studies; therefore, many of those products may not be commercially available for a number of years, if at all. 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, products 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. The first product approved by the FDA for treating PAH, Flolan has been marketed by GlaxoSmithKline PLC since 1996. In the second quarter of 2006, Myogen, Inc. (Myogen), acquired the marketing rights for Flolan in the United States. In November 2006, Myogen was acquired by Gilead Sciences, Inc., which is regarded as a large and successful biotechnology company in the United States. The generic exclusivity period for Flolan expired in April 2007, so it is possible that generic formulations of Flolan could become available for commercial sale. Flolan is delivered by intravenous infusion and considered to be an effective treatment by most PAH experts.

Ventavis. Approved in December 2004 in the United States and in September 2003 in Europe, Ventavis is the only prostacyclin analog 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. (CoTherix), in the United States and Schering AG in Europe. In January 2007, CoTherix was acquired by Actelion Ltd, the manufacturer and distributor of Tracleer. Actelion is regarded as a large and successful biotechnology company.

Tracleer. The first oral drug to be approved for PAH, Tracleer is also the first drug in its class, known as endothelin receptor antagonists. Tracleer was approved in December 2001 in the United States and in May 2002 in Europe. Tracleer is marketed by Actelion worldwide.

Revatio. Approved in June 2005 in the United States, Revatio is also an oral therapy and is marketed by Pfizer Inc. (Pfizer). Revatio is a different formulation of the very successful drug Viagra and is the first drug in its class, known as PDE5 inhibitors, to be approved for PAH. Pfizer is regarded as a large and successful pharmaceutical company in the United States.

Letairis. Approved in June 2007 in the United States, Letairis is an oral therapy, and is marketed by Gilead Sciences, Inc. in the United States for the treatment of PAH. Like Tracleer, Letairis is an endothelin receptor antagonist. GlaxoSmithKline is seeking approval of Letairis in Europe where it is known as Volibris. In February 2008, GlaxoSmithKline announced that Volibris received a positive opinion for approval in the European Union.

Thelin. Approved in August 2006 in the European Union, Thelin is an oral therapy, and is marketed by Encysive Pharmaceuticals Inc. (Encysive), for the treatment of PAH. Like Tracleer and Letairis, Thelin is an endothelin receptor antagonist. In February 2008, Pfizer announced that it had reached an agreement to acquire Encysive.

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 acquisition of CoTherix, Gilead's acquisition of Myogen, and Pfizer's pending acquisition of Encysive, each of these three companies now controls two of the seven approved therapies for PAH in the United States, the seventh of which is Remodulin. In addition to reducing competition through consolidation, each company brings considerable influence over prescribers to the sales and marketing of their respective two approved therapies through market dominance in this therapeutic area.

A number of drug companies are pursuing treatments for the hepatitis C virus and cancer that will compete with any products we may develop from our glycobiology antiviral agents and monoclonal antibodies platforms.

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.

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

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 or as a substitute for Remodulin. If this happens, doctors may reduce the dose of Remodulin they give to their patients or may prescribe other treatments instead of Remodulin. This could result in less Remodulin being used by patients and, hence, reduced sales of Remodulin.

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

Thelin. Thelin is currently being developed by Encysive Pharmaceuticals, Inc. (Encysive), worldwide for the treatment of PAH. Although Encysive has received marketing authorization in all nations in the European Union, they have not received FDA approval in the United States. In February 2008, Pfizer announced that it had reached an agreement to acquire Encysive and that it intended to conduct an additional clinical trial in order to file for FDA approval;

Cialis®. An approved oral treatment for erectile dysfunction, Cialis is currently marketed by Eli Lilly and Company (Lilly). Prior to January 2007, Cialis was jointly marketed by ICOS Corporation and Lilly. Cialis is currently being studied in patients with PAH, and is in the same class of drugs as Revatio. In January 2007, ICOS Corporation was acquired by Lilly, which is a large and successful pharmaceutical company in the United States;

Gleevec® An approved oral treatment for chronic myeloid leukemia (a cancer of the blood and bone marrow), Gleevec is currently marketed by Novartis Pharmaceuticals Corporation. Recently, experienced PAH researchers have conducted studies with Gleevec and believe that it may be effective in treating PAH;

Aviptadil. An inhaled formulation of a vasoactive intestinal peptide, Aviptadil 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-HT2B antagonist, PRX-08066 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. Currently in development by PR Pharmaceuticals, Inc., PulmoLAR 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;

Fasudil. Oral and inhaled formulations of Fasudil, a rho-kinase inhibitor, may be 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. Originally marketed by Bayer AG as Nexavar® for advanced renal cell cancer, Sorafenib is a small molecule that inhibits Raf kinase and that may interfere with the thickening of blood vessel walls associated with PAH. A Phase I clinical trial in PAH has been proposed;

Recombinant Elafin. Currently being developed by PROTEO Biotech AG, Recombinant Elafin is a synthetic version of a protein that is produced naturally in the body and may inhibit inflammatory reactions. In February 2007, Elafin was granted orphan product status in the European Union for the treatment of PAH and chronic thromboembolic pulmonary hypertension;

Cicletanine. Marketed by Navitas Pharma for hypertension in Europe, Cicletatnine is an eNOS coupler that works to increase the flexibility of blood vessel linings; and

6R-BH4. A naturally occurring enzyme cofactor that is required for numerous biochemical and physiologic processes, including the synthesis of nitric oxide, 6R-BH4 is being developed by BioMarin Pharmaceutical Inc. for the treatment of poorly controlled hypertension, peripheral arterial disease and phenylketonuria. A Phase I clinical trial of 6R-BH4 for PAH is also underway.

There may be additional drugs in development for PAH in addition to those listed above and there may also be currently approved drugs that prove effective in treating the disease. If any of these drugs in development, additional new drugs 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 pumps 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 (CMS) negotiate a new price for Remodulin. As the result of the staggered implementation of this Act, Remodulin has not yet been subject to the pricing provisions. In addition, to the extent that private insurers or managed care programs follow any Medicaid and Medicare coverage and payment developments, the adverse effects of lower Medicare payment rates may be expanded by private insurers adopting lower payment schedules. Additionally, some states have enacted health care reform legislation. Further federal and state developments are possible.

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 currently be sold in generic form. 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.

The growth of our cardiac monitoring business is dependent upon physicians utilizing our services; if we fail to maintain our current level of physician utilization, our cardiac monitoring revenues may stagnate and our business could be adversely affected.

Our ability to provide our cardiac monitoring services is dependent upon physicians prescribing our diagnostic tests to their patients. Our success in obtaining patients to monitor will be directly influenced by the relationships we develop and maintain with physicians and physician groups in a manner consistent with government regulations affecting such relationships. If we are unable to maintain such relationships and create new relationships in compliance with applicable laws, the number of patients using our cardiac monitoring services will decline, which may have a material adverse effect on our revenues and our business, financial condition and results of operations.

If we are unable to educate physicians regarding the benefits of our CardioPAL® SAVI System and achieve sufficient levels of utilization, revenues from the provision of our cardiac monitoring services could fail to grow and could decrease.

Reimbursement for cardiac monitoring services by Medicare is highly regulated and subject to change and the operation of our call centers and monitoring facilities is subject to rules and regulations governing Independent Diagnostic Testing Facilities; failure to comply with these rules could prevent us from receiving reimbursement for our cardiac services from Medicare and some commercial payers.

We receive approximately 15% of our cardiac monitoring service revenues as reimbursement from Medicare. Reimbursement from Medicare for cardiac monitoring services is subject to statutory and regulatory changes, rate adjustments and administrative rulings, all of which could materially affect the range of services covered or the reimbursement rates paid by Medicare for use of our cardiac monitoring services. In 2007, CMS adopted a change in methodology for calculating reimbursement under the Physician Fee Schedule that will be implemented over a 4 year period. This resulted in reduced reimbursement for our cardiac monitoring services from Medicare by 3% to 18%, depending on the type of service. Similar reductions have been adopted for 2008 and are expected annually through 2010. In addition, we cannot predict whether future modifications to Medicare's reimbursement policies could reduce the amounts we receive from Medicare for the services we provide. Finally, Medicare's reimbursement rates can affect the rate that commercial payers are willing to pay for our products and services.

The Medicare program is administered by CMS, which imposes extensive and detailed requirements on medical services providers, including, but not limited to, rules that govern how we structure our relationships with physicians, how and when we submit reimbursement claims, how we operate our monitoring facilities and how we provide our cardiac monitors and monitoring services. Our failure to comply with applicable Medicare rules could result in Medicare discontinuing our reimbursement, our being required to return funds already paid to us, civil monetary penalties, criminal penalties and/or exclusion from the Medicare program.

Furthermore, in order for us to receive reimbursement for cardiac monitoring services from Medicare and some commercial payers, we must have a call center certified as an Independent Diagnostic Testing Facility, or IDTF. Certification as an IDTF requires that we follow strict regulations governing how the center operates, such as requirements regarding the experience and certifications of the technicians who review data transmitted from our cardiac monitors. These rules and regulations vary from location to location and are subject to change. If they change, we may have to change the operating procedures at our monitoring facilities, which could increase our costs significantly. If we fail to obtain and maintain IDTF certification, our services may no longer be reimbursed by Medicare and some commercial payers, which could materially affect our telemedicine business adversely.

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

We are currently marketing products in two of our four therapeutic platforms: Remodulin in our prostacyclin analog platform and CardioPAL SAVI cardiac event monitors and Holter monitors in our telemedicine platform. We also have several products in the clinical trial stage. 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 some or 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 develop, market, distribute or sell our products and our future revenues could suffer.

We rely on Accredo Therapeutics, Inc., CuraScript, Inc. and Caremark, Inc. to market, distribute, and sell Remodulin in the United States. Accredo, CuraScript and Caremark are also responsible for convincing third-party payers to reimburse patients for the cost of Remodulin, which is very expensive. If our 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.

Since the commercial launch of Remodulin, all of our Remodulin distributors in the United States have been sold to larger companies. 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, Remodulin could be much less significant to these distributors. There can be no assurance that the mergers experienced by each of our distributors will not adversely affect Remodulin distribution. In addition, effective January 1, 2007, Accredo became 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.

Our operations depend on compliance with complex FDA and comparable international regulations. Failure to obtain broad approvals on a timely basis or to achieve continued compliance could delay or halt commercialization of our products.

The products that we develop must be approved for marketing and sale by regulatory authorities and, once approved, are subject to extensive regulation by the FDA and comparable regulatory agencies in other countries. 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. Potential products may fail to receive marketing approval on a timely basis, or at all. 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.

In addition, our marketed products and how we manufacture and sell these products are subject to extensive continued regulation and review. We received one warning letter from the FDA related to advertising in 2005, which was resolved satisfactorily. In early August 2007, three European Union countries requested that we perform repeat sterility testing of Remodulin vials sold in the European Union. France was our sponsoring country for European Union approval, and we had been operating under an understanding with French regulatory authorities that additional sterility testing was not necessary since these tests were already performed in the United States and meet both United States and European Union regulatory requirements. Our ability to add new patients in those countries depended on our validating and repeating the sterility testing process in the European Union. We

arranged for repeat sterility testing of Remodulin vials for use in the European Union and worked with appropriate regulatory agencies and our distributors to ensure that there was no disruption of Remodulin therapy during the repeat testing period. All Remodulin patients in the three countries remained on therapy throughout the testing process. We completed this process in September 2007. We have received regulatory clearance from all countries.

We have never experienced a sterility-related or other product specification failure with respect to our Remodulin vials. However, discovery of previously unknown problems with our marketed products or problems with our manufacturing, regulatory, promotional or other commercialization activities may result in regulatory restrictions on our products, including withdrawal of the products from the market. If we fail to comply with applicable regulatory requirements, we could be subject to penalties including fines, suspensions of regulatory approvals, product recalls, seizure of products and criminal prosecution.

If approvals are withdrawn for Remodulin or any other product, we will not be able to 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.

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 out 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 were subsequently published as a report in the CDC's *Morbidity and Mortality Weekly Report* on March 2, 2007. The slides and report were prepared in connection with a CDC retrospective inquiry at seven centers regarding a report of increased bloodstream 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. We have been informed that the SLC is planning a study to evaluate the risk of sepsis and sepsis sub-types among parenterally-delivered prostanoids. Finally, the FDA revised the Remodulin package insert in February 2008 to more fully describe the known infection risk and appropriate techniques to 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 affect physicians' prescribing practices in regard to Remodulin. If that occurs, Remodulin sales could suffer and our profitability could be diminished.

We have transitioned our manufacturing operations to a new location.

We are in the process of validating treprostinil manufacturing in our new Silver Spring, Maryland, laboratory. This manufacturing process will be done on a larger scale than that performed in our former Chicago, Illinois, facility. We closed the Chicago facility in May 2007. Until we have received FDA and international approvals for the Silver Spring laboratory, we cannot sell products made with compounds produced there. In addition, commercial treprostinil is being manufactured only by us with reliance on third parties for certain raw and advanced intermediate materials.

We depend on third parties to formulate and manufacture our products and related devices.

We rely on third parties to formulate our treprostinil-based products. We rely on Baxter Healthcare Corporation for the formulation of Remodulin from treprostinil. We rely on Catalent Pharma Solutions, Inc. for conducting stability studies on Remodulin, formulating treprostinil for inhalation use, formulating tablets for our oral clinical trials, and analyzing other products that we are developing. We also rely on third parties for the manufacture of all our products other than treprostinil. 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 clinical trials.

We also rely on NEBU-TEC, a German company, to manufacture the Optineb nebulizer used with inhaled treprostinil. NEBU-TEC is responsible for managing and controlling the manufacturing process of its device, all associated parts, and work performed by its suppliers, in accordance with all applicable regulatory requirements. Because regulatory approval of inhaled treprostinil will be linked to regulatory approval of the Optineb device, any regulatory compliance problems encountered by NEBU-TEC with respect to the manufacture of its device could delay or otherwise adversely affect regulatory approvals of inhaled treprostinil, and our revenues could suffer. In addition, following regulatory approval of inhaled treprostinil, any inability of NEBU-TEC to manufacture a sufficient quantity of nebulizers to meet patient demand could have an adverse effect on our revenue growth.

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 could 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. Cardinal Health recently sold its formulation business to Catalent Pharma Solutions, Inc. and there can be no assurances that they 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;

The supply of raw and advanced intermediate materials and components used in the manufacture and packaging of treprostinil, Remodulin and other products may become scarce or 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; 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.

Until November 2006, Medtronic MiniMed was our exclusive partner for the subcutaneous delivery of Remodulin using the MiniMed microinfusion device for PAH. Medtronic has discontinued making 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 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 devises when the available supply held by our distributors has been depleted.

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.

In November we announced we are conducting Phase III clinical studies of an oral formulation of treprostinil and are working on submission to the FDA for our completed Phase III study of inhaled treprostinil. Our glycobiology antiviral agent, UT-231B as monotherapy, completed a Phase II, proof-of-concept study in late 2004. In that trial, UT-231B did not demonstrate efficacy as a

monotherapy against hepatitis C in a population of patients that previously failed conventional treatments. We are now conducting preclinical testing of additional glycobiology drug candidates and we are exploring opportunities to accelerate our glycobiology clinical development efforts. 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: OvaRex MAb for the treatment of advanced ovarian cancer; immediate release beraprost for early stage peripheral vascular disease; Ketotop for osteoarthritis of the knee; and UT-77 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 for pharmaceutical products. The FDA and international regulatory authorities may not agree that we have demonstrated that our products are safe and effective.

Finally, because regulatory approval of inhaled treprostinil will be linked to regulatory approval of the Optineb nebulizer, any regulatory compliance problems encountered by NEBU-TEC with respect to the manufacture of its device could delay or otherwise adversely affect regulatory approval of inhaled treprostinil.

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, local 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 glycobiology antiviral agents platform, and all of the products in our monoclonal antibodies platform. 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; 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 only have the rights to market beraprost-MR for sale in North America and Europe.

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 Toray's license of beraprost-MR to us, we agreed to provisions establishing a conditional, restricted non-competition clause in Toray's favor, giving them the right to be our exclusive provider of beraprost-MR and requiring that we make certain minimum annual sales in order to maintain our exclusive rights to beraprost-MR. 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 are inadequate, our sales and profits could suffer or our 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 and the patent for inhaled treprostinil is set to expire in 2020. We believe that

some of the patents to which we have rights may be eligible for extensions of up to five years based upon patent term restoration procedures in Europe and under the Hatch-Waxman Act in the United States. Our patent for treating PAH with Remodulin has already received the maximum five-year extension. 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 or seek to invalidate our existing patents before they expire. 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.

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 enforcing 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.

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.

To the extent valid third-party patent rights cover our products or services, we or our strategic collaborators would be required to seek licenses from the holders of these patents in order to manufacture, use, or sell our products and services. Payments under these licenses would reduce our profits from these products and services. We may not be able to obtain these licenses on acceptable terms, or at all. If we fail to obtain a required license or are unable to alter the design of our technology to fall outside the scope of a third party patent, we may be unable to market some of our products and services, which would limit our profitability.

Proposed changes to United States patent law are currently pending in Congress. If these proposed patent reforms become law, it could make it easier for patents to be invalidated and/or could reduce the amount of damages in cases of patent infringement. Because we rely on patents to protect our products, the proposed patent reform could have an adverse impact on our business.

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.

Our success depends in large part on our ability to operate without infringing upon the patents or other proprietary rights of third parties.

If we infringe the patents of others, we may be prevented from commercializing products or may be required to obtain licenses from these third parties. We may not be able to obtain alternative technologies or acquire a license on reasonable terms or at all. If we fail to obtain such licenses or alternative technologies, we may be unable to develop or commercialize some or all of our products.

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 and General Counsel, Paul Mahon; our Senior Vice President for Pharmaceutical Development, David Zaccardelli, Pharm.D.; our Senior Vice President for Regulatory Affairs, Dean Bunce; 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 us until at least 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 and diagnostics involve product liability risks. Although we currently have product liability insurance covering claims up to $25 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.

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.

At least a portion of the repayment of our 0.50% Convertible Senior Notes due 2011 (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 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. Furthermore, once these materials leave our site, we cannot control what our hazardous waste removal contractors choose to do with them. In the event of an accident or 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.

We may encounter substantial difficulties managing our growth.

Several risks are inherent to our plans to grow our business. Achieving our goals will require substantial investments in research and development, sales and marketing, and facilities. For example, we have spent considerable resources building and seeking regulatory approvals for our laboratories and manufacturing facilities. These facilities may not prove sufficient to meet demand for our products or we may have excess capacity at these facilities. In addition, building our facilities is expensive, and our ability to recover these costs will depend on increased revenue from the products produced at the facilities.

If we are able to grow sales of our products, we may have difficulty managing inventory levels. Marketing new therapies is a complicated process, and gauging future demand is difficult.

Growth in our business may also contribute to fluctuations in our operating results, which may cause the price of our securities to decline.

Our financial results may be impacted by future accounting rules.

Our future, as well as our previously published financial results could be affected by new accounting rules. The FASB recently proposed FASB staff position (FSP) APB 14-a, *Accounting for Convertible Debt Instruments That May Be Settled in Cash Upon Conversion (Including Partial Cash Settlement) (FSP 14-a)*. The proposed FSP specifies that issuers of such instruments should separately account for the liability and equity components of the instrument in a manner that will reflect the entity's nonconvertible debt borrowing rate on the instrument's issuance date when interest cost is recognized in subsequent periods. Our Convertible Notes are within the scope of FSP 14-a; therefore, we would be required to record the debt portions of our Convertible Notes at their fair value on the date of issuance and amortize the resulting discount into interest expense over the life of the debt. However, there would be no effect on our cash interest payments. As currently proposed, FSP 14-a will be effective for financial statements issued for fiscal years beginning after December 15, 2008, and will be applied retrospectively to all periods presented. If adopted as proposed, these changes would be reflected in our financial statements beginning with the first quarter of 2009. We believe that the change, if adopted as proposed, could have a significant impact in the future on our results of operations.

Risks Related to Our Common Stock

The price of our common stock could be volatile and could decline.

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

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

		High	Low
January 1, 2005	December 31, 2005	$ 77.82	$ 41.37
January 1, 2006	December 31, 2006	$ 71.33	$ 47.96
January 1, 2007	December 31, 2007	$ 108.62	$ 47.87

The price of our common stock 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;

Disagreements with our licensors and vendors;

Future sales of substantial amounts of our common stock by us or our existing stockholders;

Future sales of our common stock by our directors and officers;

Rumors among investors and/or analysts concerning the company, its products or operations;

Failure to maintain, or changes to, our approvals to sell Remodulin;

Failure to successfully obtain FDA approval for our new Silver Spring, Maryland, Remodulin and monoclonal antibody laboratory;

The accumulation of significant short positions in our common stock by hedge funds or other investors or the significant accumulation of our common stock by hedge funds or other institutional investors with investment strategies that may lead to short-term holdings;

Timing and outcome of additional regulatory submissions and approvals; and

General market conditions.

We may fail to meet third party projections for our revenue or profits.

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.

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 our common stock in the public market, or investors become concerned that substantial sales might occur, the market price of our common stock could decrease. All of our 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 our 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 two executive officers and six directors have done so. 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 the Convertible Notes after the price of our common stock reached $105.67 per share dilutes 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 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 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.

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.

Provisions of Delaware law and our certificate of incorporation, by-laws, shareholder rights plan, and employment and licensing agreements could prevent or delay a change in 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, shareholder rights plan, and employment and licensing agreements 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 our 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 our common stock by limiting the voting power of such blocks. This may further result in discouraging a change in control or change in current management.

In addition, the non-competition and other restrictive covenants in all of our employees' employment agreements (other than those few employees who may be entitled to severance following a change in control) will terminate upon a change in control that is not approved by our board of directors in accordance with the terms of such employment agreements.

Further, certain of our license agreements with other companies contain a provision prohibiting each party to the agreement and its affiliates from directly or indirectly seeking to acquire or merge with us, or taking any steps in furtherance thereof, for the term of the agreement and for five years thereafter, subject to certain exceptions. As a result, the companies that are party to these license agreements with us would be prevented from pursuing an acquisition of our company unless we consent. Furthermore, other companies may be deterred from seeking to acquire our company because of the limitations that would be imposed on further acquisition activities.

Change in control restrictions in certain of our agreements could prevent or delay a change in control or change in management that could be beneficial to us and our public stockholders.

Certain of our license and other agreements with other companies contain provisions restricting our ability to assign or transfer the agreement to a company which desires to merge with or acquire us. These restrictions often require the prior consent of the other party to the agreement to a proposed change in control of our company. In the event that the other party to a contract with us chooses to withhold its consent to such a merger or acquisition, then such party could seek to terminate the agreement and we would no longer have the rights and benefits under such agreement which may adversely affect our revenues and business prospects. In addition, certain of our license and other agreements with other companies contain provisions allowing the other company to terminate the agreement if a third party attempts to acquire control of our company without our consent, unless certain conditions are met. These restrictive contractual provisions may delay or discourage a change in control of our company.

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

Our directors and named executive officers beneficially owned approximately 11% of our outstanding common stock as of December 31, 2007, 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 in 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

Maryland We own our corporate headquarters office building in Silver Spring, Maryland. We also own the three buildings and land adjacent to our corporate headquarters. We lease our laboratory facility adjacent to our corporate headquarters which is used for the synthesis of treprostinil-based compounds and monoclonal antibodies. In addition, in late 2007 we began construction on a new combination office and laboratory building which will connect to our existing laboratory facility in Silver Spring. We lease space at a warehouse near Silver Spring to maintain some of our raw material inventory used in the manufacturing and synthesis process.

Florida We own our Remodulin Therapy Assistance office building in Satellite Beach, Florida. Our subsidiary, Lung Rx, Inc., also occupies a portion of this building. Our original office building in Satellite Beach, Florida, was demolished in early 2007 as a condition of the building permit approval we received for the new office adjacent to this property. The land was returned to its natural state. Our subsidiaries, Lung Rx Inc. and Medicomp, Inc., lease manufacturing and office space, respectively, in Melbourne, Florida.

North Carolina We lease office space in Research Triangle Park, North Carolina, for our clinical development and Remodulin commercialization staff. In June 2006, we purchased approximately 54 acres of land in Research Triangle Park, where we are building a new manufacturing facility and office building that will be used by our clinical research and development and Remodulin commercialization staff. The manufacturing facility will formulate oral treprostinil. This 200,000 square foot building project began in early 2007 and is expected to be completed in early 2009.

Other locations In March 2007, we purchased land and a building adjacent to our leased legal and governmental affairs office in Washington, D.C. Our subsidiary, Unither Neurosciences, 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, Quebec, Canada.

We believe that these facilities are adequate for our current operations and that additional land and facilities for future expansion are reasonably available.

The office space in Melbourne, Florida, is 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 our common stock for the periods indicated:

	2007		2006	
	High	Low	High	Low
January 1 March 31	$ 59.13	$ 47.87	$ 71.33	$ 61.57
April 1 June 30	$ 67.64	$ 52.03	$ 66.61	$ 47.96
July 1 September 30	$ 70.04	$ 63.96	$ 59.60	$ 50.69
October 1 December 31	$ 108.62	$ 65.53	$ 62.17	$ 51.12

As of February 22, 2008, there were 53 holders of record of our common stock. We estimate that included within the holders of record are approximately 16,100 beneficial owners of our common stock. As of February 22, 2008, the closing price for our common stock was $81.98.

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.

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,				
	2007	2006	2005	2004	2003
Consolidated Statements of Operations Data:					
Revenues	$ 210,943	$ 159,632	$ 115,915	$ 73,590	$ 53,341
Operating expenses:					
Research and development	83,352	57,570	36,052	30,713	35,417
Selling, general and administrative	99,027	56,052	24,655	21,418	22,667
Cost of sales	22,261	17,028	12,315	8,250	6,783
Total operating expenses	204,640	130,650	73,022	60,381	64,867
Income (loss) from operations	6,303	28,982	42,893	13,209	(11,526)
Other income (expense):					
Interest income	13,602	10,700	5,359	2,986	2,435
Interest expense	(2,175)	(482)	(29)	(4)	(112)
Equity loss in affiliate	(321)	(491)	(754)	(785)	(953)
Other, net	(826)	1,199	53	43	187
Total other income (expense), net	10,280	10,926	4,629	2,240	1,557
Net income (loss) before income tax	16,583	39,908	47,522	15,449	(9,969)
Income tax benefit	3,276	34,057	17,494		
Net income (loss)	$ 19,859	$ 73,965	$ 65,016	$ 15,449	$ (9,969)
Net income (loss) per share:					
Basic(1)	$ 0.94	$ 3.21	$ 2.85	$ 0.71	$ (0.47)
Diluted(1)	$ 0.88	$ 3.06	$ 2.58	$ 0.66	$ (0.47)
Weighted average number of common shares outstanding:					
Basic	21,224	23,010	22,825	21,726	21,135
Diluted	22,451	24,138	25,206	23,351	21,135

	Years Ended December 31,				
	2007	2006	2005	2004	2003
Consolidated Balance Sheet Data:					
Cash, cash equivalents and marketable investments(2)	$ 299,287	$ 264,163	$ 170,347	$ 139,140	$ 117,337
Total assets	587,018	478,550	291,413	207,158	179,502
Notes and leases payable(3)	250,014	250,025	23	26	798
Accumulated deficit	(21,501)	(41,360)	(115,325)	(180,341)	(195,790)
Total stockholders' equity	295,790	204,606	275,102	191,636	167,765

(1)

See Note 2 in the *Notes to Consolidated Financial Statements* for a description of the computation of basic and diluted net income per share.

(2)

Excludes restricted marketable investments and cash of $44,195, $38,988, and $20,666 for the years ending December 31, 2007, 2006 and 2005, 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

United Therapeutics Corporation is a biotechnology company focused on the development and commercialization of unique products to address the unmet medical needs of patients with chronic and life-threatening cardiovascular and infectious diseases and cancer. We commenced operations in June 1996 and, since our inception, have devoted substantially all of our resources to acquisitions and research and development programs.

Our key therapeutic platforms are:

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;

Glycobiology antiviral agents, which are a class of small molecules that have shown pre-clinical indications of efficacy against a broad range of viruses, such as hepatitis C; and

Monoclonal antibodies, which are antibodies that activate patients' immune systems to treat cancer.

We focus most of our resources on these three key platforms. We also devote resources to the commercialization and further development of telemedicine products and services, principally for the detection of cardiac arrhythmias.

We commenced operations in June 1996. We began to earn pharmaceutical revenues in May 2002 after we received FDA approval for Remodulin, our lead product, by subcutaneous (under the skin) infusion to treat pulmonary arterial hypertension (PAH). Remodulin is also approved in 33 countries throughout the world for similar uses. Marketing authorization applications are currently under review in other countries.

Revenues

We derive substantially all of our revenue from the sale of Remodulin, a prostacyclin analog.

Our sales and marketing team consisted of approximately 65 employees as of December 31, 2007, up from approximately 20 employees as of December 31, 2006, with further growth expected in 2008. Our marketing team is divided into two approximately equal groups. The first group is primarily responsible for national and large regional medical practice accounts currently prescribing Remodulin, while the second group is primarily responsible for smaller, local, community-oriented medical practices not currently prescribing Remodulin. Our distributors augment the efforts of our sales and marketing

staff. We face stiff competition from several other companies that market and sell competing therapies and we expect this competition will continue to grow.

Remodulin is sold to patients in the United States by Accredo Therapeutics, Inc., CuraScript, Inc., and Caremark, Inc., and outside of the United States by various international distributors. We sell Remodulin in bulk shipments to these distributors. Because discontinuation of our therapy can be life-threatening to patients, we require that our distributors maintain inventory levels as specified in our distribution agreements. Due to the contractual requirement to maintain a minimum level of inventory, sales of Remodulin to distributors in any given quarter may not be indicative of patient demand during that quarter. In addition, inventory levels reported by distributors are affected by the timing of their sales around the end of each reporting period. Our U.S.-based distributors typically place one order per month, usually in the first half of the month. The timing and magnitude of our sales of Remodulin are affected by the timing and magnitude of these bulk orders from distributors. Bulk orders placed by our distributors are based on their estimates of the amount of drug required for new and existing patients, as well as maintaining the contractual level of inventory that can meet approximately thirty days' demand as a contingent supply. Effective January 1, 2007, CuraScript's minimum inventory requirement was reduced from 60 days to 30 days to make its contractual inventory requirement consistent with those of our two other U.S. distributors. This inventory reduction resulted in a decrease in CuraScript's inventory of approximately $2.0 million. Sales of Remodulin are recognized as revenue when delivered to our distributors.

In March 2007, we entered into an exclusive agreement with Mochida Pharmaceutical Co., Ltd. (Mochida), to distribute subcutaneous and intravenous Remodulin in Japan. Mochida will be responsible, with our assistance, for obtaining Japanese marketing authorization for Remodulin, including conducting bridging studies required in Japan. We will supply study drug at no charge to Mochida. Due to the bridging studies and required Japanese regulatory reviews, commercial activities in Japan are not expected to commence until 2010 or later. Upon receipt of marketing authorization and pricing approval, Mochida will purchase Remodulin from us at an agreed-upon transfer price. In addition, Mochida has agreed to make certain exclusive distribution rights payments to us. Payments for distribution rights received through the filing of the New Drug Application will be recognized ratably over the estimated period of time from when the payment is due until marketing authorization is received.

In addition to revenues from sales of Remodulin, 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 also generated revenues from sales of arginine (which deliver an amino acid that is necessary for maintaining cardiovascular function) products and from royalty fees from licensing agreements in the United States and other countries. In September 2007, we stopped selling all arginine products based on publications discounting the benefits of arginine supplementation.

Expenses

Since our inception, we devoted substantially all of our resources to acquisitions and research and development programs. We incur significant expenses in connection with our clinical trials and other aspects of our research and development programs. Since the approval of Remodulin in 2002, we have funded our operations from revenue generated from the sales of our products and services. Our operating expenses consist primarily of research and development, selling, general and administrative, cost of product sales and cost of service sales.

Major Research and Development Projects

Our major research and development projects have been and are focused on the use of treprostinil to treat cardiovascular diseases, glycobiology antiviral agents (a novel class of small molecules that may be effective as oral therapies) to treat infectious diseases, such as hepatitis C, dengue fever and Japanese encephalitis, among other viruses, and monoclonal antibodies (antibodies that activate a patient's immune response) to treat a variety of cancers.

Cardiovascular Disease Projects

Subcutaneous use of Remodulin was approved by the FDA in May 2002 and material net cash inflows from the sales of Remodulin for PAH commenced thereafter. In November 2004, the FDA approved intravenous infusion of Remodulin for patients who are not able to tolerate subcutaneous infusion. This approval was based on data establishing the bioequivalence of intravenous Remodulin with subcutaneous Remodulin.

We are working to develop an inhaled formulation of treprostinil sodium for the treatment of PAH. In June 2005, we commenced a 12-week randomized, double-blind, placebo-controlled Phase III trial of inhaled treprostinil in patients with PAH who were also being treated with and were optimized on Tracleer, an oral endothelin antagonist. This trial, TRIUMPH-1 (**TR**eprostinil **I**nhalation **U**sed in the **M**anagement of **P**ulmonary Arterial **H**ypertension), was conducted at approximately 36 centers in the United States and Europe. In May 2006, the FDA agreed to also permit the inclusion in the trial of PAH patients who were also being treated with and optimized on Revatio, an oral PDE5 inhibitor marketed by Pfizer Inc. The FDA also agreed to expand the trial size to at least 200 patients, and to permit an interim efficacy assessment after 150 patients had completed the trial. We did not conduct the interim efficacy assessment.

In November 2007, we announced the completion of our TRIUMPH-1 trial. The study population consisted of 235 patients. Preliminary Analysis of the TRIUMPH-1 results demonstrates an improvement in median six minute walk (6MW) distance by approximately 20 meters ($p<0.0006$, using the Hodges-Lehmann estimate and non-parametric analysis of covariance in accordance with the trial's pre-specified statistical analysis plan), in patients receiving inhaled treprostinil as compared to patients receiving placebo. FDA approval for inhaled treprostinil will be sought by filing a New Drug Application (NDA). The Optineb inhalation device will also be submitted for approval as part of this filing. Optineb is the ultra-sonic nebulizer that was exclusively used for administration of inhaled treprostinil in the TRIUMPH-1 trial. Optineb is manufactured by NEBU-TEC International Med Products Eike Kern GmbH. (NEBU-TEC), a German company. Optineb is approved in Germany and in other European countries, but is not yet approved in the United States. We expect to file the New Drug Application and the application for approval of the Optineb device by mid-2008. FDA review of the New Drug Application generally takes 10 months. We plan on filing for approval in the European Union using the centralized filing process by the end of 2008.

We have also begun planning an open-label study in which patients on Ventavis, the only currently approved inhaled prostacyclin, will be switched to inhaled treprostinil. The study is expected to start in late 2008 and will continue through the FDA regulatory approval process for inhaled treprostinil, which is currently expected to be completed by mid-2009.

We are developing an oral formulation of treprostinil, treprostinil diethanolamine, a novel salt form. Two multi-national placebo-controlled clinical trials of oral treprostinil in patients with PAH commenced in October 2006. These trials are Phase III trials, in which both dosing and efficacy are being studied. The FREEDOM-C trial is a 16-week study of up to 300 patients currently on approved background therapy using a PDE5 inhibitor, such as Revatio, or an endothelin antagonist, such as Tracleer, or a combination of both. The FREEDOM-M trial is a 12-week study of up to 150 patients, who are not on any background therapy. Both trials are being conducted at approximately 60 centers

throughout the United States and the rest of the world. As of December 31, 2007, there were approximately 200 and 90 patients enrolled in the FREEDOM-C and FREEDOM-M trials, respectively. As of February 18, 2008 there were approximately 240 and 100 patients enrolled in the FREEDOM-C and FREEDOM-M trials, respectively.

We are also in the early planning stages of designing a dose-ranging study for oral treprostinil to commence later in 2008 upon the completion of both FREEDOM trials. A dose-ranging study measures the therapeutic effect of a drug at predetermined escalating doses. The results of this study should show corresponding increased therapeutic benefit with increased dosage.

We incurred expenses of approximately $35.0 million and $33.0 million, and $20.1 million during the years ended December 31, 2007, 2006, and 2005, respectively, on Remodulin development. Approximately $228.9 million from inception to date has been incurred on Remodulin development.

We are also developing a modified release formulation of beraprost (beraprost-MR) for PAH. Beraprost-MR is an oral prostacyclin analog. In March 2007, Lung Rx entered into an amended agreement with Toray Industries, Inc. (Toray) to assume and amend the rights and obligations of the June 2000 agreement entered into between Toray and us concerning the commercialization of beraprost-MR. This amended agreement is discussed in greater detail in the section entitled *Strategic Licenses and Relationships*. We recognized approximately $14.0 million of expense during the year ended December 31, 2007, related to the licensing transaction. Approximately $14.4 of expenses were incurred on beraprost-MR development during the year ended December 31, 2007.

Infectious Disease Projects

We are in the planning stages of conducting a Phase II clinical trial with miglustat, a glycobiology compound which inhibits alpha-glucosidase enzymes, to initially evaluate efficacy against hepatitis C. Miglustat is approved and is currently marketed in the United States and Europe by Actelion Ltd for the treatment of Gaucher's disease, a glycolipid storage disorder. Patent protection for manufacturing the compound has expired. As a result of our research agreement with the University of Oxford, we have the exclusive right to commercialize miglustat as an anti-viral agent for the treatment of hepatitis C. Our infectious disease program also includes glycobiology antiviral drug candidates in various preclinical and clinical stages of testing. The drugs in this program are being developed for the treatment of a wide variety of viruses. Through our agreement with Oxford University, we are supporting research into new glycobiology antiviral candidates. We incurred expenses of approximately $824,000, $753,000 and $3.2 million during the years ended December 31, 2007, 2006, and 2005, respectively, on infectious disease projects. Approximately $36.5 million from inception to date has been incurred for infectious disease programs.

Cancer Disease Projects

In April 2002, we entered into an agreement with AltaRex Corp. (which later became AltaRex Medical Corp., a wholly-owned subsidiary of ViRexx Medical Corp.) (AltaRex) to exclusively license monoclonal antibody immunotherapies. In December 2007, we announced the completion of our two pivotal trials of OvaRex MAb, called IMPACT I and II. Analysis of the results demonstrated that the studies failed to reach statistical significance. The studies showed no difference between active (standard of care followed by OvaRex) and control (standard of care followed by placebo) populations. The results of IMPACT I and II were consistent with each other.

Based on the results from the IMPACT I and II trials, we decided to terminate our license agreement with AltaRex and to cease further development of the entire platform of antibodies licensed thereunder. We expect to incur approximately $1.1 million in total close-out costs for this program, of which we had incurred approximately $533,000 as of December 31, 2007.

In December 2007, we entered into two agreements with Memorial Sloan-Kettering Cancer Center (MSKCC) to exclusively license certain rights to two investigational monoclonal antibodies, 3F8 and 8H9, for the treatment of neuroblastoma and metastatic brain cancer. The monoclonal antibody 3F8 is a mouse IgG3 MAb, which is currently used in an investigational setting for the treatment of neuroblastoma, a rare cancer of the sympathetic nervous system mainly affecting children. 8H9 is also a mouse monoclonal antibody, but of the IgG1 subclass. The 8H9 antibody is highly reactive with a range of human solid tumors, including brain cancers. The 8H9 antibody is in early investigational development for metastatic brain cancer. We expect to begin clinical development of these antibodies in 2008.

We incurred expenses of approximately $13.9 million, $10.5 million and $8.7 million during the years ended December 31, 2007, 2006, and 2005, respectively, on cancer projects. Approximately $56.8 million from inception to date has been incurred for the cancer 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 the commencement of clinical trials.

If our 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 be impossible to achieve.

Selling, general and administrative expenses

Selling, general and administrative expenses consist primarily of salaries and related expenses including stock option expense for corporate and marketing personnel, travel, office expenses, insurance, rent and utilities, professional fees, advertising and marketing and depreciation and amortization.

Cost of product sales

Cost of product sales consists of the cost to manufacture or acquire products that are sold to customers. We manufacture treprostinil using advanced intermediate compounds purchased in bulk from third-party vendors. We have approved three vendors that have the capability to manufacture greater quantities of these compounds less expensively than if we did so ourselves. We expect to begin commercial manufacturing of treprostinil in our new facility in Silver Spring, Maryland, in 2008, which is when FDA approval of the facility is expected. We anticipate that upon commercialization of oral treprostinil, the need for treprostinil diethanolamine, the active ingredient in our tablet, will be greater than the need for treprostinil sodium, the active ingredient for Remodulin and inhaled treprostinil. As a result, the manufacturing process at the Silver Spring facility consists of starting with an advance intermediate compound, making treprostinil diethanolamine and then converting that compound to treprostinil as demand requires. We believe that this will allow us the most flexibility and efficiency to meet future demands for both forms of active ingredients.

Cost of service sales

Cost of service sales consists of the salaries, stock option expense, and related overhead necessary to provide telemedicine services to customers.

Future Prospects

We have experienced annual revenue growth exceeding 30% each year since Remodulin was approved in 2002. Continued growth at a high rate is contingent upon future commercial development of our pipeline. One of our goals is to expand the use of treprostinil-based drugs to include the treatment of patients at earlier stages of the PAH disease pathway. In other words, we seek to move treprostinil from the last line of treatment for the sickest patients to front line therapy for newly diagnosed patients.

We expect to file for approval of inhaled treprostinil with the FDA in mid-2008. If we are successful in obtaining FDA approval in accordance with FDA requirements and anticipated review period, then we expect to begin commercial sales of inhaled treprostinil in 2009. We are currently in the later stages of development of our oral treprostinil formulation. We expect to unblind our FREEDOM-C trial in late 2008. If this trial is successful, we expect to file for approval with the FDA in 2009 with commercial sales beginning in 2010, assuming a regular FDA review period.

We believe that our trials for both the inhaled and oral formulations of treprostinil will be successful and will lead to products that generate revenues. However, for either or both of these formulations, we could be required to do additional studies which would delay commercialization. This could reduce our ability to continue to grow our revenues at our historic rate. Delays, if they occur, should not reduce our ability to continue revenue growth of Remodulin. Because PAH is a progressive disease with no cure, more patients each year are diagnosed with the disease and many patients continue to deteriorate on the current approved oral and inhaled therapies. In addition, we will need to sign new distribution agreements on acceptable terms for the inhaled and oral formulations of treprostinil in the United States and most foreign countries.

While we have been profitable for each year since 2003, we have experienced quarterly losses. At December 31, 2007, we had an accumulated deficit of approximately $21.5 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.

Financial Position

Cash, cash equivalents and marketable investments (including all amounts classified as current and non-current, but excluding all restricted amounts) at December 31, 2007, were approximately $299.3 million, as compared to approximately $264.2 million at December 31, 2006.

Restricted marketable investments and cash totaled approximately $44.2 million at December 31, 2007, as compared to approximately $39.0 million at December 31, 2006. The restricted amounts include approximately $39.2 million pledged to secure our obligations under our financing arrangements for our Silver Spring, Maryland, laboratory facility, discussed below under *Off Balance Sheet Arrangement*, and approximately $5.0 million set aside for our Supplemental Executive Retirement Plan and placed in a Rabbi Trust.

Prepaid expenses at December 31, 2007, were approximately $5.9 million, as compared to approximately $9.2 million at December 31, 2006. The decrease was primarily due to the expensing of a portion of those assets used in operations during 2007.

Property, plant and equipment at December 31, 2007, were approximately $69.4 million as compared to approximately $34.7 million at December 31, 2006. The increase was primarily due to the acquisition for $5.7 million of an office building adjacent to our leased legal and governmental affairs office in Washington, D.C., and construction expenditures for our Research Triangle Park, North Carolina, and Silver Spring, Maryland, facilities projects of approximately $21.8 million.

Accrued expenses at December 31, 2007, were approximately $17.9 million, as compared to approximately $15.3 million at December 31, 2006. The increase was due primarily to an increase in Remodulin-related royalty expense of approximately $1.3 million and an increase in accrued bonuses of approximately $1.1 million.

Common stock subject to repurchase at December 31, 2007, was approximately $10.9 million, as compared to none at December 31, 2006. The common stock subject to repurchase represents the issuance of 200,000 shares of our common stock to Toray, which are subject to repurchase under our amended license agreement. See the *Toray Amended License Agreement* for further details.

Total stockholders' equity at December 31, 2007, was approximately $295.8 million, as compared to approximately $204.6 million at December 31, 2006. The increase in stockholder's equity is highlighted as follows (in thousands):

Balance at December 31, 2006	$	204,606
Net Income		19,859
Foreign currency translation adjustments		285
Unrealized (loss) on available-for-sale securities		(214)
Realized (loss) on available-for-sale securities		(678)
Unrealized (loss) on pension liability		(552)
Exercise of stock options		58,344
Tax benefits primarily from the exercise of stock options		32,089
Treasury stock repurchases		(67,059)
Options issued in exchange for services		48,979
Stock issued for license		131
Balance at December 31, 2007	$	295,790

Results Of Operations

Years ended December 31, 2007 and 2006

Revenues for the year ended December 31, 2007, were approximately $210.9 million, as compared to approximately $159.6 million for the year ended December 31, 2006. The increase of approximately $51.3 million was due primarily to growth in sales of Remodulin to our distributors as a result of an increase in the number of patients being treated with Remodulin.

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

	Years Ended December 31,		
	2007	2006	Percentage Change
Remodulin	$ 200,879	$ 152,478	31.7%
Telemedicine services and products	7,725	6,597	17.1%
Other products	179	557	(67.9)%
Distributor fees	2,160		N/A
Total revenues	$ 210,943	$ 159,632	32.1%

For the year ended December 31, 2007 and 2006, approximately 87% 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 distributors for services. We pay government rebates to state Medicaid agencies that pay for Remodulin. We estimate 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 distributors for services are estimated based on contractual rates for specific services applied to estimated units of service provided by the distributors 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,	
	2007	2006
Liability accounts, at beginning of period	$ 2,366	$ 1,590
Additions to liability attributed to sales in:		
Current period	12,439	9,442
Prior period	278	
Payments or reductions attributed to sales in:		
Current period	(9,838)	(7,163)
Prior period	(2,366)	(1,503)
Liability accounts, at end of period	$ 2,879	$ 2,366
Net reductions to revenues	$ 12,703	$ 9,442

Research and development expenses were approximately $83.4 million for the year ended December 31, 2007, as compared to approximately $57.6 million for the year ended December 31, 2006.

The table below summarizes research and development by major project and non-project components (dollars in thousands):

	Years Ended December 31,		Percentage Change
	2007	2006	
Project and non-project:			
Cardiovascular	$ 38,459	$ 33,005	16.5%
Cancer	13,874	10,462	32.6%
Infectious disease	824	753	9.4%
Stock option	12,373	9,240	33.9%
Other	6,809	4,110	65.7%
R&D expense from issuance of common stock for license	11,013		N/A
Total research and development expense	$ 83,352	$ 57,570	44.8%

For the year ended December 31, 2007, the increase in cardiovascular expenses was primarily due to expensing a $3.0 million milestone payment to Toray in connection with the amended license agreement for modified release beraprost (beraprost-MR). For the year ended December 31, 2007, the increase in our cancer program expenses as compared to 2006 was primarily related to the development of our OvaRex manufacturing processes. The research and development expense from issuance of common stock is related to the 200,000 shares of our common stock issued to Toray for our amended license agreement for beraprost-MR.

Selling, general and administrative expenses were approximately $99.0 million for the year ended December 31, 2007 as compared to approximately $56.1 million for the year ended December 31, 2006. The table below summarizes selling, general and administrative expenses by major categories (dollars in thousands):

	Years Ended December 31,		Percentage Change
	2007	2006	
Category:			
General and administrative	$ 34,933	$ 25,434	37.3%
Sales and marketing	24,159	14,438	67.3%
Impairment charges	3,582	2,024	77.0%
Stock option	36,353	14,156	156.8%
Total selling, general and administrative expense	$ 99,027	$ 56,052	76.7%

The increase in general and administrative expenses was due primarily to increased expenses of approximately: (1) $3.2 million for salaries and related expenses from headcount growth to support expanding operations; and (2) $1.1 million for other operating expenses supporting the growth in our operations. The increase in sales and marketing related expenses is the result of an increase in salaries and related expenses of approximately $5.4 million primarily due to an increase in staffing and an increase in travel expenses of approximately $1.3 million. In November 2006, we settled an arginine infringement case and the $1.6 million settlement payment that we received was recorded as a reduction to general and administrative expense.

Under the terms of her employment agreement, as amended, our Chief Executive Officer is entitled to receive stock options in December of each calendar year based on the average closing bid price of our stock for the month of December. At December 31, 2007, we granted her options to purchase 582,607 shares of our common stock, which represents one-eighteenth of one percent of the

increase in our market capitalization from its average in December of 2006 based on the average closing bid price of our stock for the month of December 2007. Our stock market capitalization increased approximately $1.0 billion from January 1, 2007, to December 31, 2007. We recognized stock option expense in December 2007 of approximately $20.3 million, representing the fair market value of these stock options in excess of the $3.5 million recognized at September 30, 2007. Our market capitalization increased by approximately $814.7 million from September 30, 2007, to December 31, 2007. The offset to this expense was an increase to additional paid-in capital.

An impairment of the 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. In September 2007, based on a recent Supreme Court decision concerning the enforceability of patents and a publication discounting the benefits of arginine supplementation, we decided to discontinue selling any arginine related products and we reevaluated our assumptions used in determining the recoverability of our arginine patents. As a result, an impairment charge of $1.6 million was recorded.

In December 2007, based on the announcement of the failure of the IMPACT I and II Phase III trials of OvaRex in advanced ovarian cancer, the stock price of ViRexx declined We considered this decline to be an other-than-temporary impairment of approximately $1.9 million. Based on the quoted market price at December 31, 2007, the book value of our ViRexx investment is approximately $505,000.

Cost of product sales was approximately 10% of net product sales for each of the years ended December 31, 2007 and 2006. Cost of service sales was approximately 32% and 33% of service sales for the years ended December 31, 2007 and 2006, respectively.

Interest income for the year ended December 31, 2007, was approximately $13.6 million, as compared to interest income of approximately $10.7 million for the year ended December 31, 2006. The increase was due primarily to an increase in market interest rates and amounts available to invest.

Equity loss in affiliate represents our share of Northern Therapeutics' losses. The equity loss in affiliate was approximately $321,000 for the year ended December 31, 2007, as compared to approximately $491,000 for the year ended December 31, 2006. Northern Therapeutics' loss was due primarily to expenditures for its autologous (gene transfer using materials derived from a patient's own body and not from foreign materials such as viruses) gene therapy research for PAH.

We recognized an income tax benefit of approximately $3.3 million and $34.1 million for the years ended December 31, 2007 and 2006, respectively. The tax benefit generated for 2007 was primarily due to the amount of tax credits generated during the year from our orphan drug related research and development activities. For the year ended December 31, 2006 the tax benefit recognized was due primarily to reductions of approximately $45.7 million 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 to be realizable.

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 table sets forth our revenues by source for the periods presented (dollars in thousands):

	Years Ended December 31,		Percentage Change
	2006	2005	
Remodulin	$ 152,478	$ 109,191	39.6%
Telemedicine services and products	6,597	5,773	14.3%
Other products	557	689	(19.2)%
License fees		262	N/A
Total revenues	$ 159,632	$ 115,915	37.7%

For each of the years ended December 31, 2006 and 2005, approximately 90% and 89%, respectively, of our Remodulin revenues, respectively, were earned from our three distributors located in the United States.

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	$ 2,366	$ 1,590
Net reductions to revenues	$ 9,442	$ 6,789

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. 123R 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. 123R. 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 the immediate vesting of all of his unvested stock option grants. As a result, in December 2006, 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 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 a capital gain to occur in order to be recognized. Because these events are not likely to occur in the near future, 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.

Liquidity and Capital Resources

Until May 2002, we funded the majority of our operations from the net proceeds of sales of our common stock. Since May 2002, we have funded the majority of our operations from revenues, mainly Remodulin-related, and we expect this to continue. We believe that our existing revenues, together with existing working capital resources (consisting 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 We have a history of losses and may not continue to be profitable and Item 1A Risk Factors We may fail to meet third party projections for our revenue or profits.*

Net cash provided by operating activities was approximately $49.1 million for the year ended December 31, 2007, as compared to approximately $51.8 million for the year ended December 31, 2006. The increase in cash provided by operating activities is due primarily to growth in sales of Remodulin and the collections on receivables from sales. In addition, for the year ended December 31, 2007, we also received approximately $87.9 million in stock option exercise proceeds and in excess tax benefits related to the stock option exercises as compared to approximately $25.2 million during the year ended December 31, 2006. With the increase of our common stock price in the fourth quarter of 2007, we experienced a much larger than usual volume of stock option exercises. We don't expect that the level of stock option exercises experienced in the fourth quarter of 2007 will continue into 2008 unless our common stock price increases in a similar magnitude as it did in 2007.

Our working capital at December 31, 2007, was approximately $79.7 million, as compared to approximately $258.1 million at December 31, 2006. The decrease is primarily due to the reclassification of our $250.0 million 0.50% Convertible Senior Notes (Convertible Notes) from long term debt to short term debt as of December 31, 2007, as a result of these Convertible Notes becoming eligible for conversion by the bondholders. Our expectation, based on our understanding of historical behavior of holders of convertible notes with terms similar to ours, is that our Convertible Notes will continue to be held until they mature in October 2011. Consequently, we believe that we have approximately $329.7 million of working capital available at December 31, 2007, for our operating needs.

We are currently constructing an approximately 200,000 square foot facility in Research Triangle Park, North Carolina, which will consist of a manufacturing operation and offices. The manufacturing operation will primarily be for oral treprostinil, although it is expected to support other programs, and the offices will be used by our clinical development and sales and marketing staffs, who currently occupy a leased facility in the area. Construction of this facility is expected to be completed in early 2009. The project may cost up to $107.1 million, and we expect to fund the construction of this facility from our current working capital and working capital generated from existing operations. As of December 31, 2007, we have spent approximately $19.3 million on this construction project.

In March 2007, we entered into a construction management agreement with DPR Construction, Inc. (DPR), based in Falls Church, Virginia. DPR will manage the construction of our manufacturing and office facility in Research Triangle Park, North Carolina. The agreement has a guaranteed maximum price clause in which DPR agrees that the construction cost of the facility will not exceed approximately $78.0 million, which amount is subject to change with agreed-upon changes to the scope of work. DPR will be responsible for covering any costs in excess of the guaranteed maximum price. If the ultimate cost of the project is less than the guaranteed maximum price, we will share a portion of these savings with DPR. In addition, DPR must pay us penalties if the construction is not completed by February 2009, which date is subject to change based on agreed-upon changes to the scope of work. DPR has no material relationship with us or any of our affiliates.

At the end of December 2007, we began construction of a new office and laboratory building which will connect to our current laboratory facility in Silver Spring, Maryland. The cost of this project is expected to be approximately $106.1 million. The construction of this facility is expected to take two

years to complete. Based on the current amount of working capital and working capital to be generated from future operations, we have decided to self-fund this construction project.

During the year ended December 31, 2007, we paid approximately $1.2 million in interest to the holders of our Convertible Notes. We are required to pay a semi-annual interest payment of $625,000 to our bondholders until the Convertible Notes mature in October 2011.

Under our existing license agreements we are obligated to make royalty payments on sales of Remodulin that exceed annual net sales of $25.0 million and on all arginine royalty fees received. Royalties on sales of all products currently marketed range up to 10 percent of sales of those products and are recorded as cost of sales in our consolidated statements of income.

Convertible Senior Notes

On October 30, 2006, we issued $250.0 million of Convertible 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 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 in April 2007. The Convertible Notes are unsecured unsubordinated obligations and rank equally with all other unsecured and unsubordinated indebtedness. The Convertible Notes have an initial conversion price of $75.2257 per share. The Convertible Notes may only be converted: (i) any time 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 Notes have been issued, the holders may require us to purchase all or a portion of their Convertible 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 Notes were issued contains customary covenants.

Concurrent with the issuance of the Convertible Notes (see Note 7 in the *Consolidated Financial Statements*), we purchased call options on our common stock in a private transaction with Deutsche Bank AG London (the Call Option). The Call Option allows us to purchase up to approximately 3.3 million shares of our common stock at $75.2257 per share from Deutsche Bank AG London, equal to the amount of our common stock related to the excess conversion value that we would deliver to the holders of the Convertible Notes upon conversion. The Convertible Notes are generally convertible once our stock price exceeds $75.2257 per share. The Call Option will terminate upon the earlier of the maturity dates of the related Convertible Notes or the first day all of the related Convertible Notes are no longer outstanding due to conversion or otherwise. The Call Option, which cost approximately $80.8 million, was recorded as a reduction to additional paid-in-capital.

In a separate transaction that took place concurrently with the issuance of the Convertible Notes, we sold warrants to Deutsche Bank AG London under which Deutsche Bank AG London has the right to purchase approximately 3.3 million shares of our common stock at an exercise price of $105.689 per

share (the "Warrant"). 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 Option and Warrant effectively serves to reduce the potential dilutive effect of the conversion the Convertible Notes. The Call Option has a strike price equal to the conversion price for the Convertible Notes, and the Warrant has a higher strike price of $105.689 per share that serves to cap the amount of dilution protection provided. The Call Option and Warrant are settled on a net share basis. The Warrant may be settled in registered or, subject to certain potential adjustments in the delivery amount, unregistered shares. Furthermore, if additional shares are required to be delivered with respect to a settlement in unregistered shares or any anti-dilution adjustments in the related Convertible Notes, the Warrant provides that in no event shall we be required to deliver in excess of approximately 6.6 million shares in connection with the Warrant. We have reserved approximately 6.6 million shares for the settlement of the Warrant and have sufficient shares available as of December 31, 2007, to effect such settlement.

Deutsche Bank AG London is responsible for providing 100% of the necessary shares of our common stock upon an exercise of the Call Option triggered upon conversion of the Convertible Notes by a bondholder. The shares of our common stock that Deutsche Bank AG London will deliver must be obtained from existing shareholders. If the market price per share of our common stock is above $105.689 per share, we will be required to deliver to Deutsche Bank AG London shares of our common stock representing the value in excess of the Warrant strike price. In accordance with the provisions of EITF No. 00-19 and SFAS 133, these transactions meet the definition of equity and are indexed to our common stock; therefore, the Call Option and Warrant are not considered derivative instruments or required to be accounted for separately.

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 price of our common stock for the 30 consecutive trading days ending 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, 2007, approximately 3.1 million shares have been repurchased under the program at a cost of approximately $182.5 million. Approximately 1.8 million shares of our common stock were repurchased using approximately $112.4 million of the net proceeds from the issuance of the Convertible Notes, based on the closing price of our common stock on October 24, 2006, of $62.17. The remaining shares were repurchased on the open market. As of December 31, 2007, we had approximately 912,000 shares remaining under the approved stock repurchase program. We may also repurchase shares outside of this program.

Under the amended and restated agreement with Toray entered into in March 2007, we issued to Toray 200,000 shares of our common stock which are subject to repurchase. Toray has the right, upon 30 days prior written notice, to request that we repurchase these newly issued shares at the price of $54.41 per share, which was the average closing price of our common stock between January 11, 2007, and February 23, 2007. We have not received notice from Toray to repurchase any of these shares of our common stock.

Income taxes

We recognized an income tax benefit of approximately $3.3 million, $34.1 million and $17.5 million for the years ended December 31, 2007, 2006 and 2005, respectively. The tax benefit generated for 2007

was primarily due to the amount of tax credits generated during the year from our orphan drug related research and development activities. For the years ended December 31, 2006 and 2005, the tax benefit recognized is due primarily to reductions of approximately $45.7 million and $19.7 million, respectively, 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.

At December 31, 2007, we had, for federal income tax purposes, net operating loss carryforwards of approximately $69.8 million and business tax credit carryforwards of approximately $48.8 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. We have paid and expect to continue to pay state income taxes. A portion of the net operating loss carryforwards continues to be reserved through a valuation allowance as of December 31, 2007.

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 annually reviewed our ownership change position pursuant to Section 382. Through December 31, 2006, we have determined that ownership changes have occurred in December 1997, June 1999, and November 2004 and, as a result, the utilization of certain of our net operating loss carryforwards may be limited. However, we do not expect any significant portion of our net operating loss carryforwards or general business tax credits to expire unused. We are currently reviewing the ownership changes for the year ended December 31, 2007.

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 paid fair value rent to us for use of the land during the construction phase and will pay fair value rent 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.

We pledged a portion of our marketable investments as collateral to secure our lease obligations. At December 31, 2007, approximately $39.2 million of marketable investments and cash were pledged as collateral and are reported as restricted marketable investments and cash in our consolidated balance sheet.

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 toward construction. The maximum potential amount of this guarantee is approximately $27.5 million, equivalent to 86% of the total construction costs of $32.0 million. We have reported the fair value of this guarantee as a non-current asset (prepaid rent) and non-current liability (other liability). At December 31, 2007, the liability and the corresponding asset are approximately $566,000, net of accumulated amortization.

The laboratory lease and other agreements 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 the loss of our liquid collateral, among other consequences.

Wachovia receives monthly payments 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. This monthly payment commenced when the laboratory construction was completed in May 2006 and will continue until the termination of the lease in May 2011. The monthly payment from May 2006 through December 2007 is recorded as rent expense.

Upon completion of our laboratory facility in May 2006, Wachovia advanced to us approximately $5.2 million, which constituted the remaining funds available for construction due to the lengthy process involved in finalizing construction costs. At December 31, 2007, there were no remaining construction advances.

Based on construction costs of approximately $32.0 million and the then current effective rate of approximately 5.2% (equivalent to the current 30-day LIBOR rate plus approximately 55 basis points at December 31, 2007), the payments to be made are approximately $1.7 million annually. In addition, Wachovia paid us ground rent of approximately $307,000 in June 2004 covering the construction period through May 2006. This amount is being recognized as income ratably through May 2011.

We intend to enter into a construction agreement that generally obligates us to complete construction on a new combination laboratory and office building that will connect to our existing Silver Spring, Maryland, laboratory facility. Upon execution of an amendment to our leasing agreements with Wachovia permitting us to attach the new facility to the existing Silver Spring laboratory facility, the estimated fair value of the building and the corresponding financing obligation to Wachovia will be classified as a component of our Property, Plant and Equipment and as a lease obligation in our consolidated balance sheet. The existing Silver Spring laboratory facility will not be considered a standalone structure, which is a significant factor contributing to our current off balance sheet accounting of it. We will continue to make lease payments to Wachovia as specified in the agreement; however, those payments will be recorded as interest expense and a reduction to the lease obligation instead of as an operating lease payment.

Contractual Obligations

At December 31, 2007, we had contractual obligations coming due approximately as follows (in thousands):

	Payment Due In				
	Total	2008	2009 to 2010	2011 to 2012	2013 and Later
Notes payable and capital lease obligations(1)	$ 251,272	$ 251,272	$	$	$
Operating lease obligations	9,180	2,981	5,107	1,078	14
Purchase Obligations(2)	5,764	2,764	2,000	1,000	
Other long term Obligations(3)	566			566	
Milestone payments(4)	20,555	2,430	8,910	6,590	2,625
Totals	$ 287,337	$ 259,447	$ 16,017	$ 9,234	$ 2,639

(1) In October 2006, we issued $250.0 million aggregate principal amount of Convertible Notes. The principal balance of the notes is to be repaid in cash. The notes can be redeemed by the bondholders once the market price of our common stock exceeds $90.27 for a specified period which was satisfied as of December 31, 2007. While the Convertible Notes are classifed as current, we believe that the bondholders will hold the notes until maturity in October 2011.

(2) Includes specified payments to Toray for clinical trial material and related services.

(3) Upon termination of the synthetic operating 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 Wachovia that if the laboratory is sold, Wachovia will receive at least 86% of the amount it funded towards the construction. The final cost of constructing the laboratory was approximately $32.0 million and the guarantee is estimated at approximately $27.5 million. The remaining value of the guarantee is included in other long-term liabilities reflected in the statement of financial position. See the section entitled *Off Balance Sheet Arrangement* above for additional information.

(4) We licensed products from other companies under license agreements. These agreements generally include milestone payments to be paid in cash by us upon the achievement of product development and commercialization goals set forth in each license agreement. Total milestone payments under these license agreements have been estimated based on the assumption that the products currently under study will be successfully developed and on the estimated timing of these development and commercialization goals.

(5) As of December 31, 2007, we had approximately $3.0 million of unrecognized tax benefits. The table excludes these amounts due to uncertainty of timing surrounding future payments. See Note 8 to the consolidated financial statements for additional information.

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 the entire 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, 2007, it was determined that a partial valuation allowance totaling approximately $7.5 million was necessary at December 31, 2007.

Uncertain Tax Positions

In July 2006, the FASB issued FIN 48, *Accounting for Uncertainty in Income Taxes*, and an interpretation of SFAS No. 109. 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.

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. We follow the guidance provided by Statement of Financial Accounting Standards No. 48, *Revenue Recognition When Right of Return Exists* (SFAS 48). Exchanges for expired or damaged in shipment product is generally less that 0.20% of the volume of vials that we sell. An exchange for expired vials generally occurs months after the vial was sold. Reserves for exchanges are not recorded unless product expiration or damage occurred during shipping are known to us. 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, 2007, 2006 and 2005, approximately $20.6 million, $16.6 million, and $5.3 million, respectively, was recognized as revenue from sales to this distributor who has made voluntary purchases since June 30, 2005.

We closely monitor levels of inventory in the distribution channels for contractual compliance. The shelf life of Remodulin is 30 months. Obsolescence due to dating expiration has not been a historical concern, given the rapidity with 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.

We record 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 us to use information from external sources.

Prompt payment discounts We offer our 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. Our customers have routinely taken advantage of this discount. If information is available, such as an outstanding invoice, which would indicate that the invoice will not be paid within the discount period, we adjust 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 We record 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 our total product sales. In addition, we estimate the expected unit rebate amounts to be used and adjust 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. While we have not experienced large variability in our estimated rates of rebates, using historical amounts and trends could lead to fluctuations in recorded revenue due to differences between amounts accrued and amounts actually paid.

Distributor Fee and Non-Refundable Upfront License Revenue Recognition

Our revenue recognition policy for all non-refundable upfront license and distribution rights fees and milestone arrangements are in accordance with the guidance provided in the Commission's Staff

Accounting Bulletin ("SAB") No. 101, *Revenue Recognition in Financial Statements* as amended by SAB No. 104, *Revenue Recognition*. In addition, we follow the provisions of EITF, Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*, (EITF 00-21) for multiple element revenue arrangements. EITF 00-21 provides guidance on how to determine when an arrangement that involves multiple revenue-generating activities or deliverables should be divided into separate units of accounting for revenue recognition purposes, and if this division is required, how the arrangement consideration should be allocated among the separate units of accounting. If the deliverables in a revenue arrangement constitute separate units of accounting according to the EITF's separation criteria, the revenue recognition policy must be determined for each identified unit. If the arrangement is a single unit of accounting, the revenue recognition policy must be determined for the entire arrangement.

Under arrangements where the license or distribution rights fees and research and development activities can be accounted for as separate units of accounting, non-refundable upfront license and distribution fees are deferred and recognized as revenue on a straight-line basis over the expected term of our continued involvement in the research and development process. Revenues from the achievement of certain research and development milestones, if deemed substantive, are recognized as revenue when the milestones are achieved and the milestone payments are due and collectible. Milestones are considered substantive if all the following criteria are met: (1) the milestone payment is non-refundable; (2) achievement of the milestone was not reasonably assured at the inception of the arrangement; (3) substantive effort is involved to achieve the milestone; and (4) the amount of the milestone payment appears reasonable in relation to the effort expended, the other milestones in the arrangement and the related risk associated with achievement of the milestone. If any of these conditions is not met, we would recognize a proportionate amount of the milestone payment upon receipt as revenue that correlates to work already performed and the remaining portion of the milestone payment would be deferred and recognized as we complete our performance obligations.

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 1st of each year. We continually evaluate whether events and circumstances have occurred that indicate that the remaining value of goodwill may not be recoverable. If we believe impairment has occurred, we generally use a discounted cash flow methodology to calculate the actual impairment. At December 31, 2007, 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.

Marketable Investments

Currently, we invest portions of our cash in marketable debt securities issued primarily by corporations and federally-sponsored agencies. We do invest in state and municipal government agencies, mainly auction rate securities and in selected corporate debt issues. 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 and the generally short term nature of the investments. The weighted average maturity on these investments is approximately 14 months. 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 with changes in the fair value being recorded

in our results of operations. At December 31, 2007, the amortized cost of these debt securities was approximately $141.0 million and their fair values were approximately $140.9 million.

Stock Options

Effective January 1, 2006, we adopted the fair value recognition provisions of SFAS No. 123R, *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 vest 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. 123R. 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 since adoption of SFAS No. 123R, 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. We use the historical volatility based on the weekly price observations of our 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). We believe 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. We adopted SAB 107's simplified method for estimating the expected term of share-based awards granted during the year ended December 31, 2007 and 2006. The use of SAB 107 to calculate expected term has been extended past the original curtailment date of December 31, 2007. We are evaluating the historical holding patterns of our options to determine if we can calculate a reasonable estimate of expected term for stock option grants beginning in 2008. Given the increase in our stock price, our stock options could be exercised sooner than we have seen in prior years.

Expected Dividend Yield We have never declared or paid dividends on our 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. We estimate 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, Inc. (Northern). 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 exceeds 50%, minority shareholders possess substantive participating rights that preclude Northern's 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.

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 cost of the construction was $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.

Senior Executive Retirement Plan

We account for our Senior Executive Retirement Plan (SERP) in accordance with SFAS No. 87, *Employers Accounting for Pensions* (SFAS 87), and SFAS 158, *Employers' Accounting for Defined Benefit Pension and Other Postretirement Plans* (SFAS 158), 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. Since there are no plan assets, no interest on assets is assumed earned. With the addition of a participant in 2006, there is an unrecognized prior service cost of approximately $713,000 as of December 31, 2007 which will be amortized over the next 12 years, the average expected future service period of all the plan participants. In addition, any unrealized actuarial losses 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.

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. We are currently evaluating the impact the adoption of this statement could have on our financial condition, results of operations or cash flows.

Fair Value Option for Financial Assets and Liabilities

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115*. SFAS No. 159 permits an entity to measure many financial instruments and certain other items at fair value that are not currently required to be measured at fair value. Entities that elect the fair value option will report unrealized gains and losses in earnings at each subsequent reporting date. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007. We are currently evaluating the im