

UNITED THERAPEUTICS CORP  
Form 10-K  
February 26, 2009

Use these links to rapidly review the document

[TABLE OF CONTENTS](#)

[ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA](#)

[Table of Contents](#)

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

---

**FORM 10-K**

(Mark  
One)

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

**For the fiscal year ended December 31, 2008**

**OR**

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

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission file number 0-26301**

**United Therapeutics Corporation**

(Exact Name of Registrant as Specified in Its Charter)

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

**52-1984749**  
(I.R.S. Employer  
Identification No.)

**1110 Spring Street, Silver Spring, MD**  
(Address of Principal Executive Offices)

**20910**  
(Zip Code)  
**(301) 608-9292**

Registrant's Telephone Number, Including Area Code

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

**Title of each class**  
Common Stock, par value \$.01 per share  
and associated preferred stock purchase rights

**Name of each exchange on which registered**  
Nasdaq Global Select Market

# Edgar Filing: UNITED THERAPEUTICS CORP - Form 10-K

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

**None**  
(Title of Class)

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, 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 <input checked="" type="checkbox"/>	Accelerated filer <input type="checkbox"/>	Non-accelerated filer <input type="checkbox"/>	Smaller reporting company <input type="checkbox"/>
(Do not check if a smaller reporting company)			

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

The aggregate market value of the Common Stock held by non-affiliates of the registrant, based on the closing price on June 30, 2008, as reported by the NASDAQ National Market was approximately \$2,199,200,000

**The number of shares outstanding of the issuer's common stock, par value \$0.01 per share, as of February 20, 2009, was 26,435,865**

## DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for the registrant's 2009 annual meeting of shareholders scheduled to be held on June 26, 2009, are incorporated by reference in Part III of this Form 10-K.

---

Table of Contents**TABLE OF CONTENTS**

<u>PART I</u>		
<u>Item 1.</u>	<u>Business</u>	<u>3</u>
<u>Item 1A.</u>	<u>Risk Factors</u>	<u>31</u>
<u>Item 1B.</u>	<u>Unresolved Staff Comments</u>	<u>51</u>
<u>Item 2.</u>	<u>Properties</u>	<u>51</u>
<u>Item 3.</u>	<u>Legal Proceedings</u>	<u>52</u>
<u>Item 4.</u>	<u>Submission of Matters to a Vote of Security Holders</u>	<u>52</u>
<u>PART II</u>		
<u>Item 5.</u>	<u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	<u>53</u>
<u>Item 6.</u>	<u>Selected Financial Data</u>	<u>54</u>
<u>Item 7.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>55</u>
<u>Item 7A.</u>	<u>Quantitative and Qualitative Disclosure About Market Risk</u>	<u>78</u>
<u>Item 8.</u>	<u>Financial Statements and Supplementary Data</u>	<u>F-1</u>
<u>Item 9.</u>	<u>Changes In and Disagreements With Accountants on Accounting and Financial Disclosure</u>	<u>80</u>
<u>Item 9A.</u>	<u>Controls and Procedures</u>	<u>80</u>
<u>Item 9B.</u>	<u>Other Information</u>	<u>80</u>
<u>PART III</u>		
<u>Item 10.</u>	<u>Directors, Executive Officers and Corporate Governance</u>	<u>81</u>
<u>Item 11.</u>	<u>Executive Compensation</u>	<u>81</u>
<u>Item 12.</u>	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	<u>81</u>
<u>Item 13.</u>	<u>Certain Relationships and Related Transactions, and Director Independence</u>	<u>82</u>
<u>Item 14.</u>	<u>Principal Accounting Fees and Services</u>	<u>82</u>
<u>PART IV</u>		
<u>Item 15.</u>	<u>Exhibits, Financial Statement Schedules</u>	<u>83</u>
<u>SIGNATURES</u>		
		<u>88</u>
<u>EXHIBITS</u>		
EX-10.44	Agreement between the Registrant and the Whiting-Turner Contracting Company	
EX-12.1	Computation of Earnings to Fixed Charges	
EX-21	Subsidiaries of the Registrant	
EX-23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm	
EX-31.1	Rule 13a-14(a) Certification of CEO	
EX-31.2	Rule 13a-14(a) Certification of CFO	
EX-32.1	Section 1350 Certification of CEO	
EX-32.2	Section 1350 Certification of CFO	

Table of Contents

**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 Analogues*, 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 analogue 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. Remodulin has been approved in most of Europe for the treatment of NYHA Class III patients with idiopathic (familial) PAH and in other countries for use similar to that for which it is approved in the United States. Our inhaled and oral formulations of treprostinil are in the later stages of development. A New Drug Application (NDA) for our inhaled formulation is currently under review by the FDA and a Marketing Authorization Application (MAA) is currently under review by the European Medicines Agency (EMA). We are also developing modified release beraprost (beraprost-MR), another prostacyclin analogue, for the treatment of PAH;

*Phosphodiesterase 5 (PDE5) inhibitors*, which act to inhibit the degradation of cyclic guanosine monophosphate (cGMP) in cells. cGMP is activated by nitric oxide (NO) to signal relaxation of vascular smooth muscle. Our investigational therapy in this platform is tadalafil, a product developed by Eli Lilly and Company (Lilly). Lilly's NDA for tadalafil for the treatment of PAH is currently under review by the FDA. We entered into a license agreement with Lilly to obtain certain rights to tadalafil for PAH, effective December 18, 2008;

*Monoclonal Antibodies*, which are antibodies that activate patients' immune systems to treat cancer. Our platform includes the 3F8 and 8H9 murine antibodies, which we are developing for the treatment of neuroblastoma and metastatic brain cancer, respectively. We expect to begin a Phase II clinical trial in the second quarter of 2009 of the 3F8 antibody in patients with neuroblastoma; and

*Glycobiology Antiviral Agents*, which are a novel class of small, sugar-like molecules that have shown pre-clinical indications of efficacy against a broad range of viruses, such as hepatitis C.

We devote most of our resources to developing products within our key therapeutic platforms. We also devote resources to the commercialization and further development of telemedicine products and services, principally for the detection of cardiac arrhythmias (abnormal heart rhythms).

We generate revenues from the sale of Remodulin and telemedicine products and services. Our sales and marketing staff for Remodulin, which is supplemented by our specialty pharmaceutical distributors, supports the commercial availability of Remodulin in the United States, Canada, Europe and other countries.

United Therapeutics was incorporated in Delaware in June 1996. Our principal executive offices are located at 1110 Spring Street, Silver Spring, Maryland 20910. We also maintain executive offices at 55 T.W. Alexander Drive, Research Triangle Park, North Carolina 27709.

Table of Contents

Unless the context requires otherwise or unless otherwise noted, all references in this Annual Report on Form 10-K to "United Therapeutics" and to the "company", "we", "us" or "our" are to United Therapeutics Corporation and its subsidiaries.

**Our Products**

Our product portfolio includes the following as of December 31, 2008:

<b>Product</b>	<b>Mode of Delivery</b>	<b>Indication/Market</b>	<b>Current Status</b>	<b>Our Territory</b>
Remodulin	Continuous subcutaneous	Pulmonary arterial hypertension	Commercial in the U.S., most of Europe*, Canada, Israel, Australia, Mexico, Argentina and Peru; MAA filed with EMEA	Worldwide
Remodulin	Continuous intravenous	Pulmonary arterial hypertension	Commercial in the U.S., Canada, Israel, Mexico, Argentina and Peru; MAA filed with EMEA	Worldwide
CardioPAL® SAVI and Decipher Cardiac Monitors	Telemedicine	Cardiac arrhythmias and ischemic heart disease	Commercial	Worldwide
Inhaled Treprostinil	Inhaled	Pulmonary arterial hypertension	NDA filed with FDA; MAA filed with EMEA	Worldwide
Oral Tadalafil	Oral	Pulmonary hypertension	NDA filed with FDA	United States
Oral Treprostinil	Oral	Pulmonary arterial hypertension	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
Inhaled Treprostinil	Inhaled	Pulmonary arterial hypertension associated with Idiopathic pulmonary fibrosis	Phase I	Worldwide
Inhaled Treprostinil with AERx Essence®	Inhaled	Pulmonary hypertension	Phase I	Worldwide
8H9 MAb	Intravenous	Metastatic brain cancer	Phase I	Worldwide
Celgosivir	Oral	Hepatitis C	Phase I	Worldwide
Miglustat	Oral	Hepatitis C	Pre-Clinical	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 (EU), as well as European countries that are not members of the EU. We have received formal approval letters and pricing approval in most of these countries.

Table of Contents

**Remodulin**

Our lead product for treating PAH is Remodulin (treprostinil sodium) Injection, the main ingredient of which is treprostinil sodium, a prostacyclin analogue. We sell Remodulin to our specialty pharmaceutical 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 recognized approximately \$269.7 million, \$200.9 million and \$152.5 million in Remodulin revenues, representing 96%, 95% and 96% of our net revenues in 2008, 2007 and 2006, respectively. We obtained worldwide rights for all indications to Remodulin from GlaxoSmithKline PLC (formerly Glaxo Wellcome, Inc.) (Glaxo) in January 1997 and from Pfizer, Inc. (formerly Pharmacia & Upjohn Company)(Pfizer) 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, the FDA expanded its approval to permit continuous intravenous (through a vein) infusion for patients who cannot tolerate subcutaneous infusion. In March 2006, the FDA expanded its approval to include transition of patients 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. We continue to work on expanding Remodulin commercialization to other new territories, including Japan.

PAH is a life-threatening disease that affects the blood vessels in the lungs and is characterized by increased blood pressure in the blood vessels leading from the heart to the lungs, known as the pulmonary arteries. The elevated pressure in the pulmonary arteries strains the right side of the heart as it pumps blood to the lungs leading to right heart failure and death. PAH is characterized by the disruption of blood vessel walls, the aggregation of platelets and the alteration of smooth muscle function. 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 rarity of PAH and the complexity of diagnosing it, only a small fraction of patients with PAH are being treated. There is scientific interest in identifying easier, less invasive methods of diagnosing PAH. If this research is successful, more patients could be diagnosed at an earlier stage of the disease.

The complexity of diagnosing PAH reflects in part 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 NO 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 (ERAs). Patients with PAH have also been shown to have reduced levels of the enzyme responsible for producing 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. 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 analogues, 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. We currently market Remodulin, a prostacyclin analogue, and are awaiting FDA approval to market tadalafil, a PDE5 inhibitor, for the treatment of pulmonary hypertension.

Table of Contents

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 in the study (including 130 patients who received Remodulin in combination with other PAH therapies) and 88%, 79%, 73%, and 70%, respectively, for 730 of the patients in the study who received only Remodulin. In patients with idiopathic PAH for whom baseline hemodynamics (measurement of bloodflow and pressures) were available (332 patients), survival was 91%, 82%, 76%, and 72% at years one through four, 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 prostacyclin analogue for PAH, is delivered continuously through a surgically implanted intravenous catheter connected to an external pump. 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 drug delivery to patients. Unlike Flolan, Remodulin can be delivered by subcutaneous infusion with a pager-sized miniature pump device. Subcutaneous delivery of Remodulin also eliminates the risk of central venous catheter infection and the hospitalization required to begin intravenous 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, so patients do not have to mix the drug, as they do with Flolan. Remodulin 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. Treprostinil sodium, the active ingredient in 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. In June 2008, the FDA approved a generic version of Flolan, developed by GeneraMedix, Inc., that is stable at room temperature, but still shares all of Flolan's other inconvenient attributes including, but not limited to, risk of central venous catheter infection, required hospitalization at the start of treatment, shorter half-life increasing risk of rebound PAH, mixing, greater frequency of pump refills and larger pump size.

There are noteworthy adverse events associated with Remodulin infusion. When infused subcutaneously, Remodulin causes infusion site pain and reaction (redness and swelling) 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 serious bloodstream infection known as sepsis, as does Flolan.

*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. These clinical endpoints included a composite index that measured exercise capacity and shortness of breath, cardiopulmonary hemodynamics and the signs and symptoms of the disease. Based on the favorable results of this study, we filed an NDA 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 to diminish symptoms associated with

Table of Contents

exercise. Remodulin may be prescribed for all types of PAH and is the only PAH treatment approved for patients with NYHA class II-IV symptoms.

*FDA Review of Intravenous Remodulin*

In July 2003, the FDA accepted our Investigational NDA for the development of Remodulin by intravenous delivery for the treatment of PAH. A 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, we filed a supplemental NDA 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.

On March 20, 2006, the FDA approved a supplemental NDA that we filed to satisfy of our Subpart H commitment from our original May 2002 approval for subcutaneous Remodulin. This approval added language to Remodulin's package insert indicating patients can be transitioned from Flolan to Remodulin.

In January 2007, the results of a prospective, open-label study demonstrated 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. 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 their infusion site pain even when using available pain management techniques or medication. Intravenous Remodulin has many beneficial characteristics that differentiate it from intravenous Flolan. Intravenous Remodulin does not require refrigeration whereas Flolan must be refrigerated. Furthermore, Remodulin persists in the blood for a few hours, whereas Flolan is highly unstable and only remains active in the body for a few minutes. Because Remodulin persists in the body longer, it may reduce the risk of rebound PAH, a severe recurrence of the disease that can occur when therapy is abruptly interrupted. Intravenous Remodulin can be infused continuously for up to 48 hours once the administering pump has been filled, while Flolan can only be infused for 24 hours once the drug has been mixed and the administering pump filled. This allows patients to fill their pumps with medication 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 guidelines related to the treatment of PAH patients on long-term intravenous therapy. The SLC guidelines were 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



Table of Contents

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 guidelines 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 venous catheters and to treat them appropriately. The risk of sepsis was already noted in the Remodulin package insert. In February 2008, the FDA approved a revised package insert for Remodulin that more fully described the associated infection risk and appropriate techniques to be practiced when preparing and administering Remodulin for intravenous infusion.

*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 in the EU. The mutual recognition process is described more fully in the section entitled *Governmental Regulation* below. The mutual recognition process for subcutaneous Remodulin was completed in August 2005, with positive decisions received from most EU member 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 approval of intravenous Remodulin in the EU. Licenses and pricing approvals have been received in most EU member countries. In addition, we have submitted a variation of the license for approval of intravenous Remodulin in the EU 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 currently satisfied with our application. We are working to address their concerns and believe that we will eventually receive commercial approval for intravenous Remodulin in at least some EU member countries. In the meantime, we will continue to sell (but not market) Remodulin under the named-patient system in EU member countries where we are not approved. Under the named-patient system, we are permitted to import Remodulin into EU member countries for sale to hospitals for use in treating specifically identified patients.

*Sales and Marketing*

Our marketing strategy for Remodulin is to use our sales and marketing teams to educate the prescriber community to increase PAH awareness and awareness of our products. The sales and marketing team consisted of approximately 80 employees as of December 31, 2008, up from approximately 65 employees as of December 31, 2007. We anticipate continued growth in our sales force in the near-term as we position our business for further expansion. We divide our domestic sales force into two teams. One sales team is primarily responsible for medical practice accounts that are historical Remodulin prescribers. The other sales team is primarily responsible for medical practice accounts that have not historically prescribed Remodulin. The efforts of our sales and marketing teams are supplemented by our specialty pharmaceutical distributors. For additional information about our agreements with our distributors, see the next section entitled *Domestic Distribution of Remodulin*. Our distributors are experienced in all aspects of using and administering chronic therapies, as well as patient care, the sale and distribution of these medicines and reimbursement from insurance companies and other payers. Outside of the United States, we have entered into exclusive distribution agreements covering most of Europe, South America, Israel, and parts of Asia. 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.

Table of Contents

*Domestic Distribution of Remodulin*

To market, promote and distribute subcutaneous and intravenous Remodulin through specialty pharmaceutical distributors 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) (CuraScript), Accredo Therapeutics, Inc. (a wholly-owned subsidiary of Medco Health Solutions, Inc.) (Accredo) and CVS Caremark Corporation (Caremark). 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. Our distribution agreements with Accredo and Caremark include automatic term renewals for additional one-year periods subject to notice of termination. Our distribution agreement with Curascript contains two-year term renewal periods. We update our distribution agreements from time to time to reflect changes in the regulatory environment. These changes have not had a significant impact on our operations or our relationships with our distributors, and tend to occur in the ordinary course of business. If our distribution agreements expire or terminate, we may, under certain circumstances, be required to repurchase any unsold Remodulin inventory held by our 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. None of our current agreements grants our distributors the distribution rights for inhaled or oral treprostinil in the United States.

*International Distribution of Remodulin*

We currently sell Remodulin to six distributors who have certain exclusive distribution rights for subcutaneous and intravenous Remodulin in EU member countries, and other non-EU countries, such as South America, Israel and parts of Asia. 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 by creating relationships with new distributors. In March 2007, we entered into a distribution agreement with Mochida Pharmaceutical Co., Ltd. (Mochida) to obtain approval and 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. However, certain countries, like Japan, may require that new clinical trials, called bridging studies, be conducted in order to demonstrate 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 gain approval of 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 EMEA granted orphan designation for inhaled treprostinil for the treatment of both PAH and chronic thromboembolic pulmonary hypertension. We also plan to seek orphan drug designation for inhaled treprostinil in the United States. If successful, we will be granted a seven-year period of orphan drug exclusivity for inhaled treprostinil that will begin upon the approval of our NDA.

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 optimized (therapeutically well-maintained) on Tracleer®, an oral ERA marketed by Actelion Ltd (Actelion). In May 2006, the FDA agreed that we could also include in the trial PAH patients who were optimized on Revatio®, an oral PDE5 inhibitor marketed by Pfizer. During the 12-week trial, patients were administered inhaled treprostinil or placebo

Table of Contents

in four daily inhalation sessions with a maximum dose of approximately 54 micrograms per session. The primary endpoint of the trial was the peak six-minute walk distance (6MWD) improvement test, which is a typical benchmark test of cardiovascular health. The 6MWD test measures the distance a patient walks in six minutes on a treadmill at the start of the trial as compared to additional pre-specified points in time during the trial in order to detect any improvement in the distance the patient is able to walk. This trial, TRIUMPH-1 (**T**reprostini**L** 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 November 2007, we announced the completion of our TRIUMPH-1 trial. The study population consisted of 235 patients. Ninety-eight percent of patients were classified as New York Heart Association (NYHA) Class III. 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 6MWD was approximately 350 meters.

The primary efficacy endpoint of the trial was the 6MWD at 12 weeks measured at peak exposure, defined by the trial protocol as 10-60 minutes after inhalation of treprostinil, relative to baseline. Analysis of the TRIUMPH-1 results demonstrated an improvement in median 6MWD of approximately 20 meters ( $p < 0.0005$ , 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.

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 6MWD at week 12 relative to baseline was also significantly improved, with an increase in median 6MWD of approximately 14 meters ( $p < 0.01$ ). Additionally, the 6MWD at week six measured at peak exposure relative to baseline was significantly improved, with an increase in median 6MWD of approximately 18 meters ( $p < 0.0005$ ). Quality of life was assessed using the Minnesota Living with Heart Failure Questionnaire. Both the Global Score ( $p < 0.03$ ) and the physical score ( $p < 0.04$ ) were significantly improved. NT-Pro BNP, a biomarker correlated with right ventricular function, also improved significantly at week 12 ( $p < 0.002$ ).

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 6MWD at treatment day one, did not differ significantly between the inhaled treprostinil and placebo groups ( $p > 0.05$ ).

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. 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 125 patients continue to be treated with inhaled treprostinil, with the longest duration of treatment exceeding two years.

In June 2008, we submitted an NDA to obtain FDA approval to market inhaled treprostinil for the treatment of PAH in the United States with an expected action date of April 30, 2009. The Optineb® nebulizer (the ultra-sonic nebulizer that was exclusively used for administration of inhaled treprostinil in the TRIUMPH-1 trial) was submitted for approval as part of this filing. The Optineb is manufactured by NEBU-TEC International Med Products Eike Kern GmbH (NEBU-TEC), a German company. The Optineb is CE-marked in Europe, which means that NEBU-TEC asserts that the device conforms to EU health and safety requirements. In December 2008 we filed an MAA for inhaled treprostinil in the EU using the centralized filing process. The standard time for review of an NDA by the FDA and of an MAA by the EMEA is generally 10 to 12 months. See the section entitled *Governmental Regulation* below for further discussion on the centralized filing process for the EU.

Table of Contents

This is the first time we have submitted a device to the FDA for approval. Since we do not manufacture the Optineb device, we relied on NEBU-TEC for certain design, mechanical, operational and study information needed for the filing. In December 2008, we entered into an Agreement of Sale and Transfer with NEBU-TEC under which NEBU-TEC will sell to us its Optineb business and all associated assets and rights. Closing and transfer of all the associated assets and rights is expected to occur within 30 days of receiving FDA approval for our inhaled treprostinil therapy and its use with the Optineb nebulizer. In the interim period prior to the closing of the Agreement of Sale and Transfer, both NEBU-TEC and we remain subject to an existing Clinical and Commercial Supply Agreement, as amended, pursuant to which NEBU-TEC is required to maintain all aspects of the FDA's required current good manufacturing practices. Refer to the section entitled *NEBU-TEC Agreement of Sale and Transfer* below for further details related to our asset acquisition.

We were recently notified that the FDA Office of Safety and Epidemiology has preliminarily approved the tradename Tyvaso for our inhaled treprostinil therapy. The FDA Division of Cardioresenal Drug Products will conduct the final review and approval of the tradename, which usually occurs simultaneously with NDA approval.

Currently, the only FDA approved inhaled prostacyclin analogue is Ventavis®. Ventavis is marketed by Actelion in the United States and by Schering AG in Europe. The active ingredient in Ventavis, iloprost, has a half-life of approximately 20 to 30 minutes and lacks selectivity to the lungs. The lack of selectivity to the lungs can cause a decrease in patient blood pressure if the drug is administered at too high a dose. As a result, Ventavis is inhaled via a nebulizer six to nine times per day at a low dose. Per its label, each 15 minute session on the nebulizer must be continuously inhaled. Due to the longer half-life of treprostinil and its greater selectivity to the lungs, treprostinil is administered four times a day, in six to nine breaths over an approximately one-minute session. We are currently conducting an open-label study in the United States to investigate the clinical effects of switching patients from Ventavis to inhaled treprostinil. This study began enrollment in December 2008.

The inhalation device market is ever-changing, with new technologies being discovered and improved devices being developed constantly. 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 subsidiary, Lung Rx, Inc. (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 inhaled treprostinil.

***UT-15C Sustained Release (Oral Treprostinil)***

*Pulmonary Arterial Hypertension.* 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 treprostinil at a relatively even rate in the gastrointestinal tract. In 2005, a Phase I study of normal volunteers not diagnosed with PAH 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 EMEA announced that oral treprostinil had been granted orphan product status in the EU. If we obtain a separate orphan drug designation in the United States for oral treprostinil for the treatment of PAH, then we may obtain a seven-year period of orphan drug exclusivity for oral treprostinil that will begin upon the approval of our NDA.

Table of Contents

In October 2006, we commenced two Phase III multi-national, placebo-controlled clinical trials of oral treprostinil in patients with PAH to study both dosing and efficacy. The FREEDOM-C trial was a 16-week study of patients on approved background therapy using a PDE5 inhibitor, such as Revatio, or an ERA, such as Tracleer, or a combination of both. The FREEDOM-M trial is a 12-week study of patients who are not on any background therapy. Both trials have been 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 initially began at 1 mg twice daily for both trials but during the trial, 0.5 mg and 0.25 mg tablet doses became available. 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 study endpoint of the trials is 6MWD.

We commenced both trials using a 1 mg tablet, but during the open-label extension trial (and associated pharmacokinetic substudy) we discovered that the treprostinil concentrations were higher in PAH patients than in healthy individuals due to the difference in absorption rate between these two populations. This difference in absorption rate led to a number of discontinuations by patients randomized to receive drug due to tolerability-related side effects, including nausea, jaw-pain and headaches. As a result, we introduced a 0.5 mg tablet in July 2007 to enable more gradual dose titration (increase). The 0.25 mg tablet was introduced into the trials in April 2008.

In mid-November 2008, we announced that the FREEDOM-C trial did not meet statistical significance for its primary endpoint. The study population consisted of 354 patients. The majority (~75%) of patients were World Health Organization (WHO) Class III of varied etiologies, including idiopathic or familial PAH (~65%), collagen vascular disease associated PAH (~25%), and PAH associated with HIV or other associated conditions (~10%). Mean baseline 6MWD was approximately 345 meters.

The placebo-corrected median change in 6MWD at week 16 was 11 meters ( $p=0.072$ ). A statistically significant treatment effect was observed at week 12, with a placebo-corrected median change in 6MWD of 13 meters ( $p=0.015$ ).

Exploratory analyses suggest that the inability to dose titrate was a limiting issue that suppressed the overall treatment effect. Of the 174 patients who received active drug, 25 patients discontinued due to an adverse event and 33 patients completed the trial but were unable to titrate their doses above 1 mg twice daily. Accordingly, 58 (33%) of the patients in the active treatment group were only able to maintain a suboptimal dose of below 1 mg twice daily. Adverse events that led to discontinuation or inability to dose-escalate included headache, nausea and vomiting. Dropouts were most common in patients who only had access to the 1 mg tablets during the study, which was the only size tablet available when the trial began. There were no discontinuations among patients who had access to the 0.25 mg tablet.

Preliminary analysis of other secondary efficacy measures, including change in combined 6MWD, Borg dyspnea score and Dyspnea-Fatigue index demonstrated statistically significant improvements ( $p<0.05$ ) compared to placebo. Other secondary efficacy measures including change in WHO functional class, time to clinical worsening, and PAH signs and symptoms, did not differ significantly between patients administered oral treprostinil versus placebo ( $p>0.05$ ).

Enrollment in FREEDOM-M was closed on October 31, 2008, with 171 patients enrolled in the trial. However, based on what we learned from the FREEDOM-C trial relating to patient tolerability of our three different tablet strengths of oral treprostinil, we submitted a protocol amendment to the FDA on February 20, 2009, seeking to increase the number of patients enrolled in FREEDOM-M by approximately 140 patients. These new patients will start the study on the 0.25 mg tablet, which we know from the FREEDOM-C trial is the best-tolerated tablet strength.

Table of Contents

We believe that this protocol amendment will allow us to more accurately assess the effectiveness of oral treprostinil for many reasons. First, by starting patients on the 0.25 mg tablets and titrating up to reach an effective maintenance dose, we expect there will be a reduced rate of premature discontinuation due to adverse events. Second, the study will be statistically powered using a reduced effect size (from a 50 to 45 meter change in 6MWD) and a change in statistical significance level (from 0.05 to 0.01). Finally, the primary endpoint of change in 6MWD will be tested only in patients who had access to the 0.25 mg tablets at the start of the study, which reflects the expected dosing regimen for oral treprostinil. Due to the anticipated time required to receive FDA consent to the protocol amendment and to package and ship new clinical trial supplies to study sites, we expect to begin enrolling additional patients in the second quarter of 2009.

We are also in the planning stages of designing a new FREEDOM-C clinical trial of patients with PAH who are on an approved background therapy, FREEDOM-C<sup>2</sup>. This clinical trial is expected to enroll 300 patients, all using the 0.25 mg tablet. The FREEDOM-C<sup>2</sup> clinical trial is expected to commence in late 2009. Currently, we do not anticipate filing an NDA for oral treprostinil before 2012.

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 continuum and for the treatment of other diseases.

*Peripheral Arterial Disease/Critical Limb Ischemia.* We are also developing oral treprostinil for a subset of late-stage peripheral arterial disease (PAD) known as critical limb ischemia (CLI). PAD is a narrowing of the blood vessels that carry blood to the upper or lower extremities, especially the legs. While the precise causes of PAD are unknown, diabetes, high blood pressure, smoking, eating a high fat diet and lack of exercise are associated with the disease. Blood vessels affected by PAD often have a reduced level of natural prostacyclin similar to those affected by PAH.

Severe PAD can often lead to CLI, which is characterized by extreme leg pain, non-healing ulcers or gangrene in the legs, severely reduced exercise capacity and blood flow in the legs. In the United States, it is estimated that 2 million people suffer from CLI but there are currently no drugs approved to treat it. Physicians often suggest surgical interventions, such as balloon angioplasty, stents and by-pass, 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 the disease. Due to the lack of adequate pharmaceutical treatment, approximately 160,000 leg amputations are performed each year on patients with CLI.

In September 1998, we completed a Phase II study assessing the safety and blood flow effects of intravenous Remodulin on patients with CLI. The study demonstrated that Remodulin can be administered safely to patients with CLI 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 CLI in 2002. Approximately 19 patients were enrolled but we ended the study early due to difficulty recruiting patients. We believe that more convenient formulations of treprostinil, such as our oral formulation, may be more appropriate for patients with CLI. Accordingly, we have commenced Phase I studies of oral treprostinil for patients with CLI.

We have also initiated a Phase II Study in 2009 to investigate the effectiveness of oral treprostinil in reducing the frequency and severity of ulcers located on the fingers and toes of scleroderma patients.

*Tadalafil*

Tadalafil is a PDE5 inhibitor and is also the active pharmaceutical ingredient in Cialis®, which is marketed by Lilly for the treatment of erectile dysfunction. Patients with PAH have been shown to have reduced levels of the enzyme responsible for producing NO, a naturally occurring substance in the body

Table of Contents

that has the effect of relaxing pulmonary blood vessels, which is also a cause of erectile dysfunction. NO works to relax pulmonary blood vessels by increasing intracellular levels of an intermediary known as cGMP. An established therapeutic approach in the treatment of PAH is to use PDE5 inhibitors to increase levels of NO in patients to inhibit the degradation of cGMP.

Revatio is the only currently approved PDE5 inhibitor for the treatment of PAH, and is marketed by Pfizer. Sildenafil, the active ingredient in Revatio, is also the active ingredient in Viagra®, which is also marketed by Pfizer for erectile dysfunction. Revatio has a three times daily dosing regimen. We expect tadalafil to have a once daily dosing regimen.

The PHIRST Study, which was conducted by Lilly, was a Phase III 16-week, double-blind, placebo-controlled efficacy and safety study of once-daily tadalafil in PAH patients. 405 patients with idiopathic PAH or PAH associated with connective tissue disease, anorexigen use, HIV, atrial septal defect, or surgical repair of congenital left-to-right shunt were randomized to placebo or tadalafil (2.5, 10, 20 or 40 mg) orally once daily as monotherapy or as add on therapy to bosentan, the active ingredient in Tracleer. Demographics, clinical data, and health related quality of life (HRQoL) data were collected at baseline. Clinical and HRQoL data were again collected at weeks 4, 8, 12 and 16. Cardiopulmonary hemodynamics were conducted in a subset of patients (n=93).

The 40mg dose of tadalafil was shown to increase 6MWD compared to placebo ( $p < 0.001$  +41.1m versus +9.2m). Changes in WHO functional class and Borg dyspnea score did not differ significantly compared to placebo. The 40 mg dose also delayed the time to clinical worsening compared to placebo ( $p < 0.05$ , relative risk reduction 68% less than placebo). Compared with placebo, improvements were observed in patients treated with 40 mg tadalafil-treated patients in six out of the eight SF-36 domains ( $p < 0.001$ ), the EuroQol (EQ-5D) U.S. and U.K. index scores, and for the visual analog scale (VAS) (all  $p < 0.05$ ). It was also shown to increase cardiac output (0.6 L/min) and reduced pulmonary artery pressures (-4.3mmHg) and pulmonary vascular resistance (-209dyn.s/cm<sup>5</sup>) compared to baseline ( $p < 0.05$ ). The most common treatment-related adverse event reported with tadalafil was headache (32% versus 15% with placebo). Discontinuation due to adverse events was low (tadalafil 11% versus placebo 16%). Of the 405 patients in the trial, 189 (47%) were not taking concomitant bosentan (the ERA marketed as Tracleer). In these patients, tadalafil 40mg dose increased 6MWD compared to placebo ( $p < 0.10$  +42.2m versus -2.9m).

Lilly submitted an NDA to the FDA based on these significant trial results with an expected action date of May 24, 2009.

On December 18, 2008, we completed the transactions contemplated by several agreements we entered into with Lilly and one of its subsidiaries on November 14, 2008, including a license agreement, a manufacturing and supply agreement and a stock purchase agreement. Pursuant to the license agreement, Lilly granted us an exclusive license for the right to develop, market, promote and commercialize tadalafil for the treatment of pulmonary hypertension in the United States and Puerto Rico. In connection with the license agreement, we also entered into a stock purchase agreement and a manufacturing and supply agreement. Pursuant to the manufacturing and supply agreement, Lilly agreed to manufacture tadalafil and distribute it via its wholesaler network, in the same manner that it distributes its own pharmaceutical products. In December 2008, upon closing, we made a one-time payment of \$125.0 million under the manufacturing and supply agreement and a one-time payment of \$25.0 million under the license agreement. Pursuant to the stock purchase agreement, we issued 3,150,837 shares of our common stock to Lilly from treasury for an aggregate purchase price of \$150.0 million. See the section entitled *Strategic Licenses and Relationships* below for more details on these agreements.

We intend to use our existing sales and marketing team to promote and sell tadalafil. We expect that the prescribers of tadalafil will include most of the same health care practitioners upon whom our sales force currently focuses on with respect to marketing our other PAH therapies.

Table of Contents

***Beraprost-MR***

In June 2000, we entered into an agreement with Toray Industries, Inc. (Toray) for the exclusive right to develop and market a sustained release formulation of beraprost (beraprost-SR), an oral prostacyclin, in the United States and Canada for the treatment of cardiovascular indications. Beraprost is a chemically stable, orally bioavailable prostacyclin analogue. 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 entered into an amended agreement with Toray to assume and amend the rights and obligations of our June 2000 agreement with Toray 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 treatment indication to include vascular disease (excluding renal disease), among other revisions. Although earlier clinical trials of an immediate release formulation of beraprost sodium did not provide conclusive evidence of efficacy, these trials did provide encouraging results suggesting that beraprost-MR could prove to be safe and effective for PAH. Since individual PAH patients may have varied responses to different molecules within the same general class, we believe that the development of multiple molecules within the same family is a good strategy to treat PAH. In addition, we are in the early stages of exploring the use of beraprost-MR for the treatment of other cardiovascular and cardiopulmonary indications.

In October 2007, Toray announced that beraprost-MR received regulatory approval in Japan for use in the treatment of PAH. In July 2008, beraprost-MR was granted Orphan Medicinal Product Designation by the EMEA.

***Products to Treat Cancer***

***3F8 and 8H9 Antibodies***

In December 2007, we entered into two agreements with Memorial Sloan-Kettering Cancer Center (MSKCC) to license certain exclusive 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. We expect to begin a patient trial in the second quarter of 2009 using the 3F8 antibody in patients with neuroblastoma.

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 that 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.

***OvaRex***

In April 2002, we entered into a license agreement with AltaRex Corp. which later became AltaRex Medical Corp., a wholly-owned subsidiary of ViRexx Medical Corp. (AltaRex). The license agreement with AltaRex provided us with certain exclusive rights to a platform of five investigational immunotherapeutic monoclonal antibodies: OvaRex, Brevax, OncoRex, ProstaRex and GivaRex.



Table of Contents

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 when we entered into the license agreement.

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**arian **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.

Based on the results of the IMPACT I and II trials, we decided to terminate our license agreement with AltaRex and cease further development of the entire platform of antibodies licensed thereunder. We have incurred approximately \$2.0 million in total closeout costs for this program and do not anticipate significant additional future costs related to this program.

***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 antiviral compounds, such as miglustat. We have the exclusive right to commercialize miglustat for certain infectious diseases and viruses. In 2003, by mutual consent, we terminated our license agreement with Synergy. We are now working directly with Oxford University on the development of new antiviral compounds. These glycobiology antiviral agents are small molecules that 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.

In January 2009, we entered into a license agreement with MIGENIX, Inc. (MIGENIX), a Canadian company, to obtain the exclusive worldwide rights to develop and commercialize celgosivir for hepatitis C and other viral diseases. Celgosivir is a novel antiviral agent that appears to be a potent inhibitor of alpha-glucosidase I, a host enzyme that is critical to the folding of viral proteins. Inhibition of alpha-glucosidase I leads to improper viral folding, which, in turn, prevents viral replication. This effect has many potential therapeutic applications. The rights to develop and commercialize celgosivir are contingent upon our acceptance of further preclinical studies to be performed by MIGENIX to assess celgosivir's utility in combating the hepatitis C virus. If the results of the studies are acceptable to us, MIGENIX will be entitled to milestone payments based upon the achievement of certain clinical and regulatory events and royalties based on net sales of celgosivir, if commercialized.

Table of Contents

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

***CardioPAL SAVI 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 p-wave analysis in addition 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. We recognized revenues of approximately \$9.5 million, \$7.7 million and \$6.6 million from the sales of telemedicine products and services in 2008, 2007 and 2006, 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 was then operated as Unither Pharma, Inc., our wholly-owned subsidiary. Arginine is required by the body to produce NO. Unither Pharma Inc. 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 remaining 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 United States Supreme Court decision concerning the enforceability of patents. This decision had no effect on the terms of our settlement agreements with companies selling arginine products.

Approximately \$41,000, \$123,000 and \$100,000 of revenues were earned from the sales and royalties of arginine-related products in 2008, 2007 and 2006, respectively.

Table of Contents

***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 gene therapy (gene transfer using materials derived from a patient's own body instead of foreign materials such as viruses) 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. Under this license, we are required to make incremental milestone payments to Northern depending on patient enrollment. If the planned 18 patient Phase I trial is successfully enrolled, such payments will total \$1.5 million. We did not incur any expenses associated with this agreement during 2008. For the twelve months ended December 31, 2007, we incurred approximately \$150,000 of expenses related 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. Our Canadian wholly-owned subsidiary, Unither Biotech Inc., contracts with a specialty distributor to distribute Remodulin in Canada. See the section entitled *Sales and Marketing* above for more information on our distribution arrangements in Canada.

Due to our \$5.0 million investment, we currently own approximately 68% of Northern, but only 49% of the voting rights of its common stock. Because 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*, we are precluded from controlling Northern and thus do not consolidate Northern'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 nebulizers and related supplies for use in our TRIUMPH-1 clinical trial of inhaled treprostinil and for commercial use following regulatory approval. These non-exclusive agreements require NEBU-TEC to sell us Optineb devices and supplies for clinical and commercial use at specified prices and payment terms. These agreements also specify each party's obligations with respect to regulatory approvals. In February and April 2008, we entered into amendments to the September 2006 Clinical and Commercial Supply Agreement under which the term of the agreement was extended to the earlier of the first anniversary of the date of regulatory approval of inhaled treprostinil in the United States or EU. 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 amendments 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.

Table of Contents

***NEBU-TEC Agreement of Sale and Transfer***

In December 2008, we entered into an Agreement of Sale and Transfer with NEBU-TEC, under which NEBU-TEC agreed to sell us its Optineb line of business and all its related assets and rights. Upon signing the agreement, we paid NEBU-TEC €2.5 million. Closing and transfer of the related assets and rights is expected to occur within 30 days of receiving FDA approval for our inhaled treprostinil therapy and its use with the Optineb nebulizer. In the interim period prior to the closing of the Agreement of Sale and Transfer, both NEBU-TEC and we remain subject to an existing Clinical and Commercial Supply Agreement, as amended, pursuant to which NEBU-TEC is required to maintain all aspects of the FDA's current good manufacturing practices. At closing, we will pay NEBU-TEC an additional €2.5 million. In addition, we agreed to pay future consideration of up to €10.0 million depending on the occurrence of specific events and the attainment of a certain number of patients administering inhaled treprostinil using the Optineb or NEBU-TEC's next generation inhalation device currently under development. Furthermore, if we do not receive FDA approval for inhaled treprostinil under certain circumstances, we may cancel the Agreement of Sale and Transfer in which event NEBU-TEC will be required to refund the €2.5 million paid at signing.

***Aradigm License Agreement***

In August 2007, Lung Rx entered into an exclusive license, development and commercialization agreement with Aradigm for the rights to manufacture, develop and commercialize its AERx Essence 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, Aradigm conducted and funded laboratory tests and a proof-of-concept clinical trial comparing the inhalation delivery of treprostinil using the AERx Essence technology to delivery using the Optineb nebulizer used in the TRIUMPH-1 trial.

The bridging clinical trial was completed in November 2008, and failed to prove that the drug dispersed with the AERx Essence was bioequivalent to that dispersed by the Optineb nebulizer. However, the clinical trial results revealed that the AERx Essence device delivered inhaled treprostinil with deeper lung penetration than the Optineb nebulizer. We believe that these results merit further clinical studies. Therefore, we agreed to pay the first milestone payment of \$2.0 million required under the terms of our agreement with Aradigm in the fourth quarter of 2008.

Our agreement with Aradigm specifies that second and third milestone payments are due no later than the second and third anniversaries of the effective date of the agreement, such payments increasing incrementally by \$1.0 million each year. The agreement allows for the extension of 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 once it is approved.

***Toray Amended License Agreement***

In June 2000, we licensed from Toray the exclusive right to develop and market beraprost-SR, a chemically stable oral prostacyclin analogue, in a sustained release formulation 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 our June 2000 agreement with Toray concerning the commercialization of 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

Table of Contents

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 the effective date of the amended agreement (March 16, 2007), 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 provisions of SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, EITF 00-19 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 EU 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 commenced 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 EU 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.

***Lilly Agreements Related to Tadalafil***

On December 18, 2008, we completed the transactions contemplated by several agreements we entered into on November 14, 2008 with Lilly, including a license agreement, a manufacturing and supply agreement, and a stock purchase agreement.

*License Agreement.* Under the terms of the license agreement, Lilly granted us an exclusive license for the right to develop, market, promote and commercialize tadalafil for the treatment of pulmonary hypertension in the United States and Puerto Rico. Tadalafil is also the active pharmaceutical ingredient in Cialis, which is developed and marketed by Lilly for the treatment of erectile dysfunction.

In exchange for the license, we agreed to pay Lilly a one-time fee of \$25.0 million, which was expensed upon the effective date of the agreement, December 18, 2008, since tadalafil has not yet received regulatory approval for commercial sales. We also agreed to pay Lilly royalties equal to 5% of our net sales of tadalafil in the United States and Puerto Rico, as a pass through of Lilly's third-party royalty obligations, for so long as Lilly is required to make such payments.

Table of Contents

Lilly retained the exclusive rights to develop, manufacture and commercialize pharmaceutical products containing tadalafil for the treatment of pulmonary hypertension outside of the United States and Puerto Rico and for the treatment of other diseases worldwide. Lilly will retain authority for all regulatory activities with respect to tadalafil, including retail pricing, which is expected to be at price parity with Cialis.

Early in the third quarter of 2008, Lilly filed an NDA with the FDA for tadalafil for the treatment of PAH. Pursuant to our license agreement, we may conduct additional trials for tadalafil related to the treatment of pulmonary hypertension with Lilly's prior consent. Upon approval of tadalafil by the FDA, Lilly will be responsible for manufacturing tadalafil, pursuant to a separate manufacturing and supply agreement with us, which is discussed below.

If in the future Lilly seeks to grant rights to a third party to develop or commercialize tadalafil for the treatment of pulmonary hypertension in any other country (excluding Japan), the license agreement provides that we will have a right of first negotiation to acquire those rights.

The license agreement will continue in effect until the later of: (i) expiration, lapse, cancellation, abandonment or invalidation of the last to expire claim within a Lilly patent covering the commercialization of tadalafil for the treatment of pulmonary hypertension in the United States and Puerto Rico; or (ii) expiration of any government-conferred exclusivity rights to use tadalafil for the treatment of pulmonary hypertension in the United States and Puerto Rico.

We have the right to terminate the license agreement upon six months written notice to Lilly. Lilly has the right to terminate the license agreement if a separate brand name for tadalafil is not approved by the FDA for the treatment of PAH (in which event Lilly will refund the \$25.0 million license fee), or if we experience a change of control. Either party may terminate the license agreement upon a material breach by the other party of it or the manufacturing and supply agreement, described below.

*Manufacturing and Supply Agreement.* Under the terms of the manufacturing and supply agreement, Lilly has agreed to manufacture tadalafil and distribute it via its wholesaler network, in the same manner that it distributes its own pharmaceutical products. Under the terms of this agreement, we will take title to tadalafil upon its manufacture by Lilly. Tadalafil will be shipped to customers, generally pharmaceutical wholesalers, in accordance with customers' purchase orders received by Lilly. Upon receipt of tadalafil by the wholesaler, Lilly will invoice and collect the invoice amount due from the customer subject to customary discounts and rebates, if any. Although Lilly is providing these services on our behalf, we maintain the risk of loss as it pertains to inventory and nonpayment of sales invoices. The manufacturing and supply agreement will continue in effect until expiration or termination of the license agreement.

As consideration for Lilly's agreement to manufacture and supply tadalafil, we agreed to make a one-time payment to Lilly of \$125.0 million, which was expensed upon the effective date of the manufacturing and supply agreement. Lilly will refund this payment in the event that the FDA does not approve a separate brand name for tadalafil for the treatment of PAH. We also agreed to purchase tadalafil at a fixed cost, which may be adjusted by Lilly.

*Stock Purchase Agreement.* Under the terms of the stock purchase agreement, on December 18, 2008, we issued 3,150,837 shares of our common stock to Lilly from treasury for an aggregate purchase price of \$150.0 million, representing approximately 13.6% of the then-current outstanding shares of our common stock. The shares were issued at a price of \$47.61 per share, representing 90% of the average closing price of our common stock for the five trading days commencing on and including November 17, 2008. The weighted average acquisition price of the treasury stock issued was \$52.12 per share. The excess of the acquisition cost of the treasury stock above the price paid by Lilly for the shares was approximately \$14.2 million and has been included in our accumulated deficit.

Table of Contents

**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.

***Glaxo Assignment***

In January 1997, Glaxo assigned to us all rights to the use of the stable prostacyclin analogue now known as Remodulin. The patent covering the use of Remodulin for PAH expires in the United States in October 2014 (as extended *see Patent Term Extensions* below) and on various dates from September 2009 to August 2013 in nine other countries.

***Pfizer License***

In December 1996, Pharmacia & Upjohn Company (now Pfizer) exclusively licensed to us certain patents, a patent application and know-how for the composition and production of the stable prostacyclin analogue 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.

***Lilly***

In November 2008, we entered into a license agreement with Lilly pursuant to which Lilly granted us an exclusive right to develop, market, promote and commercialize tadalafil for the treatment of pulmonary hypertension in the United States and Puerto Rico. In connection with these license rights, we made a one-time, upfront payment to Lilly of \$25.0 million. Additionally, we agreed to pay Lilly royalties of 5% of our net sales of tadalafil as a pass through of Lilly's third-party royalty obligations for as long as Lilly is required to make such royalty payments. The term of the license agreement will continue generally until the later of: (1) the expiration or lapse of the last to expire claim within a Lilly patent covering commercialization of tadalafil, or (2) expiration of any government conferred exclusivity rights to tadalafil. In addition, the license agreement may be terminated in the event that a separate brand name for tadalafil is not approved by the FDA, in which case Lilly will refund our \$25.0 million payment.

***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 NO 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 patents.

***Supernus Pharmaceutical License***

In June 2006, we entered into an exclusive license agreement with Supernus to use certain of its technologies 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

Table of Contents

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 under this license.

***Aradigm Corporation***

In August 2007, we entered into an exclusive license, development and commercialization agreement with Aradigm for the rights to manufacture, develop and commercialize the AERx Essence pulmonary drug delivery system, for use as a next-generation metered-dose inhaler with our investigational inhaled treprostinil product for patients with PAH and other conditions. The terms of the agreement include various payments to be made to Aradigm including those related to the completion of certain milestones and license fees over the course of the development period. In addition, we will fund the costs to develop, commercialize and manufacture inhaled treprostinil for use with AERx Essence.

***TransMIT License***

In March 2007, TransMIT Gesellschaft fur Technologietransfer GmbH (TransMIT), an affiliate of the University of Giessen in Germany, assigned to Lung Rx its entire interest in the German 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 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 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.



Table of Contents

**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 new product development. Research and development expenses during 2008, 2007 and 2006 totaled approximately \$239.2 million, \$83.4 million and \$57.6 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 trestonil sodium, the active ingredient for Remodulin and inhaled trestonil, and trestonil diethanolamine, the active ingredient for oral trestonil, at our manufacturing facility in Chicago, Illinois, until March 2007 at which time we transitioned these activities to our new laboratory facility in Silver Spring, Maryland. In July 2008, we submitted an application to the FDA for approval of the new facility for commercial manufacturing, and we expect to receive approval in the first half of 2009. Until we receive FDA approval, we cannot use or sell commercially any products manufactured in our 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 our Silver Spring facility, we have also changed our internal manufacturing process. When we began, we produced trestonil sodium starting with basic chemicals and completed the full manufacturing process. Over the last several years, we have been modifying the manufacturing process to begin with advanced intermediate compounds made by outside vendors. We anticipate that, upon commercialization of oral trestonil, the need for trestonil diethanolamine will be greater than the need for trestonil sodium. By beginning the manufacturing process with the advanced intermediate compound, we are able to make trestonil diethanolamine and then convert that compound to trestonil sodium as needed. We believe this process will give us the most flexibility and efficiency in meeting future demands for both forms of trestonil. We have approved three vendors to supply the advanced intermediate compounds in order to reduce the risk of supply shortages.

Baxter Healthcare Corporation (Baxter) formulates the active ingredient we manufacture into Remodulin for us. The term of our initial agreement with Baxter ended in October 2004. The agreement is renewable for successive eighteen-month terms and has been continuously renewed since October 2004. In late 2008, Baxter gave us verbal notice that it does not intend to renew our agreement upon the expiration of its current term in late October 2010. We eventually intend to formulate Remodulin ourselves in the combination office and laboratory facility that we are currently constructing adjacent to our Silver Spring laboratory facility. In the meantime, we intend to engage another third party to formulate Remodulin prior to the termination of our agreement with Baxter to serve as a secondary manufacturer. Also, although we maintain a two-year inventory of Remodulin, we believe that engaging a third-party formulator will mitigate the risk that we might not be able to formulate sufficient quantities of Remodulin to meet patient demand. In addition, we expect to increase contingent inventory levels of formulated Remodulin from an approximate two-year supply to a three-year supply based on projected demand.

We rely on Catalent Pharma Solutions, Inc. (formerly Cardinal Health, Inc.) (Catalent) to conduct stability studies on Remodulin, formulate inhaled trestonil, formulate oral trestonil for clinical trials and to analyze other products we develop. We expect to begin manufacturing oral trestonil in our new manufacturing facility in Research Triangle Park, North Carolina, during the second half of 2009.

Table of Contents

In 2009, we anticipate commencing commercial development of the 3F8 and 8H9 antibodies licensed from MSKCC at our Silver Spring, Maryland, facility. We expect that we will be able to utilize much of the equipment that we obtained for the OvaRex manufacturing process for 3F8 and 8H9 antibody development.

Our telemedicine products are currently manufactured by Winland Electronics, Inc. Prior to 2008, our telemedicine products were made by MSI of Florida, Inc.

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. See also *Item 1A Risk Factors* included elsewhere in this Annual Report on Form 10-K.

**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 the rest of the world, including the following:

Flolan. The first product approved by the FDA for treating PAH, Flolan is a prostacyclin analogue that is delivered by intravenous infusion. Glaxo began marketing Flolan in the United States in 1996. In 2006, Myogen, Inc. (Myogen) acquired the marketing rights from Glaxo for Flolan in the United States. In November 2006, Myogen was acquired by Gilead Sciences, Inc. (Gilead). The generic exclusivity period for Flolan expired in April 2007;

Generic epoprostenol. In April 2008, Teva Pharmaceuticals Industries Ltd. (Teva) announced that the FDA approved its version of generic epoprostenol for the treatment of PAH. This is the first approved generic version of Flolan. In June 2008, GeneraMedix Inc. (GeneraMedix) received FDA approval for its version of generic epoprostenol, which is stable at room temperature. In February 2009, Actelion announced that it had entered into an agreement with GeneraMedix to acquire its generic epoprostenol product;

Ventavis. Approved in December 2004 in the United States and in September 2003 in Europe, Ventavis is the only prostacyclin analogue that has been approved for inhalation. Ventavis was initially marketed by CoTherix, Inc. (CoTherix) in the United States and is marketed by Schering AG in Europe as Iloprost. In January 2007, CoTherix was acquired by Actelion, 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 ERAs. Tracleer was approved in December 2001 in the United States and in May 2002 in Europe. Tracleer is marketed worldwide by Actelion;

Revatio. Approved in June 2005 in the United States, Revatio is also an oral therapy and is marketed by Pfizer Inc. Revatio contains sildenafil, the same active ingredient as Viagra, and is the first PDE5 inhibitor, to be approved for PAH;

Letairis . Approved in June 2007 in the United States, Letairis is an oral therapy marketed by Gilead for the treatment of PAH. Like Tracleer, Letairis is an ERA. In April 2008, Glaxo received marketing authorization from the EMEA for Letairis in Europe where it is known as Volibris®; and

Table of Contents

Theelin®. Approved in August 2006 in the EU, Theelin is an oral therapy, which was developed and initially marketed in Europe by Encysive Pharmaceuticals Inc. (Encysive), for the treatment of PAH. Like Tracleer and Letairis, Theelin is an ERA. In June 2008, Pfizer completed its acquisition of Encysive. Pfizer has stated that it plans to conduct a pivotal Phase III clinical trial to support registration of Theelin in the United States and eventually seek FDA approval.

Due to their ease of use, oral therapies, such as Tracleer and Revatio, are generally considered front-line therapies for newly diagnosed PAH 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 include front line and mid-range treatment options. Furthermore, the commercialization of generic forms of other approved PAH therapies may exert downward pressure on the pricing of our products. For further discussion on this risk, see *Item 1A Risk Factors We may not successfully compete with established drugs, products 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, the EMEA in the EU and similar regulatory authorities 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 (IND) 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 an NDA to the FDA; and

FDA review and approval of the NDA 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 IND. A 30-day waiting period after the filing of each IND 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 IND 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.

Table of Contents

Clinical trials in support of an NDA 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, an NDA or a Biologics License Application is typically submitted to the FDA in the United States, and an MAA is typically submitted to the EMEA in the EU. The regulatory authorities may request additional information before accepting an application, in which case the application must be resubmitted with the additional information. Once the application has been accepted, the regulatory authority reviews the application and responds to the applicant. The review process is often significantly extended by requests from regulatory authorities for additional information or clarification. In the United States, 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 regulatory authorities may also inspect the manufacturing facility before approving an application.

In the United States, if FDA evaluations of the application and the manufacturing facilities are favorable, the FDA may issue either an approval letter or a complete response letter. A complete response 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.

At the request of an applicant, the FDA may designate a product as an "orphan drug" in the United States 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 tadalafil for the treatment of PAH without regard to drug product formulation. We believe that the orphan designation of tadalafil includes all types of PAH, regardless of etiology. However, such designation does not preclude us from seeking orphan drug designation for other formulations of tadalafil 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 tadalafil 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

Table of Contents

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 IND and the submission date of an NDA, plus all of the time between the submission date of an NDA and its approval, 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. The application was approved in February 2005, and the patent for Remodulin is currently set to expire 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 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 countries. 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 countries, 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 EU member countries for which recognition is sought. Within 90 days of receiving the application and assessment report, each EU member country 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 an EU member country, the applicant is then required to engage in pricing discussions and negotiations with a separate prescription pricing authority in that country. Commercial sales are only able to commence in a country once pricing approval has been received.

To secure European regulatory approvals for subcutaneous Remodulin for PAH, we used the mutual recognition process. 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 MAA in France in February 2001. Review of our application was completed in 2005. As a result, Remodulin was approved in 23 member 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 had to file for approval for intravenous Remodulin using the mutual recognition process since intravenous use of Remodulin is considered a variation to the original license. We filed our application with our reference member state, France, which has notified us that it is not satisfied with our filing. We are working to address France's concerns and believe that we will eventually receive commercial approval for

Table of Contents

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 are using 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 submitted our application for European approval of inhaled treprostinil in December 2008.

To secure approval of the Optineb nebulizer 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 NEBU-TEC and we meet all requirements during inspections.

To continue marketing our products after approval, applicable regulations require us to maintain a positive risk-benefit 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.

Our 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, many independent third-party payers, as well as the Medicare and Medicaid programs, reimburse Remodulin. Medicare is the federal program that provides health care benefits to senior citizens and certain disabled and chronically ill persons. 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 also 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 2009. 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 drugs at discounted prices) at prices that are significantly below the price we charge to our specialty pharmaceutical distributors. These programs and contracts are highly regulated and impose 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.

Table of Contents

**Employees**

We had approximately 360 employees as of January 29, 2009. We also maintain active independent contractor relationships with various individuals, most of whom have month-to-month or annual consulting agreements. 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 throughout the rest of the world. The information required by Item 101(b) and 101(d) of Regulation S-K relating to financial information about industry segments and geographical areas, respectively, is contained in Note 19 of the consolidated financial statements 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, Form 8-K and any and all 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 at <http://www.sec.gov/edgar/searchedgar/companysearch.html>.

Table of Contents**EXECUTIVE OFFICERS OF THE REGISTRANT**

The following is a list, as of February 21, 2009, 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.

<b>Name</b>	<b>Age</b>	<b>Position</b>
Martine A. Rothblatt, Ph.D., J.D., M.B.A.	54	Chairman, Chief Executive Officer and Director
Roger Jeffs, Ph.D.	47	President, Chief Operating Officer and Director
John M. Ferrari	54	Chief Financial Officer and Treasurer
Paul A. Mahon, J.D.	45	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 launched several satellite communications companies. 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. She is a co-inventor on three of our patents pertaining to treprostinil.

*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 beginning his accounting career in 1984.

*Paul A. Mahon, J.D.*, has served as General Counsel and 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, beginning with its formation in 1996, in his capacity as principal and managing partner of a law firm specializing in technology and media law.



Table of Contents

**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, profitability, and cash flows;

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 impact of generic products on Remodulin sales;

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

The adequacy of our intellectual property protections and expiration dates on our patents;

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 sufficiency of current and future working capital;

The expectation that our Convertible Senior Notes will be held to maturity;

The ability to obtain financing or raise cash in the future;

## Edgar Filing: UNITED THERAPEUTICS CORP - Form 10-K

The value of our common stock;

The expectation of future repurchases of those shares of our common stock subject to repurchase from Toray Industries, Inc.;

The timing and expectations of the completion and costs of our building projects;

The expected impacts of new accounting standards including FSP APB 14-1;

The expectation of liquidating our investment holdings without significant losses and expectations with respect to future credit market conditions;

The potential effects of an auction-rate securities settlement offer and our expectations of not exercising our right to borrow under the settlement offer;

The results of our clinical trials;

The pace and timing of enrollment of our clinical trials;

The expectation and timing of regulatory approvals for and the commencement of earning revenues from sales of inhaled treprostinil, oral tadalafil and oral treprostinil;

The expectation and timing of regulatory approval for our manufacturing and laboratory facility in Silver Spring, Maryland (Phase I Laboratory);

Table of Contents

- The expectation, outcome and timing of marketing approvals in European Union countries for intravenous Remodulin;
- The expectation, outcome and timing of marketing approvals in European Union countries for inhaled treprostinil;
- The timing, resubmission, completion and outcome of applications for marketing authorization of subcutaneous Remodulin in Ireland, Spain and the United Kingdom;
- The expected timing of commencing commercial activities in Japan with Mochida Pharmaceutical Co., Inc.;
- The expected timing of payments to third parties under license agreements;
- The outcome of any litigation in which we are or become involved;
- Our expectation that we will find and obtain regulatory approval of a formulator for Remodulin to replace Baxter;
- Any statements preceded by, followed by or that include any form of the words "believe," "expect," "predict," "anticipate," "forecast," "project," "intend," "estimate," "should," "could," "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 7 Management's Discussion and Analysis of Financial Condition and Results of Operations* or elsewhere in this Annual Report on Form 10-K. These statements are subject to risks and uncertainties and our actual results may differ materially from anticipated results. Factors that may cause such differences include, but are not limited to, those discussed below. We undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise.

### **Risks Related to Our Business**

#### **We have a history of losses and may not maintain profitability.**

Although we have maintained annual profitability from 2004 to 2007, we have experienced periods in which we recognized net losses. For the year ended December 31, 2008, we recognized a net loss primarily as a result of expensing one-time fees of \$150.0 million related to our license agreement and manufacturing and supply agreement with Lilly for tadalafil. In addition, we have previously incurred quarterly net losses. While we believe we formulate our annual operating budgets with reasonable assumptions and targets, certain non-cash charges and other factors that may be beyond our control could affect our profitability and cause uneven quarterly and annual operating results.

#### **We rely heavily on sales of Remodulin to produce revenues.**

During the year ended December 31, 2008, Remodulin sales accounted for approximately 96% 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 were withdrawn, we would be unable to sell our product and our revenues would suffer. In the event that Glaxo terminates its assignment agreement or Pfizer terminates its license agreement, we would have no further rights to utilize the assigned patents or trade secrets to develop and commercialize Remodulin. Any substantial change in the dosing pattern of patients using Remodulin, due to combination therapy, side effects, death or any other reason, could decrease related revenues. In addition, we rely on third parties to produce, market, distribute and sell Remodulin. The inability of one of these third parties to perform these functions, or the failure of any of these parties to perform



Table of Contents

successfully, could cause our revenues to suffer. Because we are very dependent on sales of Remodulin, any reduction in Remodulin sales 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 for subcutaneous and intravenous administration. Most of our pharmaceutical products are in various stages of clinical development; therefore, many of these products may not become 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 or may not be able to sustain any profitability we achieve.

**We may not successfully compete with established and newly-developed drugs, products and the companies that develop and market them.**

We compete with established drug companies during product development for, among other things, funding, licenses, expertise, personnel, clinical trial patients, and third-party collaborators. We also compete with these companies following the approval of our products. Most of these competitors have substantially greater financial, marketing, sales, distribution and technical resources than we do. These competitors also possess more experience in research and development, clinical trials, sales and marketing 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 as safer, more effective, more convenient and/or less expensive than Remodulin. Accordingly, sales of Remodulin may not increase, or may decrease if doctors prescribe less Remodulin than they prescribe presently.

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 the treatment of PAH, Flolan is a prostacyclin analogue that is delivered by intravenous infusion. Glaxo began marketing Flolan in the United States in 1996. In 2006, Myogen acquired the marketing rights for Flolan in the United States. In November 2006, Myogen was acquired by Gilead. The generic exclusivity period for Flolan expired in April 2007;

Generic epoprostenol. In April 2008, Teva announced that the FDA approved its version of generic epoprostenol for treatment of PAH. This is the first approved generic version of Flolan. In June 2008, GeneraMedix Inc. (GeneraMedix) received FDA approval for its version of generic epoprostenol. In February 2009, Actelion announced that it had entered into an agreement with GeneraMedix to acquire its generic epoprostenol product;

Ventavis. Approved in December 2004 in the United States and in September 2003 in Europe, Ventavis is the only prostacyclin analogue that has been approved for inhalation. Ventavis was initially marketed by CoTherix, in the United States and is marketed by Schering AG in Europe as Iloprost. In January 2007, CoTherix was acquired by Actelion, 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 of ERAs. Tracleer was approved in December 2001 in the United States and in May 2002 in Europe. Tracleer is marketed worldwide by Actelion;

Table of Contents

Revatio. Approved in June 2005 in the United States, Revatio is an oral therapy and is marketed by Pfizer. Revatio contains sildenafil, the same active ingredient as Viagra, and is the first PDE5 inhibitor to be approved for PAH;

Letairis. Approved in June 2007 in the United States, Letairis is an oral therapy marketed by Gilead in the United States for the treatment of PAH. Like Tracleer, Letairis is an ERA. In April 2008, Glaxo received marketing authorization from the EMEA for Letairis in Europe where it is known as Volibris; and

Thelin. Approved in August 2006 in the EU, Thelin is an oral therapy, and was developed and initially marketed by Encysive, for the treatment of PAH. Like Tracleer and Letairis, Thelin is an ERA. In June 2008, Pfizer completed its acquisition of Encysive. Pfizer has stated that it plans to conduct a pivotal Phase III clinical trial to support registration of Thelin in the United States and eventually receive FDA approval.

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. Lastly, as a result of merger activity, Actelion, Gilead and Pfizer presently control six of the seven non-generic approved therapies for PAH in the United States (the seventh being Remodulin). Actelion, through its acquisition of the commercial rights to GeneraMedix's generic epoprostenol, now controls one of the two approved formulations of generic epoprostenol. In addition to reducing competition through acquisition, each of these companies exerts considerable influence over prescribers through the sales and marketing of their respective therapies and through market dominance in this therapeutic area. Furthermore, the commercialization of generic forms of other approved PAH therapies may exert downward pressure on the pricing of our products.

A number of drug companies are pursuing treatments for the hepatitis C virus and various forms of 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 discover or introduce new products that render all or some of our technologies and products obsolete or noncompetitive. 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 treat 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 decrease demand for Remodulin and reduce related sales.

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

Cialis®. An approved oral treatment for erectile dysfunction, Cialis is currently marketed by Lilly. Prior to January 2007, when ICOS Corporation was acquired by Lilly, Cialis was jointly marketed by ICOS Corporation and Lilly. Cialis is in the same class of drugs as Revatio, PDE5 inhibitors. Tadalafil is the active ingredient in Cialis. The PHIRST-I trial of tadalafil for the treatment of PAH was successful. Although we have entered into a license agreement whereby Lilly has granted us the exclusive right to commercialize tadalafil for the treatment of pulmonary hypertension in

## Edgar Filing: UNITED THERAPEUTICS CORP - Form 10-K

### Table of Contents

the United States and Puerto Rico, Lilly will retain the rights to commercialize tadalafil for the treatment of pulmonary hypertension outside the United States and Puerto Rico;

Terguride. In May 2008, Ergonex Pharma announced that the FDA granted orphan drug status to Terguride for the treatment of PAH. Terguride is a serotonin receptor 5-HT<sub>2B</sub> and 5-HT<sub>2A</sub> antagonist. Terguride is currently being evaluated for the treatment of PAH in a pivotal Phase II clinical study in Europe;

Actelion-1. Actelion-1 is a tissue-targeting ERA being developed by Actelion. Actelion is conducting a Phase III study of Actelion-1 to evaluate its safety and efficacy in delaying disease progression and mortality in patients with PAH;

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. A Phase II study presented at the European Respiratory Society showed promising results for Gleevec in the treatment of PAH. Other research is ongoing;

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 Holding SA announced that it had outlicensed Aviptadil for the treatment of PAH to Biogen Idec Inc. A small study of Aviptadil showed that it tended to improve oxygenation in patients with PAH. Further studies are ongoing;

PRX-08066. A serotonin receptor 5-HT<sub>2B</sub> antagonist, PRX-08066 is being developed by Epix Pharmaceuticals, Inc. as an oral tablet for the treatment of PAH. In August 2008, Epix Pharmaceuticals, Inc. announced the initiation of a right-heart catheter study of PRX-08066 in patients with PAH from chronic obstructive pulmonary disease and moderate-to-severe pulmonary hypertension;

PulmoLAR . Currently in development by PR Pharmaceuticals, Inc., PulmoLAR is a once-a-month injectible therapy that 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 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 HealthCare AG (Bayer) as Nexavar® for advanced renal cell cancer, Sorafenib is a small molecule that inhibits Raf kinase and may interfere with the thickening of blood vessel walls associated with PAH. On May 20, 2008, the results of a University of Chicago study were released demonstrating that PAH patients taking Nexavar showed improvement in their ability to exercise;

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 March 2007, Elafin was granted orphan drug status in the EU for the treatment of PAH and chronic thromboembolic pulmonary hypertension;

NS-304. A novel orally available prostaglandin I<sub>2</sub> receptor agonist, NS-304 is being developed by Nippon Shinyaku and Actelion pursuant to an April 2008 license agreement. Under the terms of the agreement, Actelion will take over a Phase IIa clinical study of NS-304 for PAH being conducted by Nippon Shinyaku in Europe and will be responsible for global development and commercialization of NS-304 outside Japan;

Cicletanine. Marketed by Navitas Pharma for hypertension in Europe, Cicletanine is an eNOS coupler that works to increase the flexibility of blood vessel linings. In May 2008, Gilead and



Table of Contents

Navitas Assets, LLC announced that they entered into an agreement whereby Gilead acquired all of Navitas Pharma's assets related to its Cicletanine business. In December 2008, Gilead began a Phase II clinical trial to assess the efficacy, safety, and tolerability of cicletanine in PAH patients;

6R-BH4. A naturally occurring enzyme cofactor that is required for numerous biochemical and physiologic processes, including the synthesis of NO, 6R-BH4 is being developed by BioMarin Pharmaceutical Inc. for the treatment of various cardiovascular indications and phenylketonuria. Currently, several Phase II clinical trials of 6R-BH4 for cardiovascular disease are underway. A Phase II trial of 6R-BH4 for PAD failed to meet its primary endpoint;

ONO-1301. ONO-1301 is a novel, long-acting prostacyclin agonist with thromboxane synthase inhibitory activity being developed by scientists at the National Cardiovascular Center Research Institute in Osaka, Japan. Current published reports have indicated that the compound has shown promising results;

Riociguat (BAY 63-2521). Riociguat is an oral soluble guanylate cyclase stimulator that activates the major cellular receptor for NO and mediates a wide range of physiological effects through elevation of intracellular cGMP levels leading to pulmonary vasodilation and increased transpulmonary cGMP release. Riociguat is being developed by Bayer for the treatment of chronic thromboembolic pulmonary hypertension and PAH. A Phase II clinical trial of Riociguat was successfully completed and two Phase III trials are currently underway;

Aironite . Currently being developed by Aires Pharmaceuticals, Inc. under a license agreement with the National Institutes of Health. Aironite is a novel inhaled nitrite therapy that has been shown in preclinical models to prevent the progression of pulmonary hypertension. Aironite has been granted orphan drug status by the FDA. A Phase I study of Aironite for PAH has been completed; and

Generic Iloprost. The orphan drug exclusivity on Iloprost will expire in 2011. We believe that multiple manufacturers are working on a generic formulation that will result in future sales upon expiration of the patent term.

There may be other drugs in development for PAH in addition to those listed above. Furthermore, there may be currently approved drugs that prove effective in treating PAH. If any of these drugs are marketed for the treatment of PAH, sales of Remodulin could decrease.

**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, which agree 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 third-party 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. The Medicare Modernization Act requires that we negotiate a new price for Remodulin with the Centers for Medicare and Medicaid Services (CMS). As a result of the staggered implementation of this Act, Remodulin has not yet been subject to the pricing provisions. To the extent that private insurers or managed care programs follow any reduced Medicaid and Medicare coverage and payment developments, the negative impact on our business would be compounded. Additionally, some states have enacted health care reform legislation. Further federal and state developments are possible and such potential legislative activity could adversely impact our business.

Table of Contents

Third-party payers may not approve our new products for reimbursement or may not continue to approve Remodulin for reimbursement. Furthermore, third-party payers may reduce the amount of reimbursement for Remodulin based on changes in pricing of other therapies for PAH, including generic formulations of other approved therapies, such as Flolan. If third-party payers do not approve a product of ours for reimbursement or limit the amount of reimbursement, sales will decline, 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 for 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 accordance with government regulations affecting such relationships. If we are unable to maintain such relationships and create new relationships, the number of patients using our cardiac monitoring services will decline. This could adversely affect our cardiac monitoring revenues.

If we are unable to educate physicians regarding the benefits of our CardioPAL® SAVI and Decipher Holter monitor systems and fail to achieve sufficient levels of utilization, revenues from our cardiac monitoring services may not grow and could decrease.

**Reimbursement for cardiac monitoring services by Medicare is highly regulated and subject to change. The operation of our cardiac monitoring facility is subject to rules and regulations governing Independent Diagnostic Testing Facilities (IDTFs). 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 percent of our cardiac monitoring service revenues from Medicare reimbursements. Reimbursement from Medicare for cardiac monitoring services is subject to statutory and regulatory changes, rate adjustments and administrative rulings. All of these factors 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 instituted a change in the method for calculating reimbursement under the Physician Fee Schedule that will be implemented over a four-year period. Consequently, CMS has reduced reimbursement for our cardiac monitoring services each year since 2007. Similar reductions are expected through 2010. We cannot predict whether future modifications to Medicare's reimbursement policies could reduce the amounts we receive from Medicare for the services we provide. Additionally, 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. CMS imposes extensive and detailed requirements on medical service providers. These requirements include, but are 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 the discontinuance of our reimbursements, the return of funds paid to us, civil monetary penalties, criminal penalties and/or exclusion from the Medicare program.

Additionally, in order for us to receive reimbursement for cardiac monitoring services from Medicare and some commercial payers, we must maintain a call center certified as an IDTF. Certification as an IDTF requires that we follow strict regulations governing how the center operates, such as requirements regarding certifications of the technicians who review data transmitted from our cardiac monitors. If regulations change, we may have to alter operating procedures at our monitoring facilities, which could increase our costs significantly. If we fail to obtain and maintain IDTF

Table of Contents

certification, our services may no longer be reimbursed by Medicare and some commercial payers, which could negatively affect our telemedicine business.

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

We are currently marketing three products in our cardiovascular therapeutic platform: Remodulin in our prostacyclin analogue platform and CardioPAL SAVI cardiac event monitors and Decipher Holter monitors in our telemedicine platform. We also have several products across all of our therapeutic platforms in the clinical trial stage. We do not have the ability to independently conduct clinical studies, obtain regulatory approvals, market, distribute and sell all of our products. Therefore, we rely on experienced third parties to perform some of these 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 market, distribute and sell our products and future revenues could suffer.

We rely on Accredo, CuraScript and Caremark 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 distributors do not achieve acceptable profit margins, they may not continue to sell our products. Furthermore, if our distributors in the United States and abroad are unsuccessful in their efforts, our revenues will suffer.

Since the commercial launch of Remodulin, all of our distributors in the United States have merged with larger companies. When these distributors were smaller and independently managed, the Remodulin franchise commanded a more prominent share of their business. As divisions or subsidiaries of much larger organizations, these distributors may place less emphasis on selling Remodulin. There can be no assurance that the mergers experienced by each of our distributors will not adversely affect Remodulin distribution. In addition, since January 2007, Accredo became the exclusive distributor in the United States for Flolan. If our distributors devote fewer resources to sell Remodulin, our sales could be negatively affected.

**Interruptions or delays in telecommunications systems or in network or related services could impair the delivery of our services and harm our telemedicine business.**

The success of our telemedicine services and devices is dependent upon our ability to store, retrieve, process and manage data. Furthermore, we must be able to maintain and upgrade our data processing and communication capabilities. As we expand our commercial activities with respect to our cardiac monitoring business, an increased burden will be placed upon our telecommunications and data processing systems and the equipment upon which they rely. Telecommunication disruptions for any extended length of time, or other systems-related problems could have an adverse effect on our telemedicine business.

**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 we develop must be approved for marketing and sale by regulatory agencies and, once approved, are subject to extensive regulation by the FDA and comparable regulatory agencies outside the United States. 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 also 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. If granted, product approvals can be

Table of Contents

withdrawn for failure to comply with regulatory requirements. Product approvals can also be withdrawn upon the occurrence of adverse events following commercial introduction. In addition, our marketed products and how we manufacture and sell these products are subject to extensive continued regulation and review.

Although we have never experienced product specification failures with respect to Remodulin vials, discovery of previously unknown problems with our marketed products or problems with our manufacturing, regulatory, promotional or commercialization activities could 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 that may consist of fines, suspensions of regulatory approvals, product recalls, seizure of products and criminal prosecution.

**Reports of side effects, such as sepsis, associated with intravenous Remodulin could cause physicians and patients to avoid or discontinue use of 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 a large vein in the patient's chest. 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.

In 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 reminded physicians 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. In February 2008, the FDA approved a revised Remodulin package insert that more fully described the known infection risk and appropriate techniques to be practiced when preparing and administering Remodulin intravenously. In May 2008, the SLC issued a statement that it had created catheter maintenance guidelines for intravenous prostacyclin administration to minimize the risks of developing bloodstream infections.

Although a discussion of the risk of sepsis is currently included in the Remodulin label, and the occurrence of sepsis is familiar to physicians who prescribe intravenously administered therapies, concerns about bloodstream infections may adversely affect a physician's prescribing practice of Remodulin. If that occurs, sales of Remodulin and our profitability could suffer.

**We have transitioned our manufacturing operations to a new location and if the FDA and other international agencies do not approve our new location for commercial use, our ability to produce treprostinil sodium, the active ingredient in Remodulin, could suffer.**

In July 2008, we submitted a supplement to the Remodulin NDA for approval of our Phase I Laboratory. We plan to manufacture treprostinil in our Phase I Laboratory on a larger scale than we did in our facility in Chicago, Illinois, which we closed in May 2007. Until we receive FDA and international approvals of our Phase I Laboratory, we cannot sell products containing compounds manufactured there. We have maintained two years of formulated Remodulin based on anticipated demand. If we experience unexpected delays for approval of our Phase I Laboratory of more than two years, we may encounter a shortage of treprostinil and this could reduce the availability of our commercial products. Consequently, both our commercial sales and our ability to conduct clinical trials would suffer.

Table of Contents

**We depend on third parties to formulate and manufacture our products and related devices. Our ability to generate commercial sales or conduct clinical trials could suffer if our third-party vendors fail to perform.**

We manufacture tadalafil with raw materials and advanced intermediate compounds supplied by vendors. The inability of our vendors to supply these raw materials and advanced intermediate compounds in the quantities we require could delay the manufacture of tadalafil for commercial use and for use in clinical trials.

We also rely on third parties to formulate our tadalafil-based products. Baxter formulates Remodulin from the tadalafil sodium we supply. Recently, Baxter verbally informed us that it intends to discontinue the formulation of Remodulin by the end of our contractual renewal term in October 2010 due to the retirement of the formulation line that is used to produce Remodulin. We are in the process of evaluating alternative supply arrangements, including formulating Remodulin in the combination office and laboratory facility that we are currently constructing adjacent to our Phase I Laboratory. We expect to have completed construction of this facility by the end of 2009. We are also pursuing other third-party formulation arrangements. We plan on increasing our supply of formulated Remodulin to three years during 2009 and maintaining this supply level thereafter to ensure we have enough to meet expected patient demand. However, if we experience significant delays in receiving FDA approval for an alternative supply arrangement or for our Phase I Laboratory, we may not have sufficient Remodulin in stock to meet commercial demand and our revenues will suffer.

Catalent conducts stability studies on Remodulin for us, formulates tadalafil in both inhaled and oral forms for our clinical trials and analyzes other products that we are developing. Beginning in 2009, we are planning to formulate oral tadalafil at our new manufacturing facility in Research Triangle Park, North Carolina. This will be our first attempt at formulating oral tadalafil without the use of a third party. Additionally, we rely on third parties to manufacture all of our products other than tadalafil.

Winland Electronics, Inc. manufactures our telemedicine devices, and other manufacturers produce our investigational drugs and devices for use in clinical trials.

We engage NEBU-TEC to manufacture the Optineb nebulizer used with inhaled tadalafil. NEBU-TEC is responsible for managing the manufacturing process of the Optineb nebulizer in accordance with all applicable regulatory requirements. Because regulatory approval of inhaled tadalafil will be linked to regulatory approval of the Optineb nebulizer, any regulatory compliance problems encountered by NEBU-TEC relative to the manufacture of this device could delay or adversely affect regulatory approvals of inhaled tadalafil. Consequently, this could impede our growth and our revenues could suffer. In addition, following regulatory approval of inhaled tadalafil, any inability to manufacture nebulizers in sufficient quantities to meet patient demand could have an adverse effect on our revenue growth.

Pursuant to a license agreement, effective December 18, 2008, Lilly has agreed to grant us the exclusive right to commercialize tadalafil, the active ingredient in Cialis, for the treatment of pulmonary hypertension in the United States and Puerto Rico. Upon FDA approval, Lilly will manufacture tadalafil for us and we will use their wholesaler network to distribute the drug pursuant to our manufacturing and supply agreement with them. We have agreed to purchase tadalafil from Lilly at a fixed cost, which may be adjusted by Lilly from time to time. The Cialis patent expires in late 2017. As a result, there is a limited time period before generic tadalafil will be available. Any delays in FDA approval would further shorten the time period during which we are able to market tadalafil before a generic competitor becomes available and our revenues could suffer.

Although there are a few companies that could replace our current suppliers, we believe other suppliers could provide similar services and materials. A change in suppliers, could cause a delay in the

Table of Contents

distribution of Remodulin and our other products and services, and impede the progress of our clinical trials and commercial launch plans. This would adversely affect our research and development and future sales efforts.

Our manufacturing strategy presents the following risks:

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

We are planning to produce all forms of treprostinil ourselves and have never done so previously;

Delays in scale-up to commercial quantities and process validation could delay clinical studies, regulatory submissions and commercialization of our investigational products;

A long lead time is needed to manufacture treprostinil and Remodulin, and the manufacturing process is complex;

Both we and the manufacturers and formulators of our products are subject to the FDA's Current Good Manufacturing Practices in the United States and similar or more stringent regulatory standards internationally. Although we can control compliance issues with respect to our internal synthesis and manufacturing processes, we do not have control over regulatory compliance by our third-party manufacturers;

Even if we and the manufacturers and formulators of our products were to comply with domestic and international drug manufacturing regulations, the sterility and quality of the products being manufactured and formulated could be deficient. If this were to occur, such products would not be available for sale or use;

If we have to replace a 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. Furthermore, a new manufacturer or formulator, including any replacement for Baxter (who intends to discontinue formulating Remodulin in October 2010), would have to be educated in the processes necessary to manufacture and commercially validate our product;

We may be unable to manufacture or formulate products internally other than Remodulin as planned, or at all;

We may be unable to obtain manufacturers and formulators for those products that we do not plan to manufacture or formulate internally;

We may be unable to obtain manufacturers and formulators to serve as additional sources for products that we manufacture or formulate internally;

The supply of materials and components necessary to manufacture and package Remodulin and our other products may become scarce or interrupted. Disruptions to the supply of these materials could delay the manufacture and subsequent sale of such products. Any products manufactured with substituted materials or components would be subject to approvals from the FDA and international regulatory agencies before they could be sold. The timing of such FDA and international regulatory approval is difficult to predict and may be delayed;

## Edgar Filing: UNITED THERAPEUTICS CORP - Form 10-K

We may not have sufficient intellectual property rights, or we may have to share intellectual property rights to many of the improvements in the manufacturing processes or to new manufacturing processes for our products; and

Suppliers may increase the prices at which they are willing to sell materials, components or finished products, and we may be unable to adjust our prices accordingly.

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.

Table of Contents

**If our products fail in clinical studies, we will be unable to obtain or maintain FDA and international approvals and will be unable 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 our drug products, including their delivery mechanisms, are safe and effective. The FDA and international regulatory agencies may require us to perform additional clinical studies beyond those for which we have planned. If we cannot obtain approval from the FDA and international regulatory agencies for a product, that product cannot be sold and our future revenue growth may decline.

In the past, several of our product candidates have failed or been discontinued at various stages in the product development process. Some of these products include: 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.

In November 2008, we reported that our FREEDOM-C trial of oral treprostinil did not meet statistical significance for its primary endpoint. As a result, we are in the process of redesigning our current FREEDOM-M trial and planning for a new FREEDOM-C<sup>2</sup> trial and thus expect delays in completing our clinical trials for oral treprostinil. Currently, we do not anticipate filing an NDA for oral treprostinil before 2012.

The length of time that it takes for us to complete clinical trials and obtain regulatory approval for product marketing varies by product and by product use. Furthermore, we cannot predict with certainty the length of time it will take to complete necessary clinical trials or obtain regulatory approval of our future products.

Our ongoing and planned clinical studies might be delayed or halted for various reasons. These reasons include:

The drug is ineffective, or physicians believe that the drug is ineffective;

Patients do not enroll in our 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;

Our clinical study sites do not adhere to the study protocol;

Our studies do not comply with applicable regulations or guidelines;

Patients die during the study because their disease is too advanced or because they experience medical problems unrelated to the drug being studied;

Other ongoing or new clinical trials conducted by other drug companies or ourselves may reduce the number of patients available for our studies;

Drug supplies are unavailable or unsuitable for use in our studies; and

The results of preclinical testing cause delays in our studies.

In addition, the FDA and international regulatory authorities have substantial discretion over the approval process for pharmaceutical products. The FDA and international regulatory authorities may not agree that we have demonstrated the requisite level of product safety and



efficacy.

Table of Contents

**Our corporate compliance program cannot guarantee that we comply 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 regulations. While we have developed and instituted corporate compliance programs, we cannot ensure that our employees or we are or will always be in compliance with these regulations. If we fail to comply with any of these regulations, we could be subject to a range of penalties including but not limited to: the termination of clinical trials, the failure to approve a product candidate, restrictions on our products or manufacturing processes, withdrawal of our products from the market, significant fines, exclusion from government healthcare programs, and 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 such agreements.**

Our business depends upon the acquisition, assignment and license of drugs and other products that have been discovered and initially developed by others. Related drugs and other products include Remodulin, tadalafil and all other products in our prostacyclin, glycobiology antiviral agents, and monoclonal antibodies platforms. Under our product license agreements, we receive certain rights to existing intellectual property owned by third parties subject to the terms of each license agreement. Our assignment agreements transfer all right, title and interest in and to the intellectual property to us, subject to the terms of each agreement. We also obtain licenses to other third-party technologies to conduct our business. In addition, we may be required to obtain licenses to other third party technologies to commercialize our early-stage products. This dependence contains the following risks:

We may be unable to obtain future licenses or assignment agreements at a reasonable cost or at all;

If any of our licenses or assignment agreements are terminated, we will lose our rights to develop and market the products covered by such licenses or assignment agreements;

Our licenses and assignment agreements generally provide the licensor or assignor the right to terminate in the event we breach such agreements--e.g., we fail to timely pay royalties and other fees;

If a licensor or assignor fails to maintain the intellectual property licensed or assigned to us as required by most of our licenses and assignment agreements, we may lose our rights to develop and market some or all of our products. In addition, we may be forced to incur substantial costs to maintain the intellectual property ourselves or force the licensor or assignor to do so; and,

If Lilly is unable to obtain or maintain FDA approval for tadalafil, we will be unable to develop and commercialize tadalafil for the treatment of pulmonary hypertension.

**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 may 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, our rights may be limited. For instance, our rights to market tadalafil are limited to the United States and Puerto Rico, unless Lilly decides not to market the drug in another country, at which time we would have the opportunity to negotiate for rights to market the drug in that country.

Provisions in our license and assignment agreements may impose other restrictions that affect the development and marketing of our products. For example, in assigning Remodulin to us, Glaxo retained

Table of Contents

an exclusive option and right of first refusal to negotiate a license agreement with us if we decide to license any aspect of the commercialization of Remodulin anywhere in the world. Similarly, our amended license agreement with Toray to develop and market beraprost-MR includes a conditional non-compete clause benefiting Toray in that it grants Toray the right to be our exclusive provider of beraprost-MR drug substance. We must also meet certain minimum annual sales to maintain our exclusive rights to beraprost-MR. In addition, Lilly has retained authority over all regulatory activities with respect to tadalafil, and will have the right to determine the retail price for tadalafil (which will be at price parity with Cialis) and the price at which we purchase tadalafil from Lilly. Lilly also has the right to approve any additional investigatory work we do with tadalafil in other indications of pulmonary hypertension. These restrictions could affect our freedom to develop and market our products in the future.

**If our or our suppliers' patents or other intellectual property protections are inadequate, our sales and profits could suffer or our competitors could force our products out of the market.**

Our U.S. patent for the method of treating PAH with Remodulin will expire in October 2014. The patents for inhaled treprostinil will expire in 2018, and Lilly's patents for tadalafil will expire in 2017. We believe that certain patents to which we have rights may be eligible for extensions of up to five years pursuant to patent term restoration procedures in Europe and 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 and market those products after our patents expire, or design around or seek to invalidate our existing patents before they expire. If this happens, our sales would suffer and our profits could decline significantly. 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 may not be sufficient to protect our technology. Furthermore, the laws of international jurisdictions where 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 technological advances. We enter into confidentiality agreements with our employees and others, but these agreements may be ineffective in protecting our proprietary information. Others may independently develop substantially equivalent proprietary information or obtain access to our know-how.

Litigation, which can be costly, may be necessary to enforce or defend our patents or proprietary rights and may not conclude in our favor. While we have settled previous litigation to enforce our arginine patents, we may initiate future litigation against other parties we 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 related intangible assets which could significantly reduce our earnings. Any licensed rights, patents or other intellectual property we possess may be challenged, invalidated, canceled, infringed or circumvented and therefore, may not provide any competitive advantage to us.

In July 2005, Vanderbilt University filed a lawsuit in the United States District Court for the District of Delaware against ICOS Corporation (ICOS) seeking to add three of its scientists as co-inventors on the tadalafil compound and method-of-use-patents. Lilly has since acquired ICOS. The patents that are the subject of this lawsuit are the same patents licensed to us by Lilly under our December 2008 license agreement. In January 2009, the district court judge ruled in favor of ICOS/Lilly, declining to add any of these scientists as an inventor on either patent. The plaintiff may appeal this ruling. Lilly believes these claims are without legal merit and expects to prevail in any

Table of Contents

appeal of this litigation; however, it is not possible to determine the outcome. An unfavorable final outcome could have a material adverse impact on our license for tadalafil for pulmonary hypertension.

Patents may be issued to others and this could impede the manufacture or sale of our products. We may have to license those patents and pay significant fees or royalties to the owners of those patents in order to keep marketing our products. These added fees could reduce our profits.

To the extent valid third-party patents 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 the sale of related products and services. We may be unable 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 avoid infringing a third-party patent, we may be unable to market some of our products and services, which would limit our sales and future growth.

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 awarded in cases of patent infringement. Because we rely on patents to protect our products, proposed patent reform could negatively impact our business.

Pursuant to our agreements with certain business partners, any new inventions or intellectual properties arising from our activities will be jointly owned 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 developments or inventions, which may mean a loss of future profits or cost savings.

**Our success depends in large part on our ability to operate without infringing third-party patents or other proprietary rights.**

If we infringe third-party patents, we may be prevented from commercializing products or may be required to obtain licenses from those third parties. We may be unable 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.**

Our success is highly dependent on key members of our management team, including: 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 Chief Manufacturing Officer and Executive Vice President for Pharmaceutical Development, David Zaccardelli, Pharm.D.; and our Executive Vice President for Regulatory Affairs and Compliance, Dean Bunce. While these individuals are employed by us pursuant to multi-year employment agreements, such agreements do not ensure their continued retention. We do not maintain key person life insurance on these officers. However, we do incentivize our key personnel to remain employed by us until at least age 60 through our Supplemental Executive Retirement Plan. The success of our business will depend in part on retaining the services of our existing key management personnel and attracting and retaining new highly qualified personnel. Few individuals possess expertise in the field of cardiovascular medicine, infectious disease and oncology. As such, competition for qualified management and personnel is considerable.

Table of Contents

**We may not maintain adequate insurance and this could expose us to significant product liability claims.**

The testing, manufacturing, marketing, and sale of human drugs and diagnostics involve product liability risks. Although we currently are covered by product liability insurance for claims of up to \$35 million per occurrence and in the aggregate, we may not be able to maintain this insurance at an acceptable cost, if at all. In addition, our insurance coverage may not be adequate for all potential claims. If claims or losses significantly exceed our liability insurance coverage, we may be forced out of business.

**Our marketable investments maybe subject to loss.**

There has been significant deterioration and instability in the financial markets. Even though we believe we take a conservative approach to investing our funds, these periods of extraordinary disruption and readjustment in the financial markets expose us to investment risk, including the risk that the value and liquidity of our investments could deteriorate significantly and the issuers of the securities we hold could be subject to credit rating downgrades. This could result in future impairment charges with respect to our investment portfolio and our cash flows and operating results could be negatively affected.

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

We may need to spend more money than anticipated. Unplanned expenditures could be significant and may result from necessary modifications to product development plans or product offerings in response to difficulties encountered with clinical studies. We may also face unexpected costs in preparing products for commercial sales, or in maintaining sales of Remodulin. We may be unable to obtain additional funds on commercially reasonable terms or at all. If additional funds are unavailable, 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.

Settlement of our 0.50% Convertible Senior Notes due October 2011 (Convertible Senior Notes), will involve significant outlays of our cash. Specifically, the Convertible Senior Notes will require us to repay in cash, upon maturity or conversion, the \$250 million principal balance or the conversion price, whichever is less. Under the current market conditions, some of the holders of our Convertible Senior Notes may seek liquidity, which could cause them to convert their notes prior to the maturity date. If we do not have sufficient financial resources or are unable to obtain suitable financing to pay amounts due upon the maturity or conversion of the Convertible Senior Notes, we would be in default.

We adopted our Share Tracking Awards Plan (STAP) in June 2008. Awards granted under our STAP entitle participants to receive in cash an amount equal to the appreciation in our common stock, which is calculated as the positive difference between the closing price of our common stock on the date of grant and the date of exercise. Consequently, we may be required to make significant cash payments under our STAP. If we do not have sufficient funds to meet our obligations under our STAP, or are unable to secure alternative sources of financing on terms acceptable to us, we may lose key employees and could face litigation.

**Improper handling of hazardous materials used in our activities could expose us to significant liabilities.**

Our research and development and manufacturing activities involve the controlled use of chemical and hazardous substances. Furthermore, we are expanding these activities to new locations. Such activities subject us to numerous federal, state, and local environmental and safety laws and regulations. These laws and regulations govern the management, storage and disposal of hazardous materials. We

Table of Contents

may be required to incur significant costs in order to comply with current or future environmental laws and regulations. We may also be subject to substantial fines and penalties for failure to comply with these laws and regulations. While we believe we comply with laws and regulations governing these materials, the risk of accidental contamination or injury from these materials cannot be completely eliminated. Furthermore, once chemical and hazardous materials leave our site, we cannot control what our hazardous waste removal contractors choose to do with these materials. In the event of an accident, we could be liable for substantial civil damages or costs associated with the cleanup of the release of hazardous materials. Any related liability could exceed our resources and could have a materially adverse effect on our business, financial condition and results of operations.

**We may encounter substantial difficulties managing our growth.**

Several risks are inherent in our business development plans. 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 be insufficient to meet future demand for our products. Conversely, we may have excess capacity at these facilities if future demand falls short of our expectations. In addition, constructing our facilities is expensive, and our ability to recover our investment will depend on sales of the products manufactured at these facilities in sufficient volume to substantially increase our revenues.

If we experience sales growth, we may have difficulty managing inventory levels. Marketing new therapies is complicated, and gauging future demand is difficult and uncertain.

**We invest in auction-rate securities that are subject to market risk and the recent problems in the financial markets could adversely affect the value and liquidity of our investments in these securities.**

As of December 31, 2008, our non-current marketable securities included approximately \$36.8 million (par value) in auction-rate securities that are currently illiquid. In November 2008, we elected to participate in the court-ordered repurchase program by the investment firm from which we purchased our auction-rate securities. From the period beginning on June 30, 2010 and ending July 2, 2102, we can require the investment firm to repurchase any of our auction-rate securities at par value. Our ability to fully recover the carrying amount of these investments is limited in the near term and may never be fully recoverable if the investment firm fails to perform its obligations under the repurchase program or we cannot sell these securities ourselves under satisfactory terms.

**Our ability to recognize the full value of our business tax credits may be limited.**

As of December 31, 2008, we had approximately \$79.3 million of business tax credit carryforwards. These tax credit carryforwards expire on various dates through 2028. The Internal Revenue Service (IRS) has not yet audited or reviewed these business tax credits since we have not yet utilized them. We have conducted reviews of these business tax credits with the help of outside tax experts, including our independent auditors, Ernst & Young, LLP. Although we have recognized reserves for those business tax credits that we believe may be disallowed upon examination by the IRS, it is possible that the IRS may reduce our business tax credits further. Any reduction of business tax credits will increase our tax expense and shorten the time period before we are required to pay federal income taxes.

In addition, certain business tax credit carryforwards that were generated at various dates prior to December 2007 may be subject to limitations on their use pursuant to Internal Revenue Code Section 382 (Section 382) as a result of ownership changes as defined by Section 382. However, we do not expect that these business tax credits will expire unused. If we are deemed to undergo any further ownership changes in the future, then certain business tax credit carryforwards might be deferred or expire unused.

Table of Contents

Furthermore, our future operations might not generate sufficient profits to be offset by these business tax credit carryforwards. In such an event, all or a portion of our business tax credit carryforwards might expire unused.

**Risks Related to Our Common Stock**

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

The market prices for the 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:

		<b>High</b>	<b>Low</b>
January 1, 2006	December 31, 2006	\$ 71.33	\$47.96
January 1, 2007	December 31, 2007	\$ 108.62	\$47.87
January 1, 2008	December 31, 2008	\$ 115.98	\$49.01

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 results of our 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 critical 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;

future issuances of common stock by us or any other activity which could be viewed as being dilutive to our shareholders;

Edgar Filing: UNITED THERAPEUTICS CORP - Form 10-K

rumors among investors and/or analysts concerning our company, our products, or operations;

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

failure to obtain approval of NDAs, from the FDA and international regulatory agencies;

failure to successfully obtain approval for our new Phase I Laboratory from the FDA and international regulatory agencies;

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



Table of Contents

general market conditions.

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

Many independent securities analysts publish quarterly and annual projections of our revenues and profits. These projections are developed independently by the securities analysts based on their own analyses. Such estimates are inherently subject to uncertainty, particularly because we do not generally provide forward-looking guidance to the public. As a result, actual revenues and net income may differ from what was projected by securities analysts. Even small variations in reported revenues and profits compared to securities analysts' expectations can lead to significant changes in our stock price.

**Sales of shares of our common stock may depress our stock price.**

The price of our common stock could decline upon the occurrence of any of the following events: if we issue common stock to raise capital or to acquire a license or business; if our stockholders transfer ownership of our common stock, or sell substantial amounts in the public market; or, if investors become concerned that substantial sales may occur. All of our executive officers and some of our directors have announced their adoption of prearranged trading plans under Rule 10b5-1 of the Exchange Act. In accordance with these plans, our executive officers and directors periodically sell a specified number of shares of our common stock either owned by them or acquired through the exercise of stock options. However, our executive officers and directors may choose to sell additional shares outside of these trading plans and several have done so. A decrease in the price of our common stock could make it difficult for us to raise capital or fund acquisitions through the use of our stock.

The conversion of some or all of the Convertible Senior Notes when the price of our common stock reaches or exceeds \$105.67 per share would dilute the ownership interests of our existing stockholders. The Convertible Senior Notes are convertible initially into 3.3 million shares of our common stock. Any sales in the public market of our common stock issued upon such conversion could adversely affect the prevailing market price of our common stock. Furthermore, the existence of the Convertible Senior Notes may encourage short selling by market participants because the conversion of the Convertible Senior Notes could depress the price of our common stock.

To the extent outstanding options are exercised or additional shares of capital stock are issued, existing stockholder ownership may be further diluted.

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

The terms of the Convertible Senior Notes require us to purchase them for cash in the event of a fundamental change of ownership. A takeover of our company would trigger the requirement that we purchase the Convertible Senior Notes. This may delay or prevent a takeover of our company that would otherwise be beneficial to our stockholders.

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

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

a merger, tender offer or proxy contest;

the assumption of control by a holder of a large block of our securities; and

the replacement or removal of current management by our stockholders.

Table of Contents

For example, our certificate of incorporation divides our Board of Directors into three classes. Members of each class are elected for staggered three-year terms. This provision may make it more difficult for stockholders to change the majority of directors. It may also deter the accumulation of large blocks of our common stock by limiting the voting power of such blocks.

Non-compete and other restrictive covenants in most of our employment agreements will terminate upon a change in control that is not approved by our Board of Directors.

We enter into certain license agreements that generally prohibit our counterparties to these agreements or their affiliates from taking necessary steps to acquire or merge with us, either directly or indirectly throughout the term of these agreements, plus a specified period thereafter. We are also party to certain license agreements that restrict our ability to assign or transfer the rights licensed to us thereunder to third parties, including parties with whom we wish to merge, or those attempting to acquire us. These agreements often require that we obtain the prior consent of the counterparties to these agreements if we are contemplating a change in control. If our counterparties to these agreements withhold their prior consent, related agreements could be terminated and we would lose all rights thereunder. These restrictive change in control provisions could impede or prevent mergers that could benefit our stockholders.

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

Our directors and executive officers beneficially owned approximately 6% of our outstanding common stock as of December 31, 2008. Shares beneficially owned include stock options that could be exercised by those directors and executive officers within 60 days of December 31, 2008. Accordingly, these stockholders as a group may be able to influence the outcome of matters requiring stockholder approval, including the election of our directors. Such stockholder influence could delay or prevent a change in control that could benefit our stockholders.

**Because we do not intend to pay 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. As a result, the success of an investment in our common stock will depend entirely upon any future appreciation. There is no guarantee that our common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

**ITEM 2. PROPERTIES**

Maryland We own the office building that houses our corporate headquarters in Silver Spring, Maryland. We also own the four buildings and land adjacent to our corporate headquarters. We lease our Phase I Laboratory adjacent to our corporate headquarters, which is used for the synthesis of treprostiniil-based compounds and monoclonal antibodies. In late 2007 we began construction of a new combination office and laboratory, which will connect to our Phase I Laboratory in Silver Spring. Construction on this facility is expected to be completed in late 2009. We also lease space at a warehouse near Silver Spring to maintain some of our raw material inventory used in our Remodulin manufacturing and synthesis process.

Table of Contents

Florida We own our Remodulin Therapy Assistance office building in Satellite Beach, Florida. Lung Rx also occupies a portion of this building. Our subsidiaries, Lung Rx 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, and in February 2009, we completed a new 200,000 square foot manufacturing facility and office building, which is occupied by our clinical research and development and Remodulin commercialization staffs. The manufacturing facility will formulate oral treprostiniil.

Other locations In March 2007, we purchased land and a building adjacent to our leased legal and governmental affairs office in Washington, D.C., which houses our virology-related government contracting operations. Our subsidiary, Unither Neurosciences, Inc., leases office space in Burlington, Vermont. Our subsidiary, United Therapeutics Europe, Ltd., purchased land and a building near London, which will be the headquarters for this subsidiary. It also purchased a building in Oxford, which will serve as laboratory space for our glycobiology projects. In addition, United Therapeutics Europe, Ltd., and LungRx Limited lease 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.

Table of Contents**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:

	2008		2007	
	High	Low	High	Low
January 1 - March 31	\$ 103.15	\$ 74.80	\$ 59.13	\$ 47.87
April 1 - June 30	\$ 97.75	\$ 82.16	\$ 67.64	\$ 52.03
July 1 - September 30	\$ 115.98	\$ 99.37	\$ 70.04	\$ 63.96
October 1 - December 31	\$ 106.04	\$ 49.01	\$ 108.62	\$ 65.53

As of February 20, 2009, there were 43 holders of record of our common stock. We estimate that included within the holders of record are approximately 14,150 beneficial owners of our common stock. As of February 23, 2009, the closing price for our common stock was \$71.00 per share.

**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.

Table of Contents**ITEM 6. SELECTED FINANCIAL DATA**

The following selected consolidated financial data should be read in conjunction with our consolidated financial statements and the notes accompanying the consolidated financial statements 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.

	Year Ended December 31,				
	2008	2007	2006	2005	2004
<b>Consolidated Statements of Operations Data:</b>					
Revenues	\$281,497	\$210,943	\$159,632	\$115,915	\$73,590
Operating expenses:					
Research and development	239,181	83,352	57,570	36,052	30,713
Selling, general and administrative	94,306	99,027	56,052	24,655	21,418
Cost of sales	30,066	22,261	17,028	12,315	8,250
Total operating expenses	363,553	204,640	130,650	73,022	60,381
(Loss) income from operations	(82,056)	6,303	28,982	42,893	13,209
Other income (expense):					
Interest income	11,025	13,602	10,700	5,359	2,986
Interest expense	(16)	(2,175)	(482)	(29)	(4)
Equity loss in affiliate	(226)	(321)	(491)	(754)	(785)
Other, net	(1,025)	(826)	1,199	53	43
Total other income (expense), net	9,758	10,280	10,926	4,629	2,240
Net (loss) income before income tax	(72,298)	16,583	39,908	47,522	15,449
Income tax benefit	29,509	3,276	34,057	17,494	
Net (loss) income	\$ (42,789)	\$ 19,859	\$ 73,965	\$ 65,016	\$ 15,449
Net (loss) income per share:					
Basic(1)	\$ (1.87)	\$ 0.94	\$ 3.21	\$ 2.85	\$ 0.71
Diluted(1)	\$ (1.87)	\$ 0.88	\$ 3.06	\$ 2.58	\$ 0.66
Weighted average number of common shares outstanding:					
Basic	22,901	21,224	23,010	22,825	21,726
Diluted	22,901	22,451	24,138	25,206	23,351

	Year Ended December 31,				
	2008	2007	2006	2005	2004
<b>Consolidated Balance Sheet Data:</b>					
Cash, cash equivalents and marketable investments(2)	\$336,318	\$299,792	\$264,163	\$170,347	\$139,140
Total assets	871,319	587,018	478,550	291,413	207,158
Notes payable	249,978	250,000	250,000		
Accumulated deficit	(78,514)	(21,501)	(41,360)	(115,325)	(180,341)
Total stockholders' equity	507,699	295,790	204,606	275,102	191,636

(1)

Edgar Filing: UNITED THERAPEUTICS CORP - Form 10-K

See Note 11 to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K for the computation of basic and diluted net income per share.

(2)

Excludes restricted marketable investments and cash.

Table of Contents

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

The following discussion should be read in conjunction with our consolidated financial statements and related notes to the consolidated financial statements included in this Annual Report on Form 10-K. 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. These statements are based on our beliefs and expectations about future outcomes and are subject to risks and uncertainties that could cause actual results to differ materially from anticipated results. Factors that could cause or contribute to such differences include those described under the section entitled, *Item 1A Risk Factors Forward Looking Statements* appearing elsewhere in this Annual Report on Form 10-K and factors described in other cautionary statements, cautionary language and risk factors set forth in other documents filed with the SEC. We undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise.

**Overview**

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

Our key therapeutic platforms include:

Prostacyclin analogues: stable synthetic forms of prostacyclin, an important molecule produced by the body that has powerful effects on blood vessel health and function;

Phosphodiesterase 5 (PDE5) inhibitors: molecules that act to inhibit the degradation of cyclic guanosine monophosphate (cGMP) in cells. cGMP is activated by nitric oxide (NO), a naturally occurring substance in the body that signals the relaxation of vascular smooth muscle;

Monoclonal antibodies: antibodies that activate patients' immune systems to treat cancer; and

Glycobiology antiviral agents: a novel class of small, sugar-like molecules that have shown pre-clinical indications of efficacy against a broad range of viruses, such as hepatitis C.

We focus most of our resources on these key therapeutic platforms. In addition, we devote resources to the commercialization and development of telemedicine products and services, principally for the detection of cardiac arrhythmias (abnormal heart rhythms).

We began generating pharmaceutical revenues in 2002 upon receiving approval from the United States Food and Drug Administration (FDA) for our lead product, Remodulin® (treprostinil sodium) Injection (Remodulin) to be administered via subcutaneous (under the skin) infusion for the treatment of pulmonary arterial hypertension (PAH). Since 2002, the FDA has expanded its approval of Remodulin for intravenous (in the vein) use and for the treatment of patients who require transition from Flolan®. In addition to the United States, Remodulin is approved in many other countries worldwide, primarily for subcutaneous use. In June 2008, we filed a new drug application (NDA) with the FDA for our inhaled formulation of treprostinil. In December 2008, we filed a Marketing Authorization Application (MAA) for inhaled treprostinil with the European Medicines Agency (EMA) using the centralized filing process.

**Revenues**

We derive substantially all of our revenues from the sale of Remodulin.

Table of Contents

Our sales and marketing team included approximately 80 employees as of December 31, 2008, up from approximately 65 employees as of December 31, 2007. We anticipate continued growth in our sales force in the near-term as we continue to position our business for expansion. We divide our sales force into two teams. One sales team is primarily responsible for medical practice accounts that are historical Remodulin prescribers. The other sales team focuses on medical practices that have not historically prescribed Remodulin. In addition, our specialty pharmaceutical distributors supplement the efforts of our sales force. The market in which we operate is highly competitive. We face stiff competition from other companies that market and sell competing therapies, and we expect competition to increase in the future.

Our domestic distributors, Accredo Therapeutics, Inc. (Accredo), CuraScript, Inc. (CuraScript), and CVS Caremark Corporation (Caremark), sell Remodulin to patients in the United States. We also engage various international distributors to sell Remodulin abroad. Because discontinuation of Remodulin therapy can be life-threatening, we require that our distributors maintain minimum contingent inventory levels. Due to this requirement, sales of Remodulin to our distributors in any given quarter may not be entirely indicative of patient demand. Our distributors typically place one bulk order per month in the first half of the month. The size of bulk distributor orders is based on estimates of future demand and considerations of contractual minimum inventory requirements. As such, our sales of Remodulin are affected by the timing and magnitude of these bulk orders by our distributors.

Subsequent to receiving FDA approval of Remodulin in 2002, we have funded our operations mainly from sales of Remodulin in the United States and abroad. In addition to revenues derived from sales of Remodulin, we have generated revenues from telemedicine products and services sold in the United States. Our telemedicine products and services are designed to detect cardiac arrhythmias, and ischemic heart disease, a condition that causes poor blood flow to the heart.

**Expenses**

Since our inception, we have devoted substantial resources toward our research and development activities. Accordingly, we incur considerable costs relating to our clinical trials and research, conducted both internally and by third parties, on a variety of projects to develop pharmaceutical therapies. We also seek to acquire promising technologies and/or compounds from third parties to be incorporated in our developmental projects and products through licensing arrangements or acquisitions. Principal components of our operating expenses consist of research and development, selling, general and administrative, and cost of both product and service sales.

**Major Research and Development Projects**

Our major research and development projects focus on the use of treprostinil and tadalafil to treat cardiovascular diseases, monoclonal antibodies to treat a variety of cancers and glycobiology antiviral agents to treat infectious diseases.

*Cardiovascular Disease Projects*

*Inhaled treprostinil.* We are developing 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 Tracleer®, an oral endothelin receptor antagonist (ERA), or Revatio®, a PDE5 inhibitor. This trial, TRIUMPH-1 (**T**Reprostinil **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 November 2007, we announced the completion of our TRIUMPH-1 trial. Analysis of the TRIUMPH-1 results demonstrated a highly statistically significant improvement in median six-minute walk distance (6MWD) of



Table of Contents

approximately 20 meters in patients receiving inhaled treprostinil compared to patients receiving placebo.

Consequently, we submitted an NDA on June 27, 2008, to obtain FDA approval to market inhaled treprostinil in the United States. The Optineb® nebulizer (the ultra-sonic nebulizer that was used exclusively for administration of inhaled treprostinil in the TRIUMPH-1 trial) was submitted for approval as part of this filing. Optineb is manufactured exclusively by NEBU-TEC International Med Products Eike Kern GmbH (NEBU-TEC). The Optineb is CE-marked in Europe, which means that NEBU-TEC has asserted that the device conforms to European Union health and safety requirements. On December 15, 2008, we executed an Agreement of Sale and Transfer and related agreements (Agreement) with NEBU-TEC to acquire the Optineb business and all of the assets, properties and rights used in the Optineb business (Acquired Assets). We entered into the Agreement to reduce the risks associated with our dependency on NEBU-TEC and to obtain control over the production of the Optineb nebulizer. Pursuant to the Agreement, the aggregate purchase price consists of €5.0 million, and up to €10.0 million in contingent consideration (see Note 18 to the consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K). The Acquired Assets under the Agreement will not transfer to us until the closing, which is to occur following the FDA's approval of our NDA for inhaled treprostinil. Standard FDA review of an NDA generally takes 10 to 12 months from the date of submission. The Optineb nebulizer was also included as part of our December 2008 MAA submission.

We were recently notified that the FDA Office of Safety and Epidemiology has preliminarily approved the tradename Tyvaso for our inhaled treprostinil therapy. The FDA Division of Cardioresenal Drug Products will conduct the final review and approval of the tradename, which usually occurs simultaneously with NDA approval.

We are conducting a Phase IV open-label study in the United States to investigate what occurs when patients on Ventavis®, the only currently approved inhaled prostacyclin, are switched to inhaled treprostinil. Enrollment for this study is expected to range from 300 to 400 patients. We commenced enrollment for this study in December 2008.

*Oral treprostinil.* We are developing an oral formulation of treprostinil (treprostinil diethanolamine). In October 2006 we initiated two multi-national, placebo-controlled clinical trials of oral treprostinil in patients with PAH at approximately 60 centers to study both dosing and efficacy. The FREEDOM-C trial was a 16-week study of patients currently on approved background therapy using a PDE5 inhibitor, such as Revatio® or an ERA, such as Tracleer®, or a combination of both. We completed enrollment for the FREEDOM-C trial at 354 patients in May 2008 and subsequently announced the results of the FREEDOM-C trial in November 2008. Analysis of the results demonstrated that the trial did not achieve statistical significance for its primary endpoint (the change in 6MWD at week 16 compared to baseline). Initial investigation of the results suggested that the inability to dose titrate (increase the dose to tolerability) oral treprostinil above what appeared to be suboptimal dosing levels in this study was a limiting factor that suppressed the overall treatment effect. We believe that the results of the FREEDOM-C trial, particularly as they relate to treatment effect and dosing achieved, warrant the continued development of oral treprostinil. We are planning a second FREEDOM-C trial, FREEDOM-C<sup>2</sup>, to continue studying dosage and efficacy of oral treprostinil in PAH patients on approved background therapy. We estimate enrolling 300 patients in the FREEDOM-C<sup>2</sup> clinical trial beginning in late 2009.

The FREEDOM-M trial is a 12-week study of newly diagnosed patients not currently on any background therapy. Enrollment in FREEDOM-M was closed on October 31, 2008 with 171 patients enrolled in the trial. Based on what we learned from the FREEDOM-C trial relating to patient tolerability of our three different tablet strengths of oral treprostinil, we submitted a protocol amendment to the FDA on February 20, 2009 seeking to increase the number of patients enrolled in

Table of Contents

FREEDOM-M by approximately 140. These new patients will start the study on the 0.25 mg tablet, which we learned from the FREEDOM-C trial is the best-tolerated tablet strength. In addition, our amendment to the FREEDOM-M protocol seeks to limit the primary statistical analysis of the trial to those patients who started the trial using the 0.25 mg tablet.

We believe that this protocol amendment will allow us to more accurately assess the effectiveness of oral treprostinil. We hope that by starting the additional patients on the 0.25 mg tablets and titrating the doses, patients will be able to reach an effective maintenance dose with the lower dosage tablet. The study should have a reduced rate of premature discontinuation due to adverse events. If we are successful in enrolling patients for this extended portion of the study, we will then be able to statistically power our analysis using a reduced effect size (from a 50 to 45 meter change in 6MWD), a change in the study's statistical significance (from 0.05 to 0.01) and a change the 6MWD study endpoint to include only patients who had access to the 0.25 mg tablets at randomization (when study drug is first administered at the beginning of the trial). If these amendments to the study are successful, we believe that the results will reflect the expected dosing regimen for oral treprostinil. Due to the time required to receive FDA consent for the protocol amendment and to package and ship new clinical trial supplies to study sites, we expect to begin enrolling additional patients in the second quarter of 2009.

*Tadalafil.* In November 2008, we entered into the following agreements with Eli Lilly and Company and one of its subsidiaries (collectively, Lilly): a license agreement, a manufacturing and supply agreement and a stock purchase agreement. We completed the initial transactions contemplated by these agreements in December 2008. Pursuant to the license agreement, we paid an upfront fee to Lilly of \$25.0 million for the exclusive right to develop, market, promote and commercialize the orally administered tadalafil for the treatment of pulmonary hypertension in the United States and Puerto Rico. Tadalafil is the active ingredient in Cialis®, also developed and marketed by Lilly for the treatment of erectile dysfunction. Additionally, we agreed to pay Lilly royalties equal to 5% of net sales of tadalafil for pulmonary hypertension as a pass through of Lilly's third-party royalty obligations. We will purchase tadalafil from Lilly pursuant to the manufacturing and supply agreement. The terms of the manufacturing and supply agreement provide that Lilly will manufacture and distribute tadalafil through its wholesaler network as Lilly would for its other pharmaceutical products and included an upfront fee of \$125.0 million. The total upfront fees paid to Lilly in December 2008 of \$150.0 million under the license and manufacturing and supply agreements were charged to research and development expenses during the quarter ended December 31, 2008, because tadalafil had not yet received marketing approval from the FDA and therefore, commercial feasibility had not yet been established. Pursuant to the stock purchase agreement, we issued 3,150,837 shares of our common stock from treasury to Lilly in exchange for \$150.0 million. See Note 15 to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

*Beraprost-MR.* We are developing a modified release formulation of beraprost (beraprost-MR) for PAH. Beraprost-MR is an oral prostacyclin analogue. In March 2007, our subsidiary Lung Rx., Inc. (Lung Rx) entered into an amended version of the June 2000 license agreement between Toray Industries, Inc. (Toray) and us to expand our rights related to the commercialization of beraprost-MR. We are currently enrolling a Phase II clinical study of beraprost-MR to explore multiple-dose tolerability in patients with PAH and planning a Phase III clinical trial to evaluate the efficacy of beraprost-MR for the treatment of PAH. In October 2007, Toray announced that beraprost-MR received regulatory approval in Japan for the treatment of PAH. In July 2008, beraprost-MR was granted Orphan Medicinal Product Designation by the EMEA.

We incurred expenses of approximately \$210.5 million, \$49.4 million and \$33.0 million for the years ended December 31, 2008, 2007 and 2006, respectively, on our cardiovascular programs. We have spent approximately \$453.9 million from inception to December 31, 2008, on our cardiovascular programs.

Table of Contents

***Cancer Disease Projects***

In December 2007, we announced the completion of our IMPACT I and II pivotal trials of OvaRex® MAb (OvaRex), which we had exclusively licensed from AltaRex Medical Corp. (AltaRex). Results of the trials failed to reach statistical significance. Based on the results of these trials, we terminated our license agreement with AltaRex and discontinued further development of our ovarian cancer program of monoclonal antibodies. We do not expect to incur additional significant costs related to this program.

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. Neuroblastoma is a rare cancer of the sympathetic nervous system mainly affecting children. The FDA granted orphan drug status to 3F8 on October 16, 2008. 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 are currently working on clinical development plans for both antibodies and expect to begin clinical development of the 3F8 antibody in 2009.

We incurred expenses of approximately \$2.8 million, \$13.9 million and \$10.5 million for the years ended December 31, 2008, 2007, and 2006, respectively, on our cancer programs. We have spent approximately \$59.6 million from inception to December 31, 2008, on our cancer programs.

***Infectious Disease Projects***

Pursuant to our research agreement with Oxford University, we have the exclusive right to commercialize miglustat as an anti-viral agent for the treatment of all sugar-coated viruses, including hepatitis C. Our infectious disease program also includes glycobiology antiviral drug candidates in various preclinical and clinical stages of testing for the treatment of a wide variety of viruses. Through our agreement with Oxford University, we are also supporting research into new glycobiology antiviral drug candidates and technologies.

In January 2009, we entered into a license agreement with MIGENIX, Inc. (MIGENIX), a Canadian company, to obtain the exclusive worldwide rights to develop and commercialize celgosivir. Celgosivir is a novel antiviral agent that appears to be a potent inhibitor of alpha-glucosidase I, a host enzyme critical to the folding of the viral proteins. Inhibition of alpha-glucosidase I leads to improper viral folding, which, in turn, prevents viral replication. This effect has many applications. The rights to develop and commercialize celgosivir are contingent upon our acceptance of further preclinical studies to be performed by MIGENIX to assess celgosivir's ability in combating the hepatitis C virus. We incurred expenses of approximately \$1.6 million, \$824,000 and \$753,000 for the years ended December 31, 2008, 2007 and 2006, respectively, on our infectious disease projects. We have spent approximately \$38.1 million from inception to December 31, 2008, on our infectious disease programs.

***Project Risks***

There are inherent uncertainties involved in the drug development process as well as the associated regulatory review and approval processes. Consequently, we cannot reliably estimate completion dates, expected costs or the amounts and timing of cash flows associated with our various drugs currently under development. Risks and uncertainties associated with completing the development of the products discussed above include the following:

Products may fail in clinical studies;

Hospitals, physicians and patients may not be willing to participate in clinical studies;

Table of Contents

Hospitals, physicians and patients may not properly adhere to clinical study protocols;

The drugs may not be safe and effective or may be perceived as unsafe and ineffective;

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 a 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 conducted by other drug companies or ourselves may reduce the number of patients available for our studies;

Patients may not enroll in our 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 our drugs;

The FDA or international regulatory authorities may request that additional studies be performed;

We may incur higher than anticipated costs with respect to third-party manufacturers or service providers we engage to perform research or to conduct clinical trials on our behalf;

Drug supplies may be insufficient to treat 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. Therefore, potential revenues and profits from these products could be delayed or may never be realized.

**Selling, general and administrative expenses**

Selling, general and administrative expenses consist primarily of salaries and related expenses 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 comprises costs to manufacture or acquire products sold to customers. We manufacture treprostinil using advanced intermediate compounds purchased in bulk from third-party vendors. We utilize multiple vendors that are capable of manufacturing greater quantities of these compounds less expensively than we are. We expect to begin commercial production of treprostinil in our new facility in Silver Spring, Maryland, upon receiving FDA approval for the facility, which is anticipated to occur during the first half of 2009. Upon commercialization of oral treprostinil, we believe the demand for treprostinil diethanolamine, the form of treprostinil used in our oral tablet, will

exceed that for treprostinil sodium, the form of treprostinil used in Remodulin and inhaled treprostinil. Accordingly, our planned manufacturing process has been designed to give us the flexibility to produce both forms of treprostinil efficiently in proportion to forecasted demand.

**Cost of service sales**

Cost of service sales includes salaries and related expenses, share-based compensation expense, and related overhead necessary to provide telemedicine services to customers.

Table of Contents

**Future Prospects**

Our future initiatives include expanding use of our prostacyclin therapy from the last line of treatment for patients with advanced stages of PAH to front-line therapy for newly diagnosed patients. We also hope to expand the use of treprostinil-based drugs and other therapies in development to treat diseases other than PAH.

In June 2008, we submitted an NDA to the FDA for marketing approval of inhaled treprostinil. If we are successful in obtaining FDA approval within our anticipated time frame, then we expect to begin selling inhaled treprostinil in 2009. In connection with these activities, we intend to enter into new distribution agreements for our inhaled formulation of treprostinil.

In December 2008, we obtained license rights from Lilly to develop, market, promote and commercialize the orally administered drug, tadalafil, for the treatment of pulmonary hypertension in the United States and Puerto Rico. Currently, Lilly is seeking FDA approval for tadalafil. If the FDA review process proceeds as anticipated, we could begin to recognize related revenues during 2009.

Our trial for our inhaled formulation of treprostinil was successful and we believe that our FREEDOM-M and FREEDOM-C<sup>2</sup> trials for our oral formulation of treprostinil will also be successful. We expect that the products developed under these trials will generate future sources of revenue. However, prior to FDA approval of inhaled and/or oral treprostinil for marketing, we could be required to perform additional studies. If this were to occur, related delays in the possible commercialization of these products could impede our continued rate of revenue growth. However, because PAH is a progressive disease with no cure, many patients continue to deteriorate on the currently approved oral and inhaled therapies. This presents market growth opportunities for Remodulin as a viable alternative or complementary treatment to these therapies. Furthermore, we believe that the market for Remodulin will continue to expand as more patients are diagnosed with PAH each year.

Our future growth and profitability will depend on many factors. These factors include, but are not limited to, the timing of commercialization of products in the later stages of development, the selling prices of, and demand for, our products and services, the degree of reimbursement by public and private insurance organizations, and the competition we face from others within our industry.

**Financial Position**

Cash, cash equivalents and marketable investments (excluding all restricted amounts) at December 31, 2008, were approximately \$336.3 million, compared to approximately \$299.8 million as of December 31, 2007. This increase resulted from the continued growth in sales of Remodulin offset, in part, by expenditures related primarily to funding the construction and acquisition of real property.

Restricted cash and marketable investments of \$45.8 million at December 31, 2008, comprise approximately \$40.7 million pledged as security for our financing arrangements related to our Silver Spring, Maryland laboratory facility (Phase I Laboratory) and approximately \$5.1 million placed in a Rabbi Trust to fund our Supplemental Executive Retirement Plan (SERP). At December 31, 2007, approximately \$39.2 million was pledged as security for our Phase I Laboratory and approximately \$5.0 million was placed in the Rabbi Trust.

Property, plant and equipment at December 31, 2008, was approximately \$221.1 million, up \$151.7 million from approximately \$69.4 million at December 31, 2007. Since December 31, 2007, we have funded approximately \$88.8 million toward the construction of our facilities in North Carolina and Maryland. Construction of the North Carolina facility was completed in February 2009 and the Maryland facility is expected to be complete in late 2009. Additionally, as of September 30, 2008, we capitalized \$29.0 million and recognized a corresponding lease obligation associated with our Phase I Laboratory (see Note 10 to the consolidated financial statements for further details). Lastly, we

Table of Contents

purchased a building in the United Kingdom for approximately \$16.3 million in August 2008 to serve as the new headquarters for our wholly-owned subsidiary, United Therapeutics Europe, Ltd.

Noncurrent deferred tax assets increased by approximately \$82.3 million from approximately \$93.7 million at December 31, 2007, to \$176.0 million at December 31, 2008, primarily as a result of the deferred tax asset created by expensing the \$150.0 million upfront payment to Lilly pursuant to a license agreement and a related manufacturing and supply agreement regarding the rights to commercialize tadalafil for pulmonary hypertension. For tax purposes, the \$150.0 million upfront payment is considered to be a tax intangible asset which is expensed for tax purposes over an expected 15 year period.

Accounts payable increased by approximately \$18.3 million from approximately \$2.0 million at December 31, 2007 to \$20.3 million at December 31, 2008. We attribute this increase to the timing of payments based on our semi-monthly payment cycle and the timing and volume of activity with respect to our construction projects.

The classification of approximately \$250.0 million of our 0.50% Convertible Senior Notes due October 2011 (Convertible Senior Notes) shifted from a current liability at December 31, 2007, to a non-current liability at December 31, 2008, because contingent conversion criteria had not been satisfied at December 31, 2008. Specifically, the closing price of our common stock did not exceed 120% of the initial conversion price for more than 20 days during the 30 consecutive trading day period ending on December 31, 2008. As a result, the Convertible Senior Notes were not convertible at the election of their holders (Note Holders). This conversion determination is measured as of the end of each quarter. Accordingly, classification of the Convertible Senior Notes may change in future quarters.

Stockholders' equity was approximately \$507.7 million at December 31, 2008, compared to approximately \$295.8 million at December 31, 2007. The net increase of \$211.9 million in stockholders' equity was driven in large part by the following significant transactions during the year ended December 31, 2008:

Additional paid-in capital increased by approximately \$110.9 million as a result of: (1) the receipt of \$41.9 million in proceeds from the exercise of stock options during 2008; (2) the recognition of \$28.5 million in stock-option based compensation expense; and (3) the recognition of \$40.5 million in tax benefits primarily associated with share-based compensation.

Treasury stock decreased by approximately \$164.2 million. The decrease represents the cost basis of approximately 3.2 million treasury shares that we issued to Lilly in December 2008 in exchange for \$150.0 million pursuant to our November 2008 stock purchase agreement. This transaction was one of several pursuant to agreements entered into with Lilly regarding the license, manufacture and supply of tadalafil for the treatment of pulmonary hypertension.

Our accumulated deficit rose by approximately \$57.0 million during the year ended December 31, 2008 due to our \$42.8 million net loss incurred for the year ended December 31, 2008 and the loss we recognized in connection with the issuance of treasury stock to Lilly. The excess of the cost basis of the treasury shares issued over the purchase price of approximately \$14.2 million was included in our accumulated deficit.

**Results of Operations**

*Years ended December 31, 2008 and 2007*

Revenues for the year ended December 31, 2008, were approximately \$281.5 million, compared to approximately \$210.9 million for the year ended December 31, 2007. The growth in revenues experienced during 2008 resulted in large part from the increase in the number of patients prescribed Remodulin.

Table of Contents

The following table presents the components of net revenues (dollars in thousands):

	Year Ended December 31,		Percentage Change
	2008	2007	
Remodulin	\$269,718	\$200,879	34.3%
Telemedicine services and products	9,485	7,725	22.8%
Distributor fees	2,234	2,160	3.4%
Other products	60	179	(66.5)%
<b>Total revenues</b>	<b>\$281,497</b>	<b>\$210,943</b>	<b>33.5%</b>

For the year ended December 31, 2008 and 2007, approximately 89% and 87%, respectively, of net Remodulin revenues 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 sales of Remodulin in the United States. Prompt pay discounts are offered on sales of Remodulin if the related invoices are paid in full, generally within 60 days from the date of sale. We estimate 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 the estimated units of service provided by the distributors for the period.

The table below presents a reconciliation of the liability accounts associated with estimated government rebates, prompt pay discounts and fees to distributors for services and the net reductions to revenues relating to these items (in thousands):

	Year Ended December 31,	
	2008	2007
Liability accounts, at beginning of period	\$ 2,879	\$ 2,366
Additions to liability attributed to sales in:		
Current period	14,498	12,439
Prior period	129	278
Payments or reductions attributed to sales in:		
Current period	(10,725)	(9,838)
Prior period	(2,685)	(2,366)
Liability accounts, at end of period	\$ 4,096	\$ 2,879
Net reductions to revenues	\$ 14,627	\$ 12,703



Table of Contents

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

	Year Ended December 31,		Percentage Change
	2008	2007	
<b>Project and non-project:</b>			
Cardiovascular	\$ 60,549	\$ 38,459	57.4%
License fees	150,000	11,013	1262.0%
Cancer	2,771	13,874	(80.0)%
Infectious disease	1,556	824	88.8%
Share-based compensation	16,200	12,373	30.9%
Other	8,105	6,809	19.0%
Total research and development expense	\$ 239,181	\$ 83,352	187.0%

*Cardiovascular projects.* Expenses associated with our inhaled and oral treprostinil programs increased by approximately \$8.9 million for the year ended December 31, 2008. The increase in expenditures related to these programs resulted from activities associated with: (1) the progression of ongoing clinical trials; (2) the filing for regulatory approval for inhaled treprostinil in the United States and EU; and (3) the announcement of results of the FREEDOM-C trial. In addition, during the year ended December 31, 2008, expenses incurred in connection with the development of beraprost-MR rose by approximately \$6.0 million when compared to the year ended December 31, 2007. This increase was largely attributable to milestone payments made to Toray pursuant to our license agreement for the development of beraprost-MR. Lastly, the growth during 2008 of our clinical staff to focus on new and investigational cardiovascular projects resulted in a corresponding increase in salaries and related expenses of approximately \$5.1 million.

*Cardiovascular license fees.* During the quarter ended December 31, 2008, we made a one-time, upfront payment of \$150.0 million pursuant to a license agreement and a related manufacturing and supply agreement entered into with Lilly regarding the commercialization of tadalafil. We expensed these payments as research and development since tadalafil has not been approved for marketing by the FDA and therefore commercial feasibility has not yet been demonstrated.

*Cancer projects.* In December 2007, we terminated our ovarian cancer program based on the results of the IMPACT I and II trials relating to OvaRex. Consequently, expenditures associated with our cancer programs decreased substantially in the year ended December 31, 2008 compared to the year ended December 31, 2007.

*Share-based compensation.* The increase in share-based compensation in 2008 resulted from: (1) achievement awards in connection with the attainment of specific company-wide performance milestones of which a portion is paid with awards granted under Share Tracking Awards Plan (STAP); and (2) an increase in the number of employees during the 2008.

Table of Contents

The table below summarizes selling, general and administrative expense by major categories (dollars in thousands):

Category:	Year Ended December 31,		Percentage Change
	2008	2007	
General and administrative	\$41,284	\$38,515	7.2%
Sales and marketing	32,899	24,159	36.2%
Share-based compensation	20,123	36,353	(44.6)%
Total selling, general and administrative expense	\$94,306	\$99,027	(4.8)%

*General and administrative.* The increase in general and administrative expenses in 2008 reflects in part headcount growth and corresponding personnel-related expenses of approximately \$2.0 million as we expanded our administrative staff to support the anticipated growth of our business. In addition, professional fees rose by approximately \$3.5 million in 2008 and relate to services provided in connection with prospective and consummated business transactions during the year. The increases in personnel-related expenses and professional fees were partially offset by a decrease of approximately \$3.1 million in impairment-related charges during 2008.

*Sales and marketing.* For the year ended December 31, 2008, personnel-related costs increased by approximately \$3.6 million as a direct result of increases in departmental headcount. In addition, expenses associated with new marketing campaigns and initiatives and other promotional activities rose by approximately \$3.7 million during 2008.

*Share-based compensation.* During the year ended December 31, 2007, we recognized share-based compensation expense of approximately \$23.7 million, representing the fair value of the Chief Executive Officer's year-end stock option grant, which is determined based on a formula set forth in her employment agreement. Based on this formula, our Chief Executive Officer did not receive a stock option grant for the year ended December 31, 2008. The decrease in share-based compensation recognized relating to this award was partially offset by an increase in share-based compensation of approximately \$7.5 million in 2008 and resulted from: (1) achievement awards in connection with the attainment of specific company-wide performance milestones of which a portion is paid with awards granted under the STAP; and (2) an increase in the number of employees during the 2008.

*Income Tax Benefit.* As a result of our net loss incurred before income taxes for the year ended December 31, 2008, we recognized income tax benefits of \$29.5 million for the year then ended. For the year ended December 31, 2007, we recognized income tax benefits of approximately \$3.3 million, resulting principally from the generation of business tax credits during the year for our orphan drug related research and development activities.

#### ***Years ended December 31, 2007 and 2006***

Revenues for the year ended December 31, 2007, were approximately \$210.9 million, compared to approximately \$159.6 million for the year ended December 31, 2006.

Table of Contents

The following table presents the components of net revenues (dollars in thousands):

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

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 sales of Remodulin in the United States. Prompt pay discounts are offered on sales of Remodulin if the related invoices are paid in full--generally within 60 days from the date of sale. We estimated our liability for prompt pay discounts based on historical payment patterns. Fees paid to distributors for services are estimated based on contractual rates for specific services applied to the estimated units of service provided by the distributors for the period.

The table below presents a reconciliation of the liability accounts associated with estimated government rebates, prompt pay discounts and distributor fees for services and the net reductions to revenues relating to these items (in thousands):

	Year 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

Table of Contents

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

	Year Ended December 31,		Percentage Change
	2007	2006	
<b>Project and non-project:</b>			
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%
License fee	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 expense was primarily due to expensing a \$3.0 million milestone payment to Toray in connection with our 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 the year ended December 31, 2006, was primarily related to the development of our OvaRex manufacturing processes. Research and development license fee expense is related to the 200,000 shares of our common stock issued to Toray under our amended license agreement for beraprost-MR.

The table below summarizes selling, general and administrative expense by major categories (dollars in thousands):

	Year Ended December 31,		Percentage Change
	2007	2006	
<b>Category:</b>			
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 was 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 price of our common 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 2006 based on the average closing price of our common 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

Table of Contents

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 United States 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 our IMPACT I and II Phase III trials of OvaRex for advanced ovarian cancer, the stock price of ViRexx Medical Corp. 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 was 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.

We recognized 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.

**Liquidity and Capital Resources**

Subsequent to the FDA's initial approval of Remodulin in 2002, we have funded our operations principally from Remodulin-related revenues and expect to do so in the future. We believe that our existing revenues and working capital resources will be adequate to fund our operations as demand for Remodulin has grown steadily since 2002 and our customer base remains stable. Furthermore, we believe that our customer base presents minimal credit risk. We have several therapies that are in the later stages of development and believe that, if approved for marketing, they will augment future revenue growth and cash flows. However, any projections of future cash needs and cash flows are inherently subject to uncertainty. To compensate for such uncertainty, we may raise additional cash in the future and believe we have options and the ability to do so. See *Item 1A Risk Factors We have a history of losses and may not maintain profitability and Item 1A Risk Factors We may fail to meet third-party projections for our revenue or profits.*

***Operating Cash Flows and Working Capital***

Net cash used by operating activities was approximately \$49.2 million for the year ended December 31, 2008, compared to approximately \$48.9 million in net cash provided by operations for the year ended December 31, 2007. The decrease in operating cash flows was driven by a one-time upfront payment of \$150.0 million to Lilly for the license rights to tadalafil, pursuant to the licensing and the manufacturing and supply agreements which became effective in December 2008. The related one-time fee was expensed as research and development in December 2008, and was the principal factor that led to our net loss for the year. In a related transaction, we issued approximately 3.2 million shares of our common stock from treasury to Lilly for \$150.0 million pursuant to a stock purchase agreement entered into with Lilly in connection with the acquisition of license rights to tadalafil. As such, collectively, our transactions with Lilly had no impact on net cash flows.

Table of Contents

At December 31, 2008, we had working capital of approximately \$239.6 million compared to approximately \$79.7 million at December 31, 2007. The increase in working capital corresponded to the classification of Convertible Senior Notes as a non-current liability because contingent conversion criteria had not been satisfied at December 31, 2008. Specifically, the closing price of our common stock did not exceed 120% of the initial conversion price for more than 20 days during the 30 consecutive trading day period ending on December 31, 2008. As a result, the Convertible Senior Notes were not convertible at the election of the Note Holders as of December 31, 2008. This conversion determination is measured as of the end of each quarter. Accordingly, classification of the Convertible Senior Notes may change in future quarters. However, it is our expectation, based on our understanding of the historical behavior of holders of convertible notes with terms similar to ours, that most, if not all of our outstanding Convertible Senior Notes will be held until they mature in October 2011. The increase in working capital for the year ended on December 31, 2008, was offset in part by: (1) the decrease in cash and short-term investments of approximately \$54.0 million as we invested excess cash in long-term marketable investments; (2) the funding of our construction projects in North Carolina and Maryland; and (3) the increase in accounts payable and other current liabilities of approximately \$32.2 million as a result of the timing of disbursements, the increased volume of activity with respect to our construction projects and the recognition of a liability associated with our STAP.

***Auction-Rate Securities***

At December 31, 2008, we held approximately \$36.8 million (par value) of illiquid non-current municipal notes with an auction reset feature (ARS). The decline in value of these securities reflects market-related liquidity conditions resulting from the general collapse of the credit markets and not the issuers' creditworthiness. The ARS are collateralized by student loan portfolios that are approximately 91% guaranteed by the federal government and maintain a credit rating of AAA. Historically, these securities provided liquidity to investors through their interest rate reset feature i.e., interest rates on these securities are reset through a bidding process (or auction) at frequent, pre-determined intervals (typically every 7 to 28 days). At each reset date, investors could either rollover and maintain their holdings or liquidate them at par value. Since February 2008, auctions related to our ARS have failed as a result of the deterioration of the credit markets, rendering these securities illiquid.

In November 2008, we entered into an Auction Rate Securities Rights Offer (Rights Offer) with the investment firm that maintains our ARS account. Pursuant to the Rights Offer, we can sell the ARS to the investment firm for a price equal to the par value of these securities at any time between June 30, 2010 and July 2, 2012 (Put Option). In addition, at any time through July 2, 2012, the investment firm, acting as principal, can purchase the ARS from us or sell them on our behalf provided that the par value of the ARS is deposited in our account on the next business day following settlement of the transaction. While we believe we have the ability to hold these investments until the credit markets improve sufficiently to allow us to liquidate the ARS without realizing significant losses, we entered into the Rights Offer to provide us with additional flexibility to recover the full cost of our investment prior to maturity of these securities. In addition, to help meet any immediate liquidity needs, the Rights Offer provides that we can borrow up to the par value of the ARS. The Rights Offer and the related Put Option, however, carries with it counterparty credit risk. Based on our anticipated cash requirements and cash flows, we do not believe that the risks associated with the ARS will have a material impact on our ability to meet our obligations.

***Construction Projects***

In February 2009, we completed the construction of a facility in Research Triangle Park, North Carolina (RTP facility), which includes a manufacturing operation and offices. The facility is approximately 200,000 square feet. The manufacturing operation will be used primarily to formulate oral treprostinil. In addition, it is expected that the RTP facility will support the production and

Table of Contents

distribution of other drug candidates that we are developing. The offices are used by our clinical development and sales and marketing staffs.

In December 2007, we began construction of a combination office and laboratory facility that will attach to our Phase I Laboratory in Silver Spring, Maryland (Phase II Facility). Projected costs to construct this facility are anticipated to be \$100.0 million. In November 2008, we agreed to the terms of a construction management agreement with the Whiting-Turner Contracting Company (Whiting-Turner) relating to the construction of the Phase II Facility (GMP Contract). Under the terms of the GMP Contract, costs to complete the construction of the Phase II Facility generally cannot exceed \$61.3 million (the Guaranteed Maximum Price). The Guaranteed Maximum Price excludes certain costs of construction that we expect to incur and that have been included in our projected costs to complete the Phase II Facility. Whiting-Turner will be responsible for any cost overruns above the Guaranteed Maximum Price and will share a portion of the savings in the event costs of constructing the Phase II Facility are less than the Guaranteed Maximum Price. In addition, Whiting-Turner is subject to penalties in the event that construction of the Phase II Facility is not completed by November 16, 2009, unless an agreed-upon change order alters the scope of work set forth under the GMP Contract. We spent approximately \$61.2 million and \$24.5 million relating to the construction of the RTP facility and Phase II facility, respectively, during 2008. As of December 31, 2008, inception-to-date expenditures approached \$109.0 million on these two construction projects. We expect to continue to fund our construction projects using our existing cash and cash flows to be generated by our operations.

***Share Tracking Awards Plan***

Effective June 2, 2008, we adopted the STAP. Awards granted under the STAP entitle participants to receive in cash the appreciation in our common stock, which is calculated as the positive difference between the closing price of our common stock on the date of grant and the date of exercise. Accordingly, the STAP could require substantial cash payments as awards vest and participants begin exercising them. Our operating budgets incorporate anticipated outlays of cash relating to the STAP, and we believe future cash flows will be sufficient to accommodate our obligations under the STAP and the future operating requirements of our business.

***License Fees***

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. Royalty obligations on sales of currently marketed products range up to 10 percent of related sales.

***Convertible Senior Notes***

On October 30, 2006, we issued at par value \$250.0 million of Convertible Senior Notes. We pay interest on the Convertible Senior Notes in arrears semi-annually on April 15 and October 15 of each year approximately \$1.3 million annually. The Convertible Senior Notes are unsecured, unsubordinated obligations that rank equally with all of our other unsecured and unsubordinated indebtedness. The initial conversion price is \$75.2257 per share. Conversion can occur: (i) anytime after July 15, 2011; (ii) during any calendar quarter that follows a calendar quarter in which the price of our common stock exceeded 120% of the initial conversion price for at least 20 days during the 30 consecutive trading-day period ending on the last trading day of the quarter; (iii) during the ten consecutive trading-day period following any five consecutive trading-day period in which the trading price of the Convertible Senior Notes was less than 95% of the closing price of our common stock multiplied by the then current conversion rate; or (iv) upon specified distributions to our shareholders, corporate transactions, or in the event that our common stock ceases to be listed on the NASDAQ Global Select Market (NASDAQ) and is not listed for trading on another U.S. national or regional securities exchange.

Table of Contents

Upon conversion, a Note Holder will receive: (i) cash equal to the lesser of the principal amount of the note or the conversion value (equal to the number of shares underlying the Convertible Senior Notes multiplied by the then current conversion price per share); and (ii) to the extent the conversion value exceeds the principal amount of the note, shares of our common stock. In the event of a change in control, as defined in the indenture under which the Convertible Senior Notes have been issued, Note Holders may require us to purchase all or a portion of their Convertible Senior Notes for 100% of the principal plus accrued and unpaid interest, if any, plus shares of our common stock.

***Lease Obligation***

We currently lease the Phase I Laboratory pursuant to a synthetic lease arrangement (Lease) entered into in June 2004 with Wachovia Development Corporation and its affiliates (Wachovia). Under the Lease, Wachovia funded \$32.0 million toward the construction of the Phase I Laboratory on land we own. Subsequent to the completion of construction in May 2006, Wachovia leased the Phase I Laboratory to us. Monthly rent is equal to the 30-day London Interbank Offered Rate (LIBOR) plus 55 basis points (1.0% as of December 31, 2008) applied to the amount Wachovia funded toward construction. The base term of the Lease ends in May 2011 (Base Term). Upon the end of the Base Term, we will have the right to exercise one of the following options under the Lease: (1) renew the lease for an additional five-year term (subject to the approval of both parties); (2) purchase the Phase I Laboratory from Wachovia for approximately \$32.0 million; or (3) sell the Phase I Laboratory and repay Wachovia's construction costs with the proceeds from the sale. If sales proceeds are insufficient to repay Wachovia's construction costs, we must fund the shortfall up to the maximum residual value guarantee of approximately \$27.5 million. From the inception of the Lease through August 2008, we accounted for the Lease as an off-balance sheet arrangement, i.e., an operating lease.

Since December 2007, we have been constructing the Phase II Facility with funds generated from our operations. As of September 30, 2008, substantial structural progress had been made in the construction of the Phase II Facility. In addition, we received Wachovia's acknowledgement of our plan to make structural modifications to the Phase I Laboratory in order to connect it to the Phase II Facility. As a result, we could no longer consider the Phase I Laboratory a standalone structure, which was required to maintain operating lease classification. Consequently, as of September 30, 2008, we were considered the owners of the Phase I Laboratory for accounting purposes. Because the Lease failed to meet criteria set forth in EITF Issue No. 97-10, *The Effect of Lessee Involvement in Asset Construction*, and FASB Statement No. 98, *Accounting for Leases*, we are accounting for the Lease as a financing obligation. Accordingly, as of September 30, 2008, we capitalized the estimated fair value of the Phase I Laboratory, totaling \$29.0 million, and recognized a corresponding lease obligation on our consolidated balance sheet. We are accreting (increasing) the lease obligation to \$32.0 million, the purchase price of the Phase I Laboratory, through the recognition of periodic interest charges using the effective interest method. The accretion period began on September 30, 2008, and will run through the end of the Base Term. Interest charges related to the accretion of the lease obligation for the year ended December 31, 2008, were approximately \$261,000. In addition, we are depreciating the Phase I Laboratory over its estimated economic useful life. The change in accounting recognition of the Lease did not affect our cash flow requirements under the arrangement.

Using the 30-day LIBOR as of December 31, 2008, plus 55 basis points, our estimated annual rent under the Lease would be \$314,000. Approximately \$40.7 million of our marketable investments at December 31, 2008 have been pledged as collateral for the Lease and are included within restricted marketable investments and cash on our consolidated balance sheet.

***Common Stock Subject to Repurchase***

In March 2007, we amended our June 2000 agreement with Toray to expand our rights to commercialize beraprost-MR. Pursuant to our amended agreement, we issued 200,000 shares of our



Table of Contents

common stock to Toray in March 2007. The terms of our amended agreement give Toray the right to request that we repurchase these shares at the price of \$54.41 per share upon 30 days prior written notice. To date, we have not received notification from Toray that they would like us to repurchase these shares.

**Contractual Obligations and Off-Balance Sheet Arrangements**

At December 31, 2008, we had the following contractual obligations (in thousands):

	Total	Payments Due by Period			
		Less than 1 year	2-3 Years	4-5 Years	More than 6 Years
Convertible Senior Notes(1)	\$249,978	\$	\$249,978	\$	\$
Lease obligation(2)	32,000		32,000		
Operating lease obligations	6,214	2,088	2,762	1,351	13
Construction commitment(3)	59,536	59,536			
Obligations under the STAP(4)	20,214	6,738	13,476		
Purchase commitments	3,217	1,217	2,000		
Milestone payments(5)	32,715	2,530	16,675	10,590	2,920
Total(6)	\$403,874	\$72,109	\$316,891	\$11,941	\$2,933

- 
- (1) The principal balance of the Convertible Senior Notes is to be repaid in cash. Convertibility may vary depending on whether our stock price meets specified criteria which is determined on a quarterly basis.
- (2) The lease obligation assumes that the purchase option will be elected at the end of the Base Term. Refer to Note 10 to the consolidated financial statements for a complete discussion of the arrangement.
- (3) Representing our remaining obligations under agreements currently in effect relating to our construction projects in Silver Spring, Maryland and Research Triangle Park, North Carolina.
- (4) We estimated the obligation based on the intrinsic value of outstanding STAP awards expected to vest as of December 31, 2008 assuming that awards will be exercised immediately upon vesting.
- (5) We license products from other companies under various license agreements. These agreements generally require that we make specific cash payments upon the achievement of specific product development milestones and commercialization. The timing and amounts of related milestone payments have been estimated based on: (1) when we believe milestones will be achieved; and (2) the assumption that all milestones established within these license agreements will be successfully attained.
- (6) As of December 31, 2008, we had approximately \$5.9 million of unrecognized tax benefits. The contractual obligations disclosed above exclude these amounts due to the uncertainty surrounding the amounts and timing of future payments.

Table of Contents

**Summary of Critical Accounting Policies and Estimates**

We prepare our consolidated financial statements in conformity with generally accepted accounting principles in the United States (GAAP). GAAP requires that we make estimates and assumptions that affect the amounts reported in our consolidated financial statements. As additional information becomes available, these estimates and assumptions can change and impact amounts reported in the future. We have identified the following accounting policies, which require the use of our judgment and estimation in their application. We consider these policies to be critical because of the degree of judgment that is inherent in their application.

***Sales of Remodulin***

Sales of Remodulin, including related pumps and supplies, are recognized when title and risk of ownership pass to our distributors, which occurs upon delivery. We record sales of Remodulin and related equipment and supplies net of product sales allowances. These sales allowances consist of prompt payment discounts, Medicaid rebates and fees paid to distributors. Calculating these allowances involves the use of significant estimates and judgments and information from external sources. Sales allowances are estimated and recognized as reductions to revenue in the period that associated revenues are recognized. Prompt pay discounts are calculated based on the gross amount of invoices and are recorded on a net basis as our distributors have routinely taken advantage of these discounts. Medicaid rebates are generally invoiced and paid in the subsequent quarter from the date of sale. Accruals and related revenue reductions for Medicaid rebates are based on historical rebate data adjusted for anticipated changes in product sales trends and government rebate programs with regard to eligibility requirements and/or rebate pricing. We pay two of our distributors service fees. Accruals for these fees are estimated based on contracted rates applied to the estimated units of service provided by distributors for a given period.

Our distributors do not possess return rights; however, we provide exchange rights in the event that product was damaged during shipment, or has expired. We account for exchange rights in accordance with Statement of Financial Accounting Standards (SFAS) No. 48, *Revenue Recognition When Right of Return Exists* (SFAS 48). The shelf life of Remodulin is 2.5 years from the date of its manufacture; accordingly, an exchange for expired vials generally occurs months after a vial is sold. The financial effects of this exchange right have been immaterial and we expect the historic volume of exchanges to remain consistent in the future. Obsolescence due to dating expiration has historically been minimal given the fast pace at which our products move through the distribution channel. Specifically, product exchanges have comprised substantially less than 1% of the volume of vials that we sell. As such, reserves for exchange rights are not recognized in the period of sale, unless product expiration or damage occurs during shipment and are known to us. We closely monitor levels of inventory in the distribution channels for contractual compliance and do not provide incentives to our distributors to assume additional inventory levels beyond what is customary in the ordinary course of business.

***Marketable Investments***

Pursuant to SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities* (SFAS 115) we are required to periodically review our marketable investments to determine whether a decline in the value of a security is other than temporary. This review requires us to make judgments, particularly as they relate to: (1) the materiality and duration of a decline in the value of a security; (2) the probability, extent and timing of a recovery in a security's value; and (3) our ability and intent to hold a security until we can recover our initial cost, or until maturity. The scope of this evaluation requires forward-looking assessments pertaining to a security and the relevant financial markets, as well as an issuer's financial condition and business outlook. Accordingly, we must make assessments regarding current conditions, as well as future events, which involve a considerable degree of

Table of Contents

uncertainty. When we determine that the decline in value of a security is other than temporary, we are required to recognize an impairment charge within our consolidated statement of operations and establish a new cost basis for the security at its then current fair value. During the year ended December 31, 2008, we recognized an impairment charge of \$6.3 million within earnings related to our investments in ARS. Refer to Note 4 to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K for a complete discussion.

In addition, pursuant to SFAS 115, we classify certain marketable investments as held-to-maturity because we believe we have the positive intent and ability to hold related securities until they mature. This assertion requires us to make forward-looking judgments regarding our future cash flow requirements relative to the maturity dates of such securities. To reduce the level of uncertainty associated in making this determination, we invest in securities that do not possess extended maturities.

***Fair Value Measurements***

SFAS No. 157, *Fair Value Measurements* (SFAS 157), requires that we disclose assets and liabilities subject to fair value measurements within a fair value hierarchy (SFAS 157 Hierarchy). The SFAS 157 Hierarchy gives the highest priority to fair value measurements based on unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to fair value measurements derived through the use of unobservable inputs (Level 3 measurements). Assets and liabilities are classified within the SFAS 157 Hierarchy, in their entirety, based on the lowest level input that is significant to the related fair value measurement. Determining where within the fair value hierarchy a particular asset or liability should be disclosed involves judgment regarding the significance of inputs relative to a fair value measurement and where such inputs lie within the SFAS 157 Hierarchy. Furthermore, securities that are illiquid, or are not traded, have little or no price transparency (Level 3 measurements). As such, estimating the fair value of our Level 3 securities involves the use of significant subjective assumptions that we believe market participants would consider in pricing such securities. We employ a discounted cash flow model to estimate the fair value of our Level 3 securities. Accordingly, inputs to the model that include estimating the amounts and timing of expected cash flows, the expected term of the securities and a discount rate appropriately adjusted for illiquidity or other risks involve a significant degree of judgment.

***Investment in Affiliate***

We use the equity method of accounting for our investment in Northern Therapeutics, Inc. (Northern). The equity method of accounting requires that we report our share of our Northern's net losses or earnings in our consolidated financial statements. Consolidation is not required unless we possess the ability to control Northern. Generally, the ability to exercise control over an entity occurs when voting interests in that entity exceed 50%. We maintain an ownership interest in Northern of approximately 68%. However, because Northern's minority owners have substantive participation rights as described in EITF Issue No. 96-19, *Investors' Accounting for an Investee When the Investor has a Majority of the Voting Interest but Minority Shareholder or Shareholders Have Certain Approval or Veto Rights*, we concluded that we do not have the ability to control Northern's operations. Therefore, Northern's financial statements have not been included in our consolidated financial statements.

***Income Taxes***

Income taxes are accounted for in accordance with the asset and liability method set forth under SFAS No. 109, *Accounting for Income Taxes* (SFAS 109). Accordingly, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their tax bases. Deferred tax assets and liabilities are measured using the enacted tax rates that are expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Deferred tax assets

Table of Contents

are reduced by a valuation allowance when, in our opinion, it is more likely than not that some or all of the deferred tax assets will not be realized. Evaluating the realizability of deferred assets requires us to review forecasts of earnings and taxable income, among other considerations. Accordingly, the evaluation process as it relates to the realizability of deferred tax assets requires us to make significant judgments and forward-looking assessments regarding amounts and the availability of future taxable income.

We account for uncertain tax positions pursuant to FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes - an Interpretation of FASB Statement No. 109* (FIN 48). Financial statement recognition of a tax position taken or expected to be taken in a tax return is determined based on a more likely than not threshold of that position being sustained. If the tax position meets this threshold, the benefit to be recognized is measured as the largest amount that is more than 50 percent likely to be realized upon ultimate settlement. Application of FIN 48 involves considerable judgment in assessing the future tax consequences of amounts that have been recognized in our financial statements or tax returns. The ultimate resolution of uncertain tax positions could result in amounts different from those recognized on our consolidated financial statements.

***Goodwill***

We are required under SFAS No. 142, *Goodwill and Other Intangible Assets*, to test goodwill at the reporting unit level for impairment annually or more frequently if impairment indicators exist. Evaluating goodwill for impairment requires judgment particularly as it relates to determining the fair value of a reporting unit to which goodwill has been assigned. We generally use a discounted cash flow model to test goodwill for impairment, which involves the use of significant and subjective inputs. Related inputs, among others, requiring our judgment include the estimation of future cash flows, future growth rates and profitability of a reporting unit and the expected life related cash flows will occur. Changes in our business strategy or adverse changes in market conditions could impact impairment analyses and require the recognition of an impairment charge equal to the excess of the carrying value of goodwill over its estimated fair value.

***Phase I Laboratory Lease***

We currently lease the Phase I Laboratory pursuant to the Lease we entered into in June 2004 with Wachovia. Under the Lease, Wachovia funded \$32.0 million toward the construction of the Phase I Laboratory on land we own. Subsequent to the completion of construction in May 2006, Wachovia leased the Phase I Laboratory to us. Upon the end of the Base Term in May 2011, we will have the right to exercise one of the following options under the Lease: (1) renew the lease for an additional five-year term (subject to the approval of both parties); (2) purchase the Phase I Laboratory from Wachovia for approximately \$32.0 million; or (3) sell the Phase I Laboratory and repay Wachovia's construction costs with the proceeds from the sale. If such sales proceeds are insufficient to repay Wachovia's construction costs, we must fund the shortfall up to the maximum residual value guarantee of approximately \$27.5 million. From the inception of the Lease through the quarter ended June 30, 2008, we accounted for the Lease as an operating lease (an off-balance sheet arrangement).

Since December 2007, we have been constructing the Phase II Facility with funds generated from our operations. As of September 30, 2008, substantial structural progress had been made in the construction of the Phase II Facility. In addition, we received Wachovia's acknowledgement of our plan to make structural modifications to the Phase I Laboratory in order to connect it to the Phase II Facility. As a result, the Phase I Laboratory is no longer considered a standalone structure, which is required to maintain off-balance sheet accounting for the Lease. Consequently, as of September 30, 2008, we were considered the owners of the Phase I Laboratory for accounting purposes. Because the Lease failed to meet criteria set forth in EITF Issue No. 97-10, *The Effect of Lessee Involvement in Asset Construction*, and SFAS No. 98, *Accounting for Leases*, we are accounting for the Lease as a

Table of Contents

financing obligation. Accordingly, as of September 30, 2008, we capitalized the estimated fair value of the Phase I Laboratory, totaling \$29.0 million, and recognized a corresponding lease obligation on our consolidated balance sheet. We are accreting the lease obligation to \$32.0 million, the purchase price of the Phase I Laboratory, through the recognition of periodic interest charges using the effective interest method. The accretion period began on September 30, 2008 and will run through May 2011. In addition, we are depreciating the Phase I Laboratory over its estimated economic useful life.

***Pension Benefit Obligation***

We account for the SERP in accordance with SFAS No. 158, *Employers' Accounting for Defined Benefit Pension and Other Postretirement Plans* (SFAS 158), and related standards and interpretations. Accordingly, we recognize on our consolidated balance sheet a liability equal to the unfunded status of the SERP (equal to the projected benefit obligation, as we do not fund the SERP) and measure our projected benefit obligation as of the end of our fiscal year. Estimating the SERP obligation involves the use of judgments and estimates. The SERP obligation and related pension expense are derived from actuarial valuations that are developed using a number of assumptions. A key assumption to the valuation is the discount rate. The discount rate should be representative of the rate associated with high-quality, fixed-income debt securities. Changes in the discount rate can significantly impact the measurement of the SERP obligation. Other actuarial assumptions include participant demographics such as the expected rate of salary increases and withdrawal rates, among others. Actual experience may differ from actuarial assumptions. Changes in any of these assumptions can also affect the measurement of the SERP obligation.

***Share-based Compensation***

We account for share-based awards in accordance with SFAS No. 123 (revised 2004), *Share-Based Payment* (SFAS 123R), and related interpretive guidance. Our share-based awards are classified as either equity (stock options) or as liabilities (STAP awards) and compensation expense to be recognized is determined based on the fair value of related awards. We estimate the fair value of these awards using the Black-Scholes-Merton valuation model. Valuation models, like the Black-Scholes-Merton model, require the use of subjective assumptions that could materially impact the estimation of fair value and related compensation expense to be recognized. These assumptions include, among others, the expected volatility of our stock price, the expected term of awards and the expected forfeiture rate. Developing these assumptions requires the use of judgment.

**Recently Issued Accounting Standards**

In May 2008, the FASB issued Staff Position APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash Upon Conversion (Including Partial Cash Settlement)* (FSP APB 14-1). FSP APB 14-1 applies to certain convertible debt instruments that may be settled in cash or other assets, or partially in cash, upon conversion. Issuers of such instruments are required under FSP APB 14-1 to account for the liability and equity components separately in a manner that reflects the issuer's nonconvertible debt borrowing rate when interest expense is subsequently recognized. Specifically, FSP APB 14-1 requires the difference between the convertible debt proceeds and the fair value of the liability, absent any conversion rights, to be assigned to the equity component and recognized as part of stockholders' equity and as a discount for determining the carrying value of the debt. The discounted carrying value of the debt is amortized as interest expense using the interest method over the expected life of the debt. FSP APB 14-1 is effective for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years and is to be applied retrospectively to all periods presented. Our Convertible Senior Notes fall within the scope of FSP APB 14-1 see Note 9 to the consolidated financial statements included in this Annual Report on Form 10-K. While adoption of FSP APB 14-1 will not change the cash flow requirements of our Convertible Senior Notes, non-cash interest expense

Table of Contents

associated with the amortization of the discount on the Convertible Senior Notes is expected to increase significantly. Upon the adoption of FSP APB 14-1, we will no longer recognize interest expense based on the Convertible Senior Notes' stated rate of interest.

The expected impact of the retrospective application of FSP APB 14-1 from the period of issuance (October 2006) through the end of the Senior Convertible Notes' expected life excluding any effects of capitalized interest and income taxes is shown below (in thousands):

Year Ended December 31,	Interest Expense Based on the Stated Rate of Interest	Interest Expense Under FSP APB 14-1	Incremental Impact of Adoption of FSP APB 14-1
2006	\$ 208	\$ 2,227	\$ 2,019
2007	1,250	13,533	12,283
2008	1,250	14,696	13,446
2009	1,250	15,723	14,473
2010	1,250	16,829	15,579
2011(1)	1,042	15,104	14,062
<b>Total</b>	<b>\$ 6,250</b>	<b>\$ 78,112</b>	<b>\$ 71,862</b>
Debt Discount and equity component to be recognized under FSP APB 14-1	N/A	N/A	\$ 71,862

(1)

Through October 2011, the end of the expected life of the Convertible Senior Notes.

In June 2008, the FASB issued EITF Issue No. 07-5, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock* (EITF 07-5). EITF 07-5 supersedes EITF Issue No. 01-6, *The Meaning of 'Indexed to a Company's Own Stock*, and provides guidance in evaluating whether certain financial instruments or embedded features can be excluded from the scope of SFAS No. 133, *Accounting for Derivatives and Hedging Activities* (SFAS 133). EITF 07-5 sets forth a two-step approach that evaluates an instrument's contingent exercise and settlement provisions for the purpose of determining whether such instruments are indexed to an issuer's own stock (a requirement necessary to comply with the scope exception under SFAS 133). EITF 07-5 will be effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. We are currently assessing the impact related to the adoption of EITF 07-5 on our financial instruments that fall within its scope.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles* (SFAS 162). SFAS 162 identifies sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements of non-governmental entities that are presented in conformity with GAAP (GAAP Hierarchy). SFAS 162 became effective November 15, 2008. Adoption of SFAS 162 did not impact our consolidated financial statements.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities - an Amendment of FASB Statement No. 133* (SFAS 161). SFAS 161 requires companies to provide enhanced disclosures regarding derivative instruments and hedging activities and requires companies to better convey the purpose of derivative use in terms of the risks they intend to manage. Disclosures required under SFAS 161 include (a) how and why a company uses derivative instruments, (b) how derivative instruments and related hedged items are accounted for under SFAS 133 and its related interpretations, and (c) how derivative instruments and related hedged items affect a company's financial position, financial performance, and cash flows. SFAS 161 retains the same scope as SFAS 133 and is effective for fiscal years and interim periods beginning after November 15, 2008. We do not expect the adoption of SFAS 161 to have a material impact, if any, on our consolidated financial statements.

Table of Contents

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements – an amendment of ARB No. 51* (SFAS 160). SFAS 160 establishes accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. This statement is effective, prospectively, for fiscal years beginning after December 15, 2008 except for certain retrospective disclosure requirements. We do not expect the adoption of SFAS 160 to have any impact on our consolidated financial statements upon initial adoption.

In December 2007, the FASB issued SFAS No. 141 (Revised 2007), *Business Combinations – a replacement of FASB Statement No. 141* (SFAS 141R). SFAS 141R significantly changes the principles and requirements for how the acquirer of a business recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any non-controlling interest in the acquiree. SFAS 141R also provides guidance for recognizing and measuring goodwill acquired in a business combination and determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of a business combination. SFAS 141R is effective, prospectively, for fiscal years beginning after December 15, 2008, except for certain retrospective adjustments to deferred tax balances. The potential impact of adopting SFAS 141R on our consolidated financial statements will depend on whether we enter into any future acquisitions and the magnitude of such acquisitions.

In June 2007, the FASB ratified EITF Issue No. 07-1, *Accounting for Collaboration Arrangements Related to the Development and Commercialization of Intellectual Property* (EITF 07-1). EITF 07-1 provides guidance on how the parties to a collaborative agreement should account for costs incurred and revenue generated on sales to third parties and how sharing payments pursuant to a collaboration agreement should be presented in the income statement. EITF 07-1 will be effective for fiscal years beginning after December 15, 2008 and interim periods within those fiscal years and shall be applied retrospectively. We are assessing the potential impact, if any, the adoption of EITF 07-1 will have on our consolidated financial statements.

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

As of December 31, 2008, we hold investments of approximately \$36.8 million (par value) in ARS. We are exposed to market risk related to the ARS as a result of the general collapse of the credit markets and the continued uncertainty surrounding the financial markets. The ARS maintain an AAA credit rating and are backed by student-loan portfolios that are approximately 91% guaranteed by the federal government. However, since February 2008, auctions for the ARS have failed, rendering these securities illiquid. Consequently, the fair value of the ARS has continued to decline in value. Through November 2008, we classified the ARS as available-for-sale and accounted for the decline in their value as temporary within other comprehensive losses (equity) based on our intent and ability to hold these securities until they recover their value. However, upon our entering into the Rights Offer in November 2008, we could no longer assert our positive intent to hold these securities indefinitely. Consequently, we recognized an other-than-temporary impairment loss of approximately \$6.3 million within earnings during the quarter ended December 31, 2008. Concurrently, we reclassified the ARS from the available-for-sale to the trading category. With this transfer into the trading classification, all future changes in fair value of the ARS will be recognized within earnings until the securities are liquidated or otherwise disposed. Furthermore, there can be no assurances that the ARS will ever fully recover their value.

To mitigate the risks associated with our investment, we entered into the Rights Offer, under which we have a Put Option that gives us the ability to require the investment firm (the counterparty to the Rights Offer) to repurchase the ARS at a price equal to their par value during a specific period beginning in June 2010. The Put Option has been recognized at fair value as a financial asset on our consolidated balance sheet at December 31, 2008. Subsequent changes in the fair value of the Put Option will be recognized within earnings. We expect the future price movements relating to the

Table of Contents

ARS and the Put Option to largely offset one another i.e., as the value of the ARS decreases, we would expect the rights associated with the Put Option to increase in value. Refer to Note 4 to the consolidated financial statements included in this Annual Report on Form 10-K for a complete discussion of the ARS and the Rights Offer.

At December 31, 2008, we have invested approximately \$207.6 million in debt securities issued by corporations and federally-sponsored agencies. The market value of these investments varies inversely with changes in current market interest rates. In general, as rates increase, the market value of a debt investment would be expected to decrease. Similarly, as rates decrease, the market value of a debt investment would be expected to increase. To minimize market risk, we hold related investments until maturity so that they can be redeemed at their stated or face value. At December 31, 2008, our investments in debt securities issued by corporations and federally-sponsored agencies had a weighted average stated interest rate of approximately 2.8%. These investments mature at various times through December 2010 and are callable annually.

There has been significant deterioration and instability in the financial markets during 2008. This period of extraordinary disruption and readjustment in the financial markets exposes us to additional investment risk. The value and liquidity of the securities in which we invest could deteriorate rapidly and the issuers of such securities could be subject to credit rating downgrades. In light of the current market conditions and these additional risks, we actively monitor market conditions and developments specific to the securities and security classes in which we invest. We believe that we take a conservative approach to investing our funds in that we invest only in highly-rated securities with relatively short maturities and do not invest in securities that we believe involve a higher degree of risk. While we believe we take prudent measures to mitigate investment related risks, such risks cannot be fully eliminated, as there are circumstances outside of our control, as noted above in the discussion of our ARS.



Table of Contents

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

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

<u>Report of Independent Registered Public Accounting Firm</u>	<u>F-2</u>
<u>Report of Independent Registered Public Accounting Firm on Internal Control over Financial Reporting</u>	<u>F-3</u>
<u>Consolidated Balance Sheets as of December 31, 2008 and 2007</u>	<u>F-4</u>
<u>Consolidated Statements of Operations for the years ended December 31, 2008, 2007 and 2006</u>	<u>F-5</u>
<u>Consolidated Statements of Stockholders' Equity for the years ended December 31, 2008, 2007 and 2006</u>	<u>F-6</u>
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2008, 2007 and 2006</u>	<u>F-7</u>
<u>Notes to Consolidated Financial Statements</u>	<u>F-8</u>

F-1

---

Table of Contents

**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Shareholders  
United Therapeutics Corporation

We have audited the accompanying consolidated balance sheets of United Therapeutics Corporation as of December 31, 2008 and 2007, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2008. Our audits also included the financial statement schedule listed in the Index at Item 15 (a)(2). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of United Therapeutics Corporation at December 31, 2008 and 2007, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2008, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

As discussed in Note 13 to the consolidated financial statements, United Therapeutics Corporation adopted FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes - an Interpretation of FASB Statement No. 109* effective January 1, 2007.

We also have audited, in accordance with the Standards of the Public Company Accounting Oversight Board (United States), United Therapeutics Corporation's internal control over financial reporting as of December 31, 2008, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 26, 2009 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

McLean, Virginia  
February 26, 2009

Table of Contents

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

The Board of Directors and Shareholders  
United Therapeutics Corporation

We have audited United Therapeutics Corporation's internal control over financial reporting as of December 31, 2008, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). United Therapeutics Corporation's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying *Management's Report on Internal Control Over Financial Reporting*. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

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

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

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

In our opinion United Therapeutics Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2008 consolidated financial statements of United Therapeutics Corporation, and our report dated February 26, 2009, expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

McLean, Virginia  
February 26, 2009

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

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 129,452	\$ 139,323
Marketable investments	106,596	150,729
Accounts receivable, net of allowance of none for 2008 and 2007	28,311	25,654
Other receivable	752	2,959
Interest receivable	1,537	1,049
Prepaid expenses	11,600	5,948
Inventories, net	14,372	13,211
Deferred tax assets	4,827	13,588
<b>Total current assets</b>	<b>297,447</b>	<b>352,461</b>
Marketable investments	100,270	9,740
Marketable investments and cash restricted	45,755	44,195
Goodwill and other intangible assets	7,838	8,427
Property, plant, and equipment, net	221,066	69,354
Deferred tax assets	175,969	93,700
Other assets (\$7,685 measured under the fair value option)	22,974	9,141
<b>Total assets</b>	<b>\$871,319</b>	<b>\$ 587,018</b>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 20,334	\$ 2,000
Accrued expenses	20,853	17,942
Notes payable		250,000
Other current liabilities	16,639	2,818
<b>Total current liabilities</b>	<b>57,826</b>	<b>272,760</b>
Notes payable	249,978	
Lease obligation	29,261	
Other liabilities	15,673	7,586
<b>Total liabilities</b>	<b>352,738</b>	<b>280,346</b>
Commitments and contingencies:		
Common stock subject to repurchase	10,882	10,882
Stockholders' equity:		
Preferred stock, par value \$.01, 10,000,000 shares authorized, no shares issued		
Series A junior participating preferred stock, par value \$.01, 100,000 shares authorized, no shares issued		
Common stock, par value \$.01, 100,000,000 shares authorized, 27,662,151 and 26,629,189 shares issued at December 31, 2008 and 2007, respectively, and 26,431,356 and 22,247,592 outstanding at December 31, 2008 and 2007, respectively	276	266
Additional paid-in capital	659,245	548,327
Accumulated other comprehensive (loss) income	(5,913)	317
Treasury stock at cost, 1,230,795 and 4,381,597 shares at December 31, 2008 and 2007, respectively	(67,395)	(231,619)
Accumulated deficit	(78,514)	(21,501)
<b>Total stockholders' equity</b>	<b>507,699</b>	<b>295,790</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$871,319</b>	<b>\$ 587,018</b>

See accompanying notes to consolidated financial statements.

F-4

---

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

	<b>For Years Ended December 31,</b>		
	<b>2008</b>	<b>2007</b>	<b>2006</b>
<b>Revenues:</b>			
Net product sales	\$270,005	\$201,348	\$153,448
Service sales	9,258	7,435	6,184
License fees	2,234	2,160	
<b>Total revenue</b>	<b>281,497</b>	<b>210,943</b>	<b>159,632</b>
<b>Operating expenses:</b>			
Research and development	239,181	83,352	57,570
Selling, general and administrative.	94,306	99,027	56,052
Cost of product sales	26,957	19,919	14,973
Cost of service sales	3,109	2,342	2,055
<b>Total operating expenses</b>	<b>363,553</b>	<b>204,640</b>	<b>130,650</b>
(Loss) income from operations	(82,056)	6,303	28,982
<b>Other income (expense):</b>			
Interest income	11,025	13,602	10,700
Interest expense	(16)	(2,175)	(482)
Equity loss in affiliate	(226)	(321)	(491)
Other, net	(1,025)	(826)	1,199
<b>Total other income (expense), net</b>	<b>9,758</b>	<b>10,280</b>	<b>10,926</b>
Net (loss) income before income tax	(72,298)	16,583	39,908
Income tax benefit	29,509	3,276	34,057
<b>Net (loss) income</b>	<b>\$ (42,789)</b>	<b>\$ 19,859</b>	<b>\$ 73,965</b>
<b>Net (loss) income per common share:</b>			
Basic	\$ (1.87)	\$ 0.94	\$ 3.21
Diluted	\$ (1.87)	\$ 0.88	\$ 3.06
<b>Weighted average number of common shares outstanding:</b>			
Basic	22,901	21,224	23,010
Diluted	22,901	22,451	24,138

See accompanying notes to consolidated financial statements.

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

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Treasury Stock	Accumulated Deficit	Total
	Shares	Amount					
Balance, December 31, 2005	23,845,004	\$ 239	\$ 393,469	\$ 3,593	\$ (6,874)	\$ (115,325)	\$ 275,102
Net income						73,965	73,965
Foreign currency translation adjustments				336			336
Unrealized loss on available-for-sale securities				(2,453)			(2,453)
Total other comprehensive income				(2,117)		73,965	71,848
Exercise of stock options	787,149	7	14,437				14,444
Tax benefit from exercises of non-qualified stock options			12,236				12,236
Treasury stock repurchases					(157,686)		(157,686)
Cost of call spread options, net			(35,400)				(35,400)
Options issued in exchange for services			24,062				24,062
Balance, December 31, 2006	24,632,153	246	408,804	1,476	(164,560)	(41,360)	204,606
Net income						19,859	19,859
Foreign currency translation adjustments				285			285
Unrealized loss on available-for-sale securities				(892)			(892)
Unrealized loss on pension liability				(552)			(552)
Total other comprehensive income				(1,159)		19,859	18,700
Exercise of stock options	1,797,036	18	58,326				58,344
Tax benefit from exercises of non-qualified stock options			32,089				32,089
Treasury stock repurchases					(67,059)		(67,059)
Options issued in exchange for services			48,979				48,979
Stock issued for license right	200,000	2	129				131
Balance, December 31, 2007	26,629,189	266	548,327	317	(231,619)	(21,501)	295,790
Net loss						(42,789)	(42,789)
Foreign currency translation adjustments				(5,489)			(5,489)
Unrealized loss on available-for-sale securities				(191)			(191)
Unrealized loss on pension liability				(550)			(550)
Total other comprehensive loss				(6,230)		(42,789)	(49,019)
Issuance of treasury stock					164,224	(14,224)	150,000
Exercise of stock options	1,032,962	10	41,926				41,936
Tax benefit from exercises of non-qualified stock options			40,524				40,524
			28,468				28,468

Edgar Filing: UNITED THERAPEUTICS CORP - Form 10-K

Options issued in exchange for  
services

Balance, December 31, 2008	27,662,151	\$	276	\$	659,245	\$	(5,913)	\$	(67,395)	\$	(78,514)	\$	507,699
----------------------------	------------	----	-----	----	---------	----	---------	----	----------	----	----------	----	---------

See accompanying notes to consolidated financial statements.

F-6

---



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

	<b>Years Ended December 31,</b>		
	<b>2008</b>	<b>2007</b>	<b>2006</b>
<b>Cash flows from operating activities:</b>			
Net (loss) income	\$ (42,789)	\$ 19,859	\$ 73,965
<b>Adjustments to reconcile net (loss) income to net cash provided by operating activities:</b>			
Depreciation and amortization	4,536	3,427	2,713
Provisions for bad debt and inventory obsolescence	586	1,975	256
Share-based compensation	28,703	48,704	24,062
Unrealized losses on trading securities and impairments	1,595	3,582	2,024
Deferred tax benefit	(31,211)	(3,276)	(37,047)
Amortization of discount or premium on investments	(999)	(4,065)	(1,249)
Equity loss in affiliate and other	840	1,530	599
Excess tax benefit from share-based compensation	(21,090)	(29,604)	(10,761)
Issuance of stock for license		11,013	
<b>Changes in assets and liabilities:</b>			
Restrictions on cash	(8,766)	(5,176)	(2,396)
Accounts receivable	(2,329)	(4,030)	(8,869)
Inventories	(2,630)	(2,339)	(1,006)
Prepaid expenses	(5,682)	3,642	(2,867)
Other assets	(14,528)	(868)	1,577
Accounts payable	18,509	(1,072)	(1,082)
Accrued expenses	3,641	2,667	4,892
Other liabilities	22,442	2,978	4,446
Net cash (used in) provided by operating activities	(49,172)	48,947	49,257
<b>Cash flows from investing activities:</b>			
Purchases of property, plant and equipment	(124,415)	(38,658)	(15,634)
Purchases of held-to-maturity investments	(321,363)	(221,986)	(120,405)
Purchases of available-for-sale investments	(24,600)	(80,000)	(84,350)
Maturities of held-to-maturity investments	266,051	260,888	32,360
Sales of available-for-sale investments	31,850	58,050	86,400
Net cash used in investing activities	(172,477)	(21,706)	(101,629)
<b>Cash flows from financing activities:</b>			
Proceeds from the sale of treasury stock	150,000		
Proceeds from exercise of stock options	41,936	58,344	14,445
Proceeds from the issuance of convertible notes, net of issuance costs			242,024
Payments to repurchase common stock		(67,059)	(157,686)
Purchase of call spread options, net			(35,400)
Excess tax benefits associated with share-based compensation	21,090	29,604	10,761
Principal payments on debt	(23)	(10)	(16)
Net cash provided by financing activities	213,003	20,879	74,128
Effect of exchange rate changes on cash and cash equivalents	(1,225)	136	131
Net (decrease) increase in cash and cash equivalents	(9,871)	48,256	21,887
Cash and cash equivalents, beginning of year	139,323	91,067	69,180
Cash and cash equivalents, end of year	\$ 129,452	\$ 139,323	\$ 91,067

**Supplemental cash flow information:**

Edgar Filing: UNITED THERAPEUTICS CORP - Form 10-K

Cash paid for interest	\$ 1,250	\$ 1,210	\$ 7
Cash paid for income taxes	\$ 1,628	\$ 1,555	\$ 304
Non-cash investing and financing activity: lease obligation incurred	\$ 29,000	\$	\$

See accompanying notes to consolidated financial statements.

F-7

---

Table of Contents

**UNITED THERAPEUTICS CORPORATION**

**Notes to Consolidated Financial Statements**

**1. Organization and Business Description**

United Therapeutics Corporation (United Therapeutics) is a biotechnology company focused on the development and commercialization of unique products to address the unmet medical needs of patients with chronic and life-threatening cardiovascular and infectious diseases and cancer. We were incorporated on June 26, 1996, under the laws of the State of Delaware and have the following wholly-owned subsidiaries: Lung Rx, Inc., Unither Pharmaceuticals, Inc., Unither Telmed, Ltd., Unither.com, Inc., United Therapeutics Europe, Ltd., Unither Therapeutik GmbH, Unither Pharma, Inc., Medicomp, Inc., Unither Neurosciences, Inc., LungRx Limited, Unither Biotech Inc., and Unither Virology, LLC. As used in these notes to the consolidated financial statements, unless the context otherwise requires, the terms "we," "us," "our," and similar terms refer to United Therapeutics and its consolidated subsidiaries.

Our lead product is Remodulin® (treprostinil sodium) Injection (Remodulin), a stable synthetic form of prostacyclin. Prostacyclin is an important molecule produced by the body that has powerful effects on blood vessel health and function. Remodulin was first approved in 2002 by the United States Food and Drug Administration (FDA) for use as a continuous subcutaneous infusion for the treatment of pulmonary arterial hypertension (PAH). Since 2002, the FDA has expanded its approval of Remodulin for intravenous use and for the treatment of patients who require transition from Flolan®, another intravenously administered prostacyclin. Remodulin is also approved for use in countries outside of the United States, predominantly for subcutaneous administration.

We have generated pharmaceutical revenues from sales of Remodulin, distributor fees and arginine royalty payments in the United States, Canada, the European Union (EU), South America and Asia. In addition, we have generated non-pharmaceutical revenues from telemedicine products and services in the United States.

**2. Summary of Significant Accounting Policies**

*Principles of Consolidation*

The accompanying consolidated financial statements include the accounts of United Therapeutics and its wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

*Use of Estimates*

The preparation of the consolidated financial statements in accordance with accounting principles generally accepted in the United States (GAAP) requires management to make estimates and assumptions that affect reported amounts of assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

*Fair Value of Financial Instruments*

The carrying amounts of cash and cash equivalents, accounts receivables, accounts payable, and accrued expenses, approximate fair value because of their short maturities. The fair values of marketable investments and notes payable are reported in Notes 4 and 5, respectively.

Table of Contents

**UNITED THERAPEUTICS CORPORATION**

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

**2. Summary of Significant Accounting Policies (Continued)**

***Fair Value Measurements***

We include expanded disclosures about fair value measurements pursuant to Financial Accounting Standards Board (FASB) Statement of Financial Accounting Standard (SFAS) No. 157, *Fair Value Measurements* (SFAS 157) which we adopted as of January 1, 2008. SFAS 157 defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. Such transactions to sell an asset or transfer a liability are assumed to occur in the principal or most advantageous market for the asset or liability. Accordingly, fair value as described by SFAS 157 is determined based on a hypothetical transaction at the measurement date, considered from the perspective of a market participant rather than from a reporting entity's perspective. SFAS 157 applies to existing accounting pronouncements that require or permit fair value measurements and does not require any new fair value measurements.

SFAS 157 establishes a three-level fair value hierarchy with respect to the inputs (or assumptions) used in fair value measurements. Observable inputs such as unadjusted quoted market prices for identical assets or liabilities are given the highest priority within the hierarchy (Level 1). When observable inputs are unavailable, SFAS 157 permits the use of unobservable inputs i.e., inputs that a reporting entity believes market participants would use in pricing that are developed based on the best information available. Unobservable inputs are given the lowest priority within the hierarchy (Level 3). The level within the hierarchy at which a fair value measurement lies is determined based on the lowest level input that is significant to the fair value measurement in its entirety. As required by SFAS 157, we have categorized financial assets and liabilities measured at fair value within the fair value hierarchy. Refer to related disclosures at Note 5 of these consolidated financial statements.

***Cash Equivalents***

Cash equivalents consist of highly liquid investments with maturities of three months or less from the date of acquisition and include money market funds, commercial paper, and certificates of deposit. Approximately \$1.0 million at December 31, 2008 and 2007, is subject to a compensating balance arrangement in order to reduce bank-related fees. The related balance, however, is not subject to any withdrawal restrictions.

***Trade Receivables***

Trade receivables are stated at the amount we expect to collect. We establish an allowance for doubtful accounts based on our assessment of the collectability of specific customer accounts.

***Marketable Investments***

We classify debt securities as held-to-maturity when we have the positive intent and ability to hold the securities to maturity. Held-to-maturity securities are recorded as either current or non-current on our consolidated balance sheet based on their contractual maturity dates and are stated at amortized cost, adjusted for the amortization of discounts or premiums. Related discounts and premiums are amortized over the term of held-to-maturity securities as an adjustment to yield using the effective interest method.

Table of Contents**UNITED THERAPEUTICS CORPORATION****Notes to Consolidated Financial Statements (Continued)****2. Summary of Significant Accounting Policies (Continued)**

Debt and equity securities that we may acquire with the intention to sell in the near term are classified as trading securities. Trading securities are recorded at fair value with unrealized gains and losses recognized in earnings.

We classify publicly traded equity investments that we do not intend to hold until maturity or sell in the near term as available-for-sale. Available-for-sale securities are carried at fair value with unrealized gains and losses reported net of tax as a component of comprehensive income within the equity section of the consolidated balance sheet.

We monitor our investment portfolio for impairment quarterly or more frequently if circumstances warrant. In the event that the carrying value of an investment exceeds its fair value and the decline in value is determined to be other-than-temporary, we record an impairment charge within earnings and establish a new cost basis for the investment at its then current fair value. In determining whether a decline in the value of an investment is other-than-temporary, we evaluate available quantitative and qualitative factors. These factors include general market conditions, the duration and extent to which fair value has been less than the carrying value, our intent and ability to hold an affected investment until anticipated recovery in fair value, and the investment issuer's financial condition and business outlook.

***Inventories***

Inventories are stated at the lower of cost (first-in, first-out method) or market (current replacement cost) and consist of the following, net of reserves (in thousands):

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
Remodulin:		
Raw materials	\$ 3,387	\$ 3,364
Work in progress	6,558	4,782
Finished goods	4,085	4,615
Remodulin delivery pumps and medical supplies	194	291
Cardiac monitoring equipment components and supplies	148	159
<b>Total inventories</b>	<b>\$ 14,372</b>	<b>\$ 13,211</b>

Inventories include Remodulin and cardiac monitoring equipment that are formulated and/or produced by third-party manufacturers.

***Goodwill and Other Intangible Assets***

Goodwill represents the excess of purchase price over the fair value of net identifiable assets associated with previous acquisitions. Other intangible assets consist of technology and patents, and are being amortized over their respective estimated useful lives of ten to eighteen years.

We review the carrying value of goodwill for impairment annually during the fourth quarter or more frequently if impairment indicators exist. In determining whether goodwill is impaired, we compare the estimated fair value of the reporting unit to which goodwill has been assigned to its carrying value. We estimate the fair value of a reporting unit by calculating its expected future

Table of Contents**UNITED THERAPEUTICS CORPORATION****Notes to Consolidated Financial Statements (Continued)****2. Summary of Significant Accounting Policies (Continued)**

discounted cash flows based on historical operating results adjusted for anticipated future market and operating conditions. Estimating the fair value of a reporting unit involves judgment particularly as it relates to the determination of expected future cash flows and a discount rate that is reasonable and appropriate in relation to our business profile. If the carrying amount of a reporting unit exceeds its fair value, then the amount of an impairment loss is measured as the excess of the carrying amount of goodwill over its implied fair value.

Intangible assets subject to amortization are reviewed for impairment whenever events or changes in circumstances indicate that an intangible asset's carrying amount may not be recoverable. Impairment losses for other intangible assets are recognized when the undiscounted expected future cash flows associated with an intangible asset are less than the asset's carrying value.

Goodwill and other intangible assets comprised the following (in thousands):

	As of December 31, 2008			As of December 31, 2007		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Goodwill	\$ 7,465	\$	\$7,465	\$ 7,465	\$	\$7,465
Other intangible assets:						
Technology and patents	4,532	(4,159)	373	4,532	(3,570)	962
Total	\$11,997	\$ (4,159)	\$7,838	\$11,997	\$ (3,570)	\$8,427

Total amortization expense for the years ended December 31, 2008, 2007 and 2006, was approximately \$588,000, \$545,000 and \$324,000, respectively. As of December 31, 2008, the aggregate amortization expense related to intangible assets for each of the five succeeding years is estimated as follows (in thousands):

Years ending December 31,	
2009	\$ 153
2010	111
2011	72
2012	30
2013	7
	\$373

Table of Contents

## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## 2. Summary of Significant Accounting Policies (Continued)

*Property, Plant and Equipment*

Property, plant and equipment are recorded at cost and depreciated over their estimated useful lives using the straight-line method. The estimated useful lives of property, plant and equipment by major category are as follows:

Buildings	39 Years
Building improvements	15-39 Years
Furniture, equipment and vehicle	3-15 Years
Holter and event cardiac monitoring systems	3-7 Years
Leasehold improvements	Remaining lease term, or the estimated useful life of the improvement, whichever is shorter

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

	December 31,	
	2008	2007
Land	\$ 11,987	\$ 10,507
Buildings, building improvements and leasehold improvements	61,511	19,203
Buildings under construction	115,022	26,134
Holter and event cardiac monitoring systems	4,552	3,915
Furniture, equipment and vehicle	41,743	19,955
	234,815	79,714
Less accumulated depreciation	(13,749)	(10,360)
Property, plant and equipment, net	\$ 221,066	\$ 69,354

Depreciation expense for the years ended December 31, 2008, 2007 and 2006, was approximately \$3.9 million, \$2.9 million and \$2.4 million, respectively.

Buildings under construction relate to the construction of our facilities in Silver Spring, Maryland, and Research Triangle Park, North Carolina, and are stated at cost, which includes the cost of construction and other direct costs attributable to construction. Depreciation is not recognized on buildings under construction until construction is completed and related assets are available for their intended use. As of December 31, 2008, the estimated costs to complete these facilities were anticipated to be \$93.8 million. We capitalize interest cost incurred on funds used to construct these facilities. During the years ended December 31, 2008 and 2007, we capitalized interest of approximately \$3.1 million and \$689,000, respectively.

*Treasury Stock*

Treasury stock is recorded at cost, including commissions and fees. The cost of treasury shares sold is determined using the first-in, first-out method. Related gains and losses on sales of treasury stock are recognized as adjustments to stockholders' equity.

Table of Contents

**UNITED THERAPEUTICS CORPORATION**

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

**2. Summary of Significant Accounting Policies (Continued)**

***Revenue Recognition***

*General.* Revenue is recognized when realizable and earned. We consider revenue realizable and earned when all of the following criteria have been met: persuasive evidence of an arrangement exists; delivery has occurred; the seller's price to the buyer is fixed or determinable; and collection is reasonably assured.

*Remodulin Sales.* We recognize revenue on sales of Remodulin and related pumps and supplies, upon delivery when title and risk of ownership pass to our distributors. Our distributors do not possess return rights; however, we provide exchange rights in the event that product is damaged during shipment, or has expired. Historically, the financial effects of this exchange right have been immaterial and we expect this trend to continue.

We record sales of Remodulin and related equipment and supplies net of product sales allowances. These sales allowances consist of prompt payment discounts, Medicaid rebates and fees paid to distributors. Calculating these allowances involves the use of significant estimates, judgments and information from external sources. Sales allowances are estimated and recognized as reductions to revenue in the period that associated revenues are recognized. Prompt pay discounts are calculated based on the gross amount of invoices and are recorded on a net basis as our distributors have routinely taken advantage of these discounts. Medicaid rebates are generally invoiced and paid in the subsequent quarter from the date of sale. Accruals and related revenue reductions for Medicaid rebates are based on historical rebate data adjusted for anticipated changes in product sales trends and government rebate programs with regard to eligibility requirements and/or rebate pricing. We pay two of our distributors service fees. Accruals for these fees are estimated based on contracted rates applied to the estimated units of service provided by distributors for a given period.

*Distributor fees and non-refundable license revenues.* Our revenue recognition policy for all non-refundable upfront license and distribution rights fees and milestone arrangements is determined in accordance with the Staff Accounting Bulletin (SAB) No. 101, *Revenue Recognition in Financial Statements*, as amended by SAB No. 104, *Revenue Recognition*, issued by the Securities and Exchange Commission (SEC). In addition, multiple-element revenue arrangements are accounted for pursuant to FASB's Emerging Issues Task Force (EITF) Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables* (EITF 00-21). 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, revenue recognition must be determined for each unit.

Under arrangements where 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 in their entirety, 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 and relates solely to past performance; (2) achievement of the milestone



Table of Contents

**UNITED THERAPEUTICS CORPORATION**

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

**2. Summary of Significant Accounting Policies (Continued)**

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, other milestones in the arrangement and the related risk associated with achievement of the milestone. If any of these conditions is not met, we 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 is deferred and recognized as we complete our performance obligations.

*Telemedicine service and equipment revenue.* Revenues from cardiac monitoring analysis services are recognized when the services are performed. Product sales of cardiac monitoring systems are recognized upon delivery and installation.

***Research and Development***

Research and product development costs are expensed as incurred except for payments made in advance of services to be provided to us. Related expenses consist of internal labor and overhead, costs to acquire pharmaceutical products and product rights for development, materials used in clinical trials and amounts paid to third parties for services and materials relating to drug development and clinical trials.

We recognize the following as research and development expense in the period related costs are incurred:

Costs associated with production activities in our manufacturing facilities prior to receiving FDA approval for such facilities;

Costs incurred in licensing the rights to technologies in the research and development stage that have no alternative future uses; and

Upfront payments made pursuant to license and distribution rights arrangements prior to regulatory approval of the underlying pharmaceutical product absent any alternative future uses.

***Share-Based Compensation***

We account for share-based awards in accordance with SFAS No. 123 (revised 2004), *Share-Based Payment* (SFAS 123R), as interpreted, by SAB 107 and SAB 110 issued by the SEC. For stock option awards, the amount of compensation expense to be recognized is based on the grant date fair value. Related compensation expense is recognized on a straight-line basis over the requisite service period, or vesting period of option awards that are expected to vest. We measure and recognize compensation expense associated with share-based awards issued to nonemployees pursuant to SFAS 123R and EITF Issue No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services*. Share-based awards that require cash settlement upon exercise (share-tracking awards) are classified as a liability. Accordingly, the fair value of related awards is measured at each reporting date until awards are exercised or are otherwise no longer outstanding. Related changes in the fair value of outstanding awards at each reporting date are recognized as share-based compensation expense.

Table of Contents

**UNITED THERAPEUTICS CORPORATION**

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

**2. Summary of Significant Accounting Policies (Continued)**

***Advertising Costs***

Advertising costs are expensed as incurred. Advertising expense recognized during the years ended December 31, 2008, 2007 and 2006, was approximately \$1.2 million, \$1.2 million and \$630,000, respectively.

***Income Taxes***

Income taxes are accounted for in accordance with the asset and liability method set forth under SFAS No. 109, *Accounting for Income Taxes* (SFAS 109). Accordingly, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their tax bases. Deferred tax assets and liabilities are measured using the enacted tax rates that are expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in the period that includes the enactment date. Deferred tax assets are reduced by a valuation allowance when, in our opinion, it is more likely than not that some or all of the deferred tax assets will not be realized.

We account for uncertain tax positions pursuant to FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* an *Interpretation of FASB Statement No. 109*. Financial statement recognition of a tax position taken or expected to be taken in a tax return is determined based on a more likely than not threshold of that position being sustained. If the tax position meets this threshold, the benefit to be recognized is measured as the largest amount that is more than 50 percent likely to be realized upon ultimate settlement. It is our policy to record interest and penalties related to uncertain tax positions as a component of income tax expense.

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

Basic (loss) earnings per share is computed by dividing net (loss) income by the weighted average number of shares of common stock outstanding during the period. Diluted earnings per common share is computed by dividing net income by the weighted average number of shares of common stock outstanding during the period, plus the potential dilutive effect of other securities if such securities were converted or exercised. During periods in which we incur net losses, weighted average shares outstanding exclude potentially dilutive securities, because their effect would be anti-dilutive.

***Concentrations of Credit Risk, Suppliers, Products, Revenues and Customers***

***Concentration of credit risk.*** Financial instruments that are exposed to credit risk consist of cash, money market funds, commercial paper, marketable investments, and trade receivables. We maintain our cash and money market funds with financial institutions that are federally insured. While balances deposited in these institutions often exceed Federal Deposit Insurance Corporation limits, we have not experienced any losses on related accounts to date. Furthermore, we limit our risk exposure by maintaining funds in substantial financial institutions that we believe are creditworthy and financially sound. Our investments in commercial paper and marketable debt investments have been issued by corporate, state and local government agencies and federally-sponsored agencies. We mitigate the risks associated with holding these types of securities by investing in only highly-rated securities with relatively short maturities that we believe do not involve a significant degree of risk. At any given period, our trade receivables are concentrated among a small number of principal customers. If any of

Table of Contents

## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

**2. Summary of Significant Accounting Policies (Continued)**

these financial institutions, issuers or customers failed to perform their obligations under the terms of these financial instruments, our maximum exposure to potential losses would approximate amounts reported on our consolidated balance sheets.

*Concentration of suppliers.* We currently rely on a single supplier to perform stability studies on Remodulin, formulate treprostinil in both oral and inhaled forms, and analyze other products we are developing. In addition, Remodulin is formulated and packaged by a single producer and our cardiac monitoring devices are produced by one manufacturer. Although our current suppliers could be replaced, we believe that a change in suppliers could disrupt the distribution of Remodulin and other products and services, and impede the progress of clinical trials and commercial launch.

*Concentration of products, revenues and customers.* During the years ended December 31, 2008, 2007 and 2006, sales of Remodulin accounted for approximately 96%, 95% and 96%, respectively, of our total net revenues. Net sales of Remodulin in the United States to our three distributors comprised approximately 89%, 88% and 90%, respectively, of such revenues. At December 31, 2008 and 2007, approximately 79% and 84%, respectively, of accounts receivable were due from these distributors. While we rely on our distributors to market Remodulin, there are several other qualified distributors that could replace any one of our current distributors.

During the year ended December 31, 2008, we derived approximately 74% of our total net domestic revenues and approximately 69% of our total net Remodulin revenues from one customer in our pharmaceutical segment. Gross revenues from that customer are as follows (in thousands):

	Years Ended December 31,		
	2008	2007	2006
Accredo Therapeutics, Inc.	\$ 184,865	\$ 136,975	\$ 101,584

**3. Recently Issued Accounting Standards**

In May 2008, the FASB issued Staff Position APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash Upon Conversion (Including Partial Cash Settlement)* (FSP APB 14-1). FSP APB 14-1 applies to certain convertible debt instruments that may be settled in cash or other assets, or partially in cash, upon conversion. Issuers of such instruments are required under FSP APB 14-1 to account for the liability and equity components separately in a manner that reflects the issuer's nonconvertible debt borrowing rate when interest expense is subsequently recognized. Specifically, FSP APB 14-1 requires the difference between the convertible debt proceeds and the fair value of the liability, absent any conversion rights, to be assigned to the equity component and recognized as part of stockholders' equity and as a discount for determining the carrying value of the debt. The discounted carrying value of the debt is amortized as interest expense using the interest method over the expected life of the debt. FSP APB 14-1 is effective for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years and is to be applied retrospectively to all periods presented. Our 0.50% Convertible Senior Notes due October 2011 (Convertible Senior Notes) fall within the scope of FSP APB 14-1 see Note 9 to these consolidated financial statements. While adoption of FSP APB 14-1 will not change the cash flow requirements of our Convertible Senior Notes, non-cash interest expense associated with the amortization of the discount on the Convertible Senior Notes is expected to increase significantly. Upon the adoption of FSP APB 14-1, we will no longer recognize interest expense based on the Convertible Senior Notes' stated rate of interest.

Table of Contents

## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## 3. Recently Issued Accounting Standards (Continued)

The expected impact of the retrospective application of FSP APB 14-1 from the period of issuance (October 2006) through the end of the Senior Convertible Notes' expected life excluding any effects of capitalized interest and income taxes is shown below (in thousands):

Year Ended December 31,	Interest Expense Based on the Stated Rate of Interest	Interest Expense Under FSP APB 14-1	Incremental Impact of Adoption of FSP APB 14-1
2006	\$ 208	\$ 2,227	\$ 2,019
2007	1,250	13,533	12,283
2008	1,250	14,696	13,446
2009	1,250	15,723	14,473
2010	1,250	16,829	15,579
2011(1)	1,042	15,104	14,062
<b>Total</b>	<b>\$ 6,250</b>	<b>\$ 78,112</b>	<b>\$ 71,862</b>
Debt Discount and equity component to be recognized under FSP APB 14-1	N/A	N/A	\$ 71,862

(1)

Through October 2011, the end of the expected life of the Convertible Senior Notes.

In June 2008, the FASB issued EITF Issue No. 07-5, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock* (EITF 07-5). EITF 07-5 supersedes EITF Issue No. 01-6, *The Meaning of 'Indexed to a Company's Own Stock'*, and provides guidance in evaluating whether certain financial instruments or embedded features can be excluded from the scope of SFAS 133, *Accounting for Derivatives and Hedging Activities* (SFAS 133). EITF 07-5 sets forth a two-step approach that evaluates an instrument's contingent exercise and settlement provisions for the purpose of determining whether such instruments are indexed to an issuer's own stock (a requirement necessary to comply with the scope exception under SFAS 133). EITF 07-5 will be effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. We are currently assessing the impact related to the adoption of EITF 07-5 on our financial instruments that fall within its scope.

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles* (SFAS 162). SFAS 162 identifies sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements of non-governmental entities that are presented in conformity with GAAP (GAAP Hierarchy). SFAS 162 became effective November 15, 2008. Adoption of SFAS 162 did not impact our consolidated financial statements.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities - an Amendment of FASB Statement No. 133* (SFAS 161). SFAS 161 requires companies to provide enhanced disclosures regarding derivative instruments and hedging activities and requires companies to better convey the purpose of derivative use in terms of the risks they intend to manage. Disclosures required under SFAS 161 include: (a) how and why a company uses derivative instruments; (b) how derivative instruments and related hedged items are accounted for under SFAS 133 and its related interpretations; and (c) how derivative instruments and related hedged items affect a company's financial position, financial performance, and cash flows. SFAS 161 retains the same

Table of Contents

**UNITED THERAPEUTICS CORPORATION**

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

**3. Recently Issued Accounting Standards (Continued)**

scope as SFAS 133 and is effective for fiscal years and interim periods beginning after November 15, 2008. We do not expect the adoption of SFAS 161 to have a material impact, if any, on our consolidated financial statements.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements - an amendment of ARB No. 51* (SFAS 160). SFAS 160 establishes accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. This statement is effective, prospectively, for fiscal years beginning after December 15, 2008, except for certain retrospective disclosure requirements. We do not expect the adoption of SFAS 160 to have any impact on our consolidated financial statements upon initial adoption.

In December 2007, the FASB issued SFAS No. 141 (Revised 2007), *Business Combinations - a replacement of FASB Statement No. 141* (SFAS 141R). SFAS 141R significantly changes the principles and requirements for how the acquirer of a business recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree. SFAS 141R also provides guidance for recognizing and measuring goodwill acquired in a business combination and determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of a business combination. SFAS 141R is effective, prospectively, for fiscal years beginning after December 15, 2008, except for certain retrospective adjustments to deferred tax balances. The potential impact of adopting SFAS 141R on our consolidated financial statements will depend on whether we enter into any future acquisitions and the magnitude of such acquisitions.

In June 2007, the FASB issued EITF Issue No. 07-1, *Accounting for Collaboration Arrangements Related to the Development and Commercialization of Intellectual Property* (EITF 07-1). EITF 07-1 provides guidance on how the parties to a collaborative agreement should account for costs incurred and revenue generated on sales to third parties and how sharing payments pursuant to a collaboration agreement should be presented in the income statement. EITF 07-1 will be effective for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years and shall be applied retrospectively. We are assessing the potential impact, if any, the adoption of EITF 07-1 will have on our consolidated financial statements.

Table of Contents

## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## 4. Marketable Investments

*Held-to-maturity Investments*

Marketable investments classified as held-to-maturity consist of the following (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Government sponsored enterprises at December 31, 2008	\$ 154,115	\$ 1,718	\$ (18)	\$ 155,815
Corporate notes and bonds at December 31, 2008	53,509	140	(151)	53,498
<b>Total</b>	<b>\$ 207,624</b>	<b>\$ 1,858</b>	<b>\$ (169)</b>	<b>\$ 209,313</b>

As reported on the consolidated balance sheet at December 31, 2008:

Current marketable securities	\$ 106,596
Noncurrent marketable securities	101,028
<b>Total</b>	<b>\$ 207,624</b>

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Government sponsored enterprises at December 31, 2007	\$ 66,905	\$ 103	\$ (214)	\$ 66,794
Corporate notes and bonds at December 31, 2007	74,082	38	(15)	74,105
<b>Total</b>	<b>\$ 140,987</b>	<b>\$ 141</b>	<b>\$ (229)</b>	<b>\$ 140,899</b>

As reported on the consolidated balance sheet at December 31, 2007:

Current marketable securities	\$ 96,223
Noncurrent marketable securities	44,764
<b>Total</b>	<b>\$ 140,987</b>

Certain held-to-maturity investments have been pledged as collateral to Wachovia Development Corporation under the laboratory lease described in Note 10 to these consolidated financial statements, and are classified as restricted marketable investments and cash on our consolidated balance sheets as of December 31, 2008 and 2007.

Table of Contents

## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## 4. Marketable Investments (Continued)

The following table summarizes gross unrealized losses and the length of time marketable investments have been in a continuous unrealized loss position (in thousands):

	December 31,		2007	
	2008			
	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss
Government sponsored:				
Less than one year	\$ 9,886	\$ (18)	\$	\$
Greater than one year			35,765	(214)
	9,886	(18)	35,765	(214)
Corporate notes:				
Less than one year	21,278	(151)	17,197	(15)
Greater than one year				
	21,278	(151)	17,197	(15)
Total	\$31,164	\$ (169)	\$52,962	\$ (229)

We attribute the unrealized losses on held-to-maturity securities as of December 31, 2008 and 2007, to the variability in related market interest rates. We invest in debt securities that we believe possess low risk profiles and have the ability and intent to hold these investments until maturity. As such, we do not consider these investments to be other-than-temporarily impaired.

The following table summarizes the contractual maturities of held-to-maturity marketable investments at December 31, 2008 (in thousands):

	December 31, 2008	
	Amortized Cost	Fair Value
Due in less than one year	\$ 106,596	\$ 107,146
Due in one to two years	101,028	102,167
Due in three to five years		
Due after five years		
Total	\$207,624	\$209,313

*Available-for-sale Investments*

Through November 2008, marketable investments we classified as available-for-sale consisted of auction-rate securities issued by state and local government sponsored agencies (ARS). In November of 2008, we made a one-time transfer of available-for-sale securities to the trading classification as discussed below. The ARS maintain an AAA credit rating and are secured by pools of student loans that are approximately 91% insured by the federal government. Historically, these securities provided liquidity to investors through their interest rate reset feature i.e., interest rates on these securities are reset through a bidding process (or auction) at frequent, pre-determined intervals. At each reset date, investors could either rollover and maintain their holdings or liquidate them at par value. Prior to





Table of Contents

**UNITED THERAPEUTICS CORPORATION**

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

**4. Marketable Investments (Continued)**

February 2008, the fair value of the ARS was equal to their par value. Since February 2008, auctions related to the ARS have failed as a result of the deterioration of the credit markets, rendering these securities illiquid. Consequently, the fair value of the ARS has been estimated using both a discounted cash flow (DCF) analysis and a market comparables method. Both methods have been given equal weight in estimating the fair value of the ARS.

We consider market data pricing because we believe that it provides relevant information as to the extent similar securities are currently being discounted upon sale. While we do not believe that all of these transactions result from distressed or forced sales, the use of such market-related data to estimate the fair value of the ARS involves a significant degree of judgment. As such, we also rely equally on a DCF model to support our estimation of fair value.

The key assumptions to the DCF model are subjective and include the following: a reference, or benchmark rate of interest based on the London Interbank Offered Rate (LIBOR), the amounts and timing of cash flows, and the weighted average expected life of a security and its underlying collateral. In addition, the model considers the risks associated with the creditworthiness of the issuer, the quality of the collateral underlying the investment and illiquidity. The benchmark interest rate is then adjusted upward depending on the degree of risk associated with each security within our auction-rate portfolio. We have estimated the illiquidity premium based on an analysis of the average discounts relating to sales of comparable auction-rate securities within the secondary market.

On November 13, 2008, we entered into an Auction Rate Securities Rights Offer (Rights Offer) with the investment firm that maintains our ARS account. Pursuant to the Rights Offer, we can sell our holdings of ARS to the investment firm for a price equal to the par value of the securities (\$36.8 million) at any time between June 30, 2010 and July 2, 2012 (Put Option). In addition, at any time through July 2, 2012, the investment firm, acting as principal, can purchase the ARS from us or sell the securities on our behalf provided that the par value of the ARS is deposited in our account on the next business day following settlement of the transaction. To help meet any immediate liquidity needs, the Rights Offer provides that we can borrow up to the par value of the ARS. Interest on related borrowings will generally be equal to the then-applicable interest paid by the issuers of the ARS. We do not expect to borrow against the value of the ARS.

The Put Option represents a freestanding, non-transferable financial instrument that is initially measured and recorded at fair value and accounted for separately from the ARS. Because the Put Option does not meet the definition of a derivative under SFAS 133, it is not subsequently adjusted for changes in its fair value. In substance, however, the Put Option acts as a hedge to protect against the future decline in fair value of the ARS. To better account for the substance of the arrangement, we believe that the future changes in the fair value of the Put Option should be recognized in order to offset subsequent price movements of the ARS. Therefore, we elected the fair value option set forth in SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an amendment of FASB Statement No. 115* (SFAS 159), to account for the Put Option. Under SFAS 159, all subsequent changes in fair value of the Put Option will be recognized in earnings. Approximately \$7.7 million representing the fair value of the Put Option at December 31, 2008, was recognized within other non-current assets on our consolidated balance sheet. We recognized a corresponding gain during the year ended December 31, 2008, associated with the fair value of the Put Option within other income on our consolidated statement of operations. Since there is not an observable market for the Put Option, its fair value has been estimated using significant unobservable inputs. Accordingly, the fair

Table of Contents

**UNITED THERAPEUTICS CORPORATION**

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

**4. Marketable Investments (Continued)**

value of the Put Option has been included as a Level 3 asset within the SFAS 157 hierarchy (See Note 5 of these consolidated financial statements for related disclosures).

We employed a DCF model to estimate the fair value of the Put Option. We believe that the estimated value of the Put Option represents the incremental value associated with the ability to recover the full cost of the ARS significantly earlier than would be otherwise possible, if at all, and the ability to obtain an immediate loan under the Rights Offer, as this right possesses value regardless of whether we expect to borrow under the Rights Offer. Key assumptions used in the DCF model are judgmental and include the following:

A discount factor equal to the rate of interest consistent with the expected term of the Put Option and risk profile of the investment firm subject to the Put Option;

Amount and timing of expected cash flows;

Expected life of the Put Option prior to its exercise; and

Assumed loan amounts.

The DCF methodology considered two scenarios. The first scenario assumed that we would borrow up to 50% of the ARS and the second scenario assumed that we would borrow up to 75% of the ARS. Under the DCF analysis, increases in the assumed loan balance would result in an increase in the fair value of the Put Option because the risk of counterparty non-performance diminishes. The estimated fair values generated under both scenarios were given equal weight in determining the pricing of the Put Option.

Concurrent with the acceptance of the Rights Offer, we made a one-time transfer of the ARS from the available-for-sale classification to the trading classification. Given the unprecedented circumstances underlying the transfer i.e., the collapse of the credit markets and the unique nature of the Rights Offer we believe that such a transfer is in accordance with the guidance provided under SFAS No. 115 *Accounting for Certain Investments in Debt and Equity Securities*, regarding transfers into the trading category. We made this one-time transfer so that the changes in the fair value of both the ARS and the Put Option will be recognized in a consistent manner, since we elected the fair value option to account for the Put Option. Consequently, all changes in fair value of the ARS subsequent to the transfer will be recognized within earnings. Because we do not believe it is likely that the ARS will be liquidated or otherwise disposed of within the next 12 months, the securities have been classified within non-current marketable investments on our consolidated balance sheet at December 31, 2008.

Prior to November 2008, we characterized and accounted for the declines in the fair value of the ARS as temporary. We supported this determination in large part by our intent and ability to hold the ARS until the credit markets stabilized sufficiently to allow us to liquidate the securities without realizing significant losses. Accordingly, related unrealized losses had been recorded as a component of equity within other comprehensive income. By entering into the Rights Offer, however, we can no longer demonstrate the positive intent to hold these securities indefinitely. As such, we recognized within earnings an other-than-temporary impairment charge of approximately \$6.3 million during the fourth quarter of 2008 associated with all previously accumulated unrealized losses relating to the ARS.

Table of Contents

## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## 4. Marketable Investments (Continued)

Available-for-sale investments consist of the following (in thousands):

	Amortized Cost Or Par Value	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Municipal notes at December 31, 2008	\$	\$	\$	\$
Municipal notes at December 31, 2007	\$ 54,000	\$	\$	\$ 54,000

Proceeds, realized gains and losses from sales of available-for-sale investments are as follows (in thousands):

	Years Ended December 31,		
	2008	2007	2006
Gross proceeds	\$31,850(1)	\$58,050	\$86,400
Realized gains	\$	\$	\$
Realized losses	\$	\$	\$

(1)

Gross proceeds on sales of ARS at par from January 1, 2008 through February 29, 2008

For purposes of determining gross realized gains and losses on sales of available-for-sale investments, the cost of securities sold is determined by specific identification.

During the year ended December 31, 2008, approximately \$6.3 million in gross losses (recognized as an other-than-temporary impairment) was reclassified from accumulated other comprehensive income to earnings upon acceptance of the Rights Offer in November 2008.

**Trading Investments**

During the fourth quarter of 2008, we made a one-time transfer of ARS we classified as available-for-sale into the trading category.

Trading securities consisted of the following (in thousands):

	Amortized Cost Or Par Value	Gross Trading Gains	Gross Trading Losses	Other Than Temporary Impairment	Estimated Fair Value
Municipal notes at December 31, 2008	\$ 36,750	\$	\$ (2,466)	\$ (6,308)	\$ 27,976
Municipal notes at December 31, 2007	\$	\$	\$	\$	\$

F-23

Table of Contents

**UNITED THERAPEUTICS CORPORATION**

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

**4. Marketable Investments (Continued)**

*Equity Investments*

Equity holdings consist of our investment in ViRexx Medical Corp. (ViRexx) and Twin Butte Energy Ltd (Twin Butte). Both of these investments were acquired in connection with our license agreements for the rights to the ViRexx platform of antibodies to treat various forms of cancer. Based on the results of the clinical trials related to these antibodies, we discontinued development of this platform in November 2007. Equity investments are accounted for as available-for-sale securities and are reported at their fair values, based on quoted market prices.

Because of the continued decline in the price of ViRexx's common stock and ViRexx's filing for bankruptcy during 2008, we recognized an other-than-temporary impairment loss of \$505,000 during the year ended December 31, 2008 to write off the remaining basis of our investment. The fair value of our investment in Twin Butte was \$97,000 and \$398,000 as of December 31, 2008 and 2007, respectively. We own less than 1% of Twin Butte.

In August 2008, we invested \$5.0 million in Transoma Medical, Inc. (Transoma), a privately owned corporation, in exchange for approximately 1.5 million shares of Transoma's Series D preferred stock. Our investment represents an ownership interest of approximately 3.5% in Transoma. We account for our investment in Transoma at cost as the fair value of these equity securities is not readily determinable.

**5. Fair Value Measurements**

Effective January 1, 2008, we adopted the provisions of SFAS 157. SFAS 157 defines fair value, establishes a fair value hierarchy for assets and liabilities measured at fair value and requires expanded disclosures about fair value measurements. Adoption of SFAS 157 did not have any impact on our consolidated financial position or results of operations. The SFAS 157 hierarchy ranks the quality and reliability of inputs, or assumptions, used in the determination of fair value and requires assets and liabilities carried at fair value to be classified and disclosed in one of the following categories based on the lowest level input used that is significant to a particular fair value measurement:

Level 1 Fair value is determined by using unadjusted quoted prices that are available in active markets for identical assets and liabilities.

Level 2 Fair value is determined by using inputs other than Level 1 quoted prices that are directly or indirectly observable. Inputs can include quoted prices for similar assets and liabilities in active markets or quoted prices for identical assets and liabilities in inactive markets. Related inputs can also include those used in valuation or other pricing models such interest rates and yield curves that can be corroborated by observable market data.

Level 3 Fair value is determined by inputs that are unobservable and not corroborated by market data. Use of these inputs involves significant and subjective judgments to be made by a reporting entity--e.g., determining an appropriate adjustment to a discount factor for illiquidity associated with a given security.

We have deferred the application of the provisions of SFAS 157 to our non-financial assets and liabilities in accordance with FASB Staff Position No. FAS 157-2, *Effective Date of FASB Statement No. 157* (FSP FAS 157-2), issued in February 2008. FSP FAS 157-2 defers the effective date of SFAS 157 to fiscal years beginning after November 15, 2008, and interim periods within those fiscal years for non-financial assets and liabilities, except those that are recognized or disclosed at fair value

Table of Contents

## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## 5. Fair Value Measurements (Continued)

in the financial statements on a recurring basis (at least annually). Fair value measurements within the scope of this deferral include those associated with goodwill impairment assessments, non financial assets acquired or liabilities assumed in business combinations and impairment evaluations of other long-lived assets. We expect the adoption of FSP FAS 157-2 will result in additional fair value disclosures, but will not impact our consolidated financial statements.

In October 2008, the FASB issued Staff Position No. 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset is Not Active* (FSP 157-3). FSP 157-3 clarifies the application of SFAS 157 to financial assets for which an active market does not exist. Specifically, FSP 157-3 addresses the following issues: (1) how a reporting entity's own assumptions should be considered in measuring fair value when observable inputs do not exist; (2) how observable inputs in inactive markets should be considered when measuring fair value; and (3) how the use of market quotes should be considered when assessing the relevance of inputs available to measure fair value. FSP 157-3 applies to financial assets within the scope of accounting pronouncements that require or permit fair value measurements in accordance with SFAS 157 and was effective upon issuance. Adoption of FSP 157-3 did not materially affect our methodology for determining Level 3 pricing.

We evaluate financial assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level at which to classify them each reporting period. This determination requires us to make subjective judgments as to the significance of inputs used in determining fair value and where such inputs lie within the SFAS 157 hierarchy.

Financial assets and liabilities subject to fair value measurements were as follows (in thousands):

	As of December 31, 2008			
	Level 1	Level 2	Level 3	Balance
<b>Assets</b>				
Auction-rate securities(1)	\$	\$	\$27,976	\$ 27,976
Equity securities	97			97
Put Option (See Note 4 to the consolidated financial statements)			7,685	7,685
Money market funds(2)	96,179			96,179
Federally-sponsored and corporate debt securities(3)		209,313		209,313
<b>Total Assets</b>	<b>\$ 96,276</b>	<b>\$ 209,313</b>	<b>\$ 35,661</b>	<b>\$ 341,250</b>
<b>Liabilities</b>				
Convertible Senior Notes	\$239,429	\$	\$	\$239,429

(1) Included in non-current marketable investments on the accompanying consolidated balance sheet. To validate the reasonableness of Level 3 pricing, we perform a sensitivity analysis that contemplates various scenarios. Our method for estimating the fair value of these securities incorporates the assumptions that we believe market participants would consider in pricing these securities. Differing viewpoints regarding the assumptions market participants would use in pricing, or different valuation methodologies, could result in fair value measurements that differ materially.

(2) Included in cash and cash equivalents and marketable investments and cash restricted on the accompanying consolidated balance sheet.

Table of Contents

## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## 5. Fair Value Measurements (Continued)

- (3) Included in current and non-current marketable investments on the accompanying consolidated balance sheet. The fair value of these securities is derived from pricing models using observable market data, including interest rates, yield curves, recently reported trades of comparable securities, credit spreads and benchmark securities.

The tables below provide a reconciliation of the beginning and ending balances of assets measured at fair value using significant unobservable inputs (Level 3) for the year ended December 31, 2008 (in thousands):

	Auction-rate Securities	Auction-rate Securities Put Option	Total
Balance January 1, 2008	\$	\$	\$
Transfers to (from) Level 3	36,750		36,750
Total gains/(losses) realized/unrealized included in earnings(4)	(8,774)		(8,774)
Total gains/(losses) included in other comprehensive income			
Purchases/issuances/settlements, net		7,685	7,685
Balance December 31, 2008	\$ 27,976	\$ 7,685	\$ 35,661

- (4) Includes total losses of \$2,466 for the year ended December 31, 2008 attributable to the change in unrealized losses relating to trading securities still held at December 31, 2008 (recognized within other income)

## 6. Investment in Northern Therapeutics, Inc.

We own approximately 68% of the outstanding common stock of Northern Therapeutics, Inc. (Northern). Northern was formed in 2000 to develop a particular form of gene therapy for the treatment of PAH and to distribute Remodulin and our other products in Canada. Although we own a majority of Northern's outstanding common stock, we may appoint only two of the Northern's seven board seats. Substantially all of Northern's key business decisions require unanimous consent from its board including decisions related to personnel selection and compensation and the establishment of operating and capital budgets. As such, the minority owners of Northern have substantive participating rights as described in EITF Issue No. 96-16, *Investors' Accounting for an Investee when the Investor has a Majority of the Voting Interest but the Minority Shareholder or Shareholders Have Certain Approval or Veto Rights*. As a result of these substantive participating rights, we do not control Northern; therefore, consolidation is prohibited. We account for our investment in Northern under the equity method and as such, the related investment balance is adjusted for our cumulative share in Northern's losses. At December 31, 2008, the investment balance is approximately \$1.0 million and has been included within other non-current assets on our consolidated balance sheet as of December 31, 2008.

Table of Contents**UNITED THERAPEUTICS CORPORATION****Notes to Consolidated Financial Statements (Continued)****6. Investment in Northern Therapeutics, Inc. (Continued)**

Summarized financial information for Northern is presented below (in thousands):

	As of, and for the Year ended December 31,		
	2008	2007	2006
Total assets	\$ 904	\$ 1,404	\$ 1,576
Total liabilities	\$ 83	\$ 31	\$ 111
Total revenues	\$ 284	\$ 485	\$ 1,434
Net loss	\$(331)	\$ (469)	\$ (718)

We are also party to a license agreement with Northern as described in Note 15 to these consolidated financial statements.

**7. Accrued Expenses**

Accrued expenses consisted of the following (in thousands):

	December 31,	
	2008	2007
Royalties and rebates	\$ 10,640	\$ 8,481
Payroll related	6,727	5,981
Research related	1,930	1,617
Other	1,556	1,863
<b>Total</b>	<b>\$ 20,853</b>	<b>\$ 17,942</b>

**8. Share Tracking Awards Plan**

On June 2, 2008, our Board of Directors (the Board) adopted the United Therapeutics Corporation Share Tracking Awards Plan (STAP). The maximum number of awards that can be granted under the STAP subject to adjustment for specified events is 3,000,000. Awards under the STAP convey the right to receive an amount in cash equal to the appreciation in our common stock (Awards), which is calculated as the positive difference between the closing price of our common stock on the date of grant and the date of exercise (the Appreciation). The Compensation Committee of the Board (the Administrator) has the sole authority to grant Awards to STAP participants and determine related terms. Unless otherwise determined by the Administrator, Awards generally vest in one-third increments on each of the first three anniversaries of the grant date and expire on the tenth anniversary of the grant date. Upon the exercise of a vested Award, participants are entitled to receive the Appreciation in cash. The STAP does not permit Awards to be settled through the issuance of our common stock. Any expired, canceled, or forfeited Awards may be subsequently used for future grants. Our Board has the authority to amend, alter, or terminate the STAP at any time.

On November 24, 2008, the Administrator amended the exercise price of outstanding Awards to \$50.63, the closing price of our common stock on that date. This amendment was subsequently ratified by the Board on December 3, 2008. A total of 1,811,482 outstanding Awards with a weighted average exercise price of \$102.57 were repriced. All other terms and conditions of the Awards remained unchanged after their repricing. The modification to the Awards did not affect the manner in which we are recognizing our obligation and related share-based compensation expense as described below.

Table of Contents

**UNITED THERAPEUTICS CORPORATION**

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

**8. Share Tracking Awards Plan (Continued)**

In accordance with SFAS 123R, we account for and classify Awards as a liability, as we are required to pay cash to participants upon exercise. Accordingly, we estimate the fair value of the Awards using the Black-Scholes-Merton valuation model and re-measure the fair value of outstanding Awards at each quarterly reporting date until settlement occurs or Awards are otherwise no longer outstanding. The fair value of outstanding Awards is recognized as a current liability on our consolidated balance sheet adjusted for the percentage of the requisite service period that has been rendered prior to the fulfillment of the vesting requirement. As of December 31, 2008, the STAP liability balance was approximately \$8.5 million. The change in the fair value of outstanding Awards at each reporting date is recognized as compensation expense on our consolidated statement of operations.

In estimating the fair value of our Awards, we are required to use subjective assumptions that can materially impact the estimation of fair value and related compensation. These assumptions include the expected volatility of our common stock, risk-free interest rate, expected term of Awards, expected forfeiture rate and the expected dividend yield. We also consider the impact of our credit risk when estimating the fair value of Awards due to the STAP's cash settlement provision.

A description of the key inputs used in estimating the fair value of the Awards is provided below:

*Expected volatility* Volatility is a measure of the amount the price of our common stock has fluctuated (historical volatility) or is expected to fluctuate (expected volatility) during a period. We use historical volatility based on weekly price observations of our common stock during the period immediately preceding an Award that is equal to the expected term of an Award (up to a maximum of five years). We believe the volatility in the price of our common stock over the preceding five years provides the best representation of future long term volatility.

*Risk-free interest rate* The risk-free interest rate 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 an Award.

*Expected term of Awards* An Award's expected term reflects the estimated time period we expect an Award to remain outstanding. We apply the provisions of SAB No. 107, as amended by SAB No. 110, regarding the use of the simplified method in developing an estimate of the expected term. We employ this methodology for estimating the expected term of Awards until such time that more refined estimates based on historical exercise behavior of the Awards can be established

*Expected forfeiture rate* The expected forfeiture rate is an estimated percentage of Awards granted that are expected to be forfeited or canceled on an annual basis prior to becoming fully vested. We derive our estimate based on historical forfeiture experience of our stock options for similar classes of employees. We expect forfeiture experience with respect to Awards to be materially comparable to that of our stock options, which contain similar terms and conditions.

*Expected dividend yield* We do not pay dividends on our common stock and do not expect to do so in the future. Therefore, the dividend yield is assumed to be zero.



Table of Contents

## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## 8. Share Tracking Awards Plan (Continued)

The table below presents the assumptions used to re-measure the fair value of Awards at December 31, 2008:

Expected volatility	48.0%
Risk-free interest rate	1.6%
Expected term of options (in years)	5.6
Forfeiture rate	6.3%
Expected dividend	0.0%

A summary of the status and activity of the STAP is presented below:

	Number of Awards	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in 000s)
Outstanding at June 2, 2008 (effective date of the STAP)		\$		
Granted	1,831,265	50.64		
Exercised				
Forfeited	(19,767)	50.63		
Canceled				
Outstanding at end of period	1,811,498	\$ 50.64	9.6	\$ 21,583
Awards exercisable at December 31, 2008		\$		\$
Awards expected to vest at December 31, 2008	1,697,220	\$ 50.64	9.6	\$ 20,214

The weighted average fair value of Awards granted from the period beginning June 2, 2008, and ending December 31, 2008, was \$32.25. As of December 31, 2008, we had approximately \$46.2 million of unrecognized compensation expense related to unvested Awards, which we expect to recognize over a period of 2.6 years. Unrecognized compensation cost has been estimated using the fair value of Awards, which is based in large part on the price of our common stock, as of December 31, 2008. As we subsequently re-measure the fair value of outstanding Awards at future quarterly reporting dates, the amount of compensation expense may vary significantly.

Share-based compensation expense relating to the STAP was as follows (in thousands):

	Period from June 2, 2008 to December 31, 2008
Cost of service sales	\$ 17
Research and development	3,463
Selling, general and administrative	4,965
Share-based compensation expense before taxes	8,445
Related income tax benefits	(3,378)
Share-based compensation expense, net of taxes	\$ 5,067
	\$ 72

Total share-based compensation expense capitalized in  
inventory

F-29

---

Table of Contents

**UNITED THERAPEUTICS CORPORATION**

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

**9. Debt**

*Convertible Senior Notes*

On October 30, 2006, we issued at par value \$250.0 million of Convertible Senior Notes. In connection with the issuance of the Convertible Senior Notes, we also entered into a call spread option (see Note 11 to these consolidated financial statements). We pay interest on the Convertible Senior Notes in arrears semi-annually on April 15 and October 15 of each year. The Convertible Senior Notes are unsecured, unsubordinated obligations that rank equally with all of our other unsecured and unsubordinated indebtedness. The initial conversion price is \$75.2257 per share. Conversion can occur: (i) anytime after July 15, 2011; (ii) during any calendar quarter that follows a calendar quarter in which the price of our common stock exceeded 120% of the initial conversion price for at least 20 days during the 30 consecutive trading day period ending on the last trading day of the quarter (the Conversion Determination); and (iii) during the ten consecutive trading-day period following any five consecutive trading-day period in which the trading price of the Convertible Senior Notes was less than 95% of the closing price of our common stock multiplied by the then current conversion rate; or (iv) upon specified distributions to our shareholders, corporate transactions, or in the event that our common stock ceases to be listed on the NASDAQ Global Select Market (NASDAQ) and is not listed for trading on another U.S. national or regional securities exchange.

Upon conversion, a Convertible Senior Note holder (Note Holder) will receive: (i) cash equal to the lesser of the principal amount of the note or the conversion value (equal to the number of shares underlying the Convertible Senior Notes multiplied by the then current conversion price per share); and (ii) to the extent the conversion value exceeds the principal amount of the note, shares of our common stock. In the event of a change in control, as defined in the indenture under which the Convertible Senior Notes have been issued, Note Holders may require us to purchase all or a portion of their Convertible Senior Notes for 100% of the principal plus accrued and unpaid interest, if any, plus shares of our common stock.

For the quarter ended December 31, 2007, our stock price exceeded the requirements of the Conversion Determination; therefore, our Convertible Senior Notes were eligible for conversion by Note Holders in the subsequent quarter. Consequently, our Convertible Senior Notes have been presented as a current liability on our consolidated balance sheet as of December 31, 2007. For the quarter ending December 31, 2008, our stock price did not meet Conversion Determination requirements; therefore, our Convertible Senior Notes were not eligible for conversion by Note Holders in the subsequent quarter. Accordingly, the Convertible Senior Notes have been presented as a non-current liability on our consolidated balance sheet as of December 31, 2008.

The Convertible Senior Notes fall within the scope of FSP APB 14-1 which will be effective for us beginning January 1, 2009. FSP APB 14-1 must be retrospectively applied and we expect the impact of adopting FSP APB 14-1 will be material as discussed in Note 3 to these consolidated financial statements.

Table of Contents

## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

**9. Debt (Continued)***Interest Expense*

Details of interest expense have been presented below (in thousands):

	Year Ended December 31,	
	2008	2007
Interest expense	\$ 3,122	\$2,864
Capitalized interest(1)	(3,106)	(689)
<b>Total</b>	<b>\$ 16</b>	<b>\$2,175</b>

(1)

Interest associated with the construction of our facilities in Maryland and North Carolina.

**10. Commitments and Contingencies***Lease Obligation*

We currently lease a laboratory facility in Silver Spring, Maryland (Phase I Laboratory), pursuant to a synthetic lease arrangement (Lease) entered into in June 2004 with Wachovia Development Corporation and its affiliates (Wachovia). Under the Lease, Wachovia funded \$32.0 million toward the construction of the Phase I Laboratory on land we own. Subsequent to the completion of construction in May 2006, Wachovia leased the Phase I Laboratory to us. Monthly rent is equal to the 30-day LIBOR plus 55 basis points (1.0% as of December 31, 2008) applied to the amount Wachovia funded toward construction. The base term of the Lease ends in May 2011 (Base Term). Upon the end of the Base Term, we will have the right to exercise one of the following options under the Lease: (1) renew the lease for an additional five-year term (subject to the approval of both parties); (2) purchase the Phase I Laboratory from Wachovia for approximately \$32.0 million; or (3) sell the Phase I Laboratory and repay Wachovia's construction costs with the proceeds from the sale. If sales proceeds are insufficient to repay Wachovia's construction costs, we must fund the shortfall up to the maximum residual value guarantee of approximately \$27.5 million. From the inception of the Lease through the quarter ended June 30, 2008, we accounted for the Lease as an off-balance sheet arrangement--i.e., an operating lease.

Since December 2007, we have been constructing a combination office and laboratory facility that will attach to the Phase I Laboratory (Phase II Facility) with funds generated from our operations. As of September 30, 2008, substantial structural progress had been made in the construction of the Phase II Facility. In addition, we received Wachovia's acknowledgement of our plan to make structural modifications to the Phase I Laboratory in order to connect it to the Phase II Facility. As a result, we could no longer consider the Phase I Laboratory a standalone structure, which was required to maintain off-balance sheet accounting for the Lease. Consequently, as of September 30, 2008, we were considered the owners of the Phase I Laboratory for accounting purposes. Because the Lease failed to meet criteria set forth in EITF Issue No. 97-10, *The Effect of Lessee Involvement in Asset Construction*, and FASB Statement No. 98, *Accounting for Leases*, we are accounting for the Lease as a financing obligation. Accordingly, as of September 30, 2008, we capitalized the estimated fair value of the Phase I Laboratory, totaling \$29.0 million, and recognized a corresponding lease obligation on our consolidated balance sheet. We are accreting the lease obligation to \$32.0 million, the purchase price of the Phase I

Table of Contents**UNITED THERAPEUTICS CORPORATION****Notes to Consolidated Financial Statements (Continued)****10. Commitments and Contingencies (Continued)**

Laboratory, through the recognition of periodic interest charges using the effective interest method. The accretion period began on September 30, 2008 and will run through the end of the Base Term. Related interest charges for the year ended December 31, 2008 were \$261,000. In addition, we are depreciating the Phase I Laboratory over its estimated economic useful life. The change in accounting recognition of the Lease did not affect our cash flow requirements under the arrangement.

The Lease and other lease agreements to which we are a party require that we comply with certain covenants throughout the term of these leases. If we are unable to comply with these covenants and cannot reach a satisfactory resolution in the event of a noncompliance, these agreements could terminate. Termination could result in the loss of our liquid collateral, among other consequences. As of December 31, 2008, we pledged approximately \$40.7 million of our marketable securities as collateral for the Lease. Related amounts have been included in restricted marketable investments and cash on our consolidated balance sheet.

***Operating Leases***

We lease primarily facilities space and office equipment under operating lease arrangements that have terms expiring at various dates through 2014. Certain lease arrangements include renewal options and escalation clauses.

Minimum rent commitments under non-cancelable operating leases are as follows (in thousands):

<b>Years ending December 31,</b>	
2009	\$2,088
2010	1,814
2011	948
2012	764
2013	587
	\$6,201

Total rent expense was approximately \$2.5 million, \$3.3 million and \$2.7 million for the years ended December 31, 2008, 2007 and 2006, respectively.

***Construction Commitment***

In November 2008, we agreed to the terms of a construction management agreement with the Whiting-Turner Contracting Company (Whiting-Turner) relating to the construction of the Phase II Facility (GMP Contract). Under the terms of the GMP Contract, costs to complete the construction of the Phase II Facility generally cannot exceed \$61.3 million (the Guaranteed Maximum Price). Whiting-Turner will be responsible for any cost overruns above the Guaranteed Maximum Price and will share a portion of the savings in the event costs of constructing the Phase II Facility are less than the Guaranteed Maximum Price. The contractor is subject to penalties under the GMP Contract in the event that construction of the Phase II Facility is not completed by November 16, 2009, unless an agreed-upon change order alters the scope of work set forth under the GMP Contract. As of December 31, 2008, the remaining obligation under the GMP Contract was approximately \$44.1 million.

Table of Contents**UNITED THERAPEUTICS CORPORATION****Notes to Consolidated Financial Statements (Continued)****10. Commitments and Contingencies (Continued)*****Milestone and Royalty Payments***

We are party to certain license agreements as described in Note 15 to these consolidated financial statements. Generally, these agreements include milestone payments in cash upon the achievement of certain product development and commercialization goals.

Future milestone payments under these arrangements have been estimated as follows (in thousands):

<b>Years ending December 31,</b>	<b>(1)</b>
2009	\$ 2,530
2010	7,480
2011	9,195
2012	5,195
2013 and thereafter	8,315
	\$32,715

---

(1)

The amounts and timing of future milestone payments may vary depending on when related milestones will be attained, if at all.

Additionally, certain agreements described in Note 15 to these consolidated financial statements require us to pay royalties. Related royalties are generally based on a percentage of net sales of related products or other products and range from 1.0% to 12.0% of net product revenues.

***Research agreement***

We maintain a research agreement with the University of Oxford (Oxford) to develop antiviral compounds licensed from Synergy Pharmaceuticals and from Oxford. Under the terms of the agreement, we are required to fund related research and make milestone payments for the successful completion of clinical trials. We are also obligated to pay royalties to Oxford equal to a percentage of our net sales from discoveries and products developed by Oxford. Milestone payments and royalties are subject to reduction depending upon third-party contributions to discoveries and/or third-party licenses necessary to develop products. In October 2006, the term of the research agreement was extended through September 30, 2011. In connection with the agreement's extension, we are obligated to make 60 equal monthly payments totaling approximately \$3.7 million. As of December 31, 2008, approximately \$1.6 million in monthly payments remained outstanding. During the twelve months ended December 31, 2008, 2007 and 2006, we incurred approximately \$734,000, \$652,000 and \$562,000, respectively, in expenses under the terms of the agreement.

Table of Contents

**UNITED THERAPEUTICS CORPORATION**

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

**11. Stockholders' Equity**

*Equity Incentive Plan*

Our Board of Directors adopted an equity incentive plan in November 1997 (EIP). Subsequently, in April 1999, our Board and shareholders approved an amendment and restatement of the EIP to increase the number of shares available for issuance under the EIP. The EIP, as amended and restated, provides for the issuance of up to 14,939,517 shares of our common stock, of which 7,939,517 have been reserved for issuance to our CEO in accordance with her employment agreement. As of December 31, 2008, there were 6,149,663 shares available for issuance under the EIP. Pursuant to the EIP, we may only grant, beginning in November 2007, nonqualified stock options and other share-based awards to participants. Options granted under the EIP are nontransferable, contain a maximum contractual term of ten years, and typically have vested in one-third increments on each of the first three anniversaries of the grant date. The exercise price of related awards can be no less than the fair market value of our common stock on the date of grant. Historically, we have issued new shares of our common stock upon the exercise of options.

*Stock Option Exchange*

Pursuant to an Offer to Exchange (the Offer), on December 26, 2008 (Exchange Date), certain outstanding options with exercise prices above \$65.00 (Original Options) were cancelled and replaced with options having an exercise price of \$61.50 (Replacement Options), the closing price of our common stock on the Exchange Date. Original Options submitted for exchange were replaced on a one-for-one basis with Replacement Options. Additionally, the Replacement Options retain all terms and conditions of the Original Options except for the reduction to the exercise price as described above and the following:

Original Options submitted for exchange that were vested and exercisable as of the Exchange Date, are subject to a one-year vesting term--i.e., related Replacement Options will be exercisable beginning on the one-year anniversary of the Exchange Date; and

Replacement Options are nonqualified stock options regardless of whether Original Options submitted for exchange were incentive options.

Under SFAS 123R, the Offer is considered a modification of existing option award terms. As such, total compensation associated with the Replacement Options will consist of the grant date fair value of the Original Options for which the requisite service period is expected to be rendered (or has already been rendered) at the Exchange Date, plus the incremental cost associated with the modification of terms. The incremental compensation expense is measured as the excess of the fair value of the Replacement Options over the fair value of the Original Options re-measured as of the Exchange Date. A total of 1,572,616 Original Options with a weighted average exercise price of \$81.06 were exchanged for Replacement Options. Incremental compensation expense associated with the Offer was approximately \$9.1 million, of which \$9.0 million will be recognized over a weighted average period of 1.4 years.

*Employee Options*

We estimate the fair value of stock options using the Black-Scholes-Merton valuation model. Option valuation models, including Black-Scholes-Merton, require the input of highly subjective assumptions that can materially impact the estimation of fair value and related compensation expense.

Table of Contents

## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

**11. Stockholders' Equity (Continued)**

These assumptions include the expected volatility of our common stock, risk-free interest rate, expected term of Awards, expected forfeiture rate and the expected dividend yield.

A description of the key inputs used in estimating the fair value of the stock options is provided below:

*Expected volatility* Volatility is a measure of the amount the price of our common stock has fluctuated (historical volatility) or is expected to fluctuate (expected volatility) during a period. We use historical volatility based on weekly price observations of our common stock during the period immediately preceding a stock option grant that is equal to the expected term of the grant (up to a maximum of five years). We believe the volatility in the price of our common stock over the preceding five years provides the best representation of future long-term volatility.

*Risk-free interest rate* The risk-free interest rate 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 a stock option grant.

*Expected term* The expected term reflects an estimation of the time period we expect an option grant to remain outstanding. We adopted SAB No. 107, as amended by SAB No. 110 regarding the use of the simplified method in developing an estimate of the expected term.

*Expected forfeiture rate* The expected forfeiture rate is the estimated percentage of options granted that are expected to be forfeited or cancelled on an annual basis prior to becoming fully vested. We derive our estimate based on historical forfeiture experience for similar classes of employees.

*Expected dividend yield* We do not pay dividends on our common stock and do not expect to do so in the future. Therefore, the dividend yield is assumed to be zero.

The following weighted-average assumptions were used in estimating the fair value of stock options granted to employees:

	Year ended December 31,		
	2008	2007	2006
Expected volatility	47.6%	39.8%	42.6%
Risk-free interest rate	1.6%	4.1%	4.8%
Expected term of options (in years)	4.8	5.7	6.0
Forfeiture rate	3.0%	4.7%	8.2%
Expected dividend	0.0%	0.0%	0.0%

F-35



Table of Contents

## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## 11. Stockholders' Equity (Continued)

A summary of the status and activity of employee stock options is presented below:

	Shares	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in 000s)
Outstanding at January 1, 2008	5,613,749	\$ 57.28		
Granted(1)	1,691,616	63.42		
Exercised	(992,365)	41.29		
Forfeited	(1,028)	62.88		
Canceled(1)	(1,725,281)	79.42		
Outstanding at end of period	4,586,691	\$ 54.75	7.0	\$ 251,624
Options exercisable at end of period	2,344,564	\$ 49.55	5.7	\$ 116,142
Expected to vest at December 31, 2008	2,147,763	\$ 60.18	8.3	\$ 129,252

(1)

Includes the impact of the Offer described above.

The weighted average fair value of options granted during the year ended December 31, 2008, 2007 and 2006, was \$26.80, \$31.44 and \$27.27, respectively. The total fair value of shares vested during the years ended December 31, 2008, 2007 and 2006 was approximately \$68.8 million, \$42.2 million and \$20.5 million, respectively.

Total employee stock option expense recognized for the years ended December 31, 2008, 2007 and 2006, is as follows (in thousands):

	Year ended December 31,		
	2008	2007	2006
Cost of service sales	\$ 52	\$ 42	\$ 117
Research and development	10,344	10,969	6,679
Selling, general and administrative	15,158	36,353	14,156
Stock option expense before taxes	25,554	47,364	20,952
Related income tax benefits	(10,222)	(17,927)	(8,278)
Total stock option expense, net of taxes	\$ 15,332	\$ 29,437	\$ 12,674
Total stock option expense capitalized in inventory	\$ 520	\$ 213	\$ 505

As of December 31, 2008, there was approximately \$29.9 million of total unrecognized compensation cost related to unvested employee stock options which is expected to be recognized over a weighted-average period of 1.4 years.



Table of Contents

## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

**11. Stockholders' Equity (Continued)**

Information regarding both employee and non-employee option exercises is summarized below (dollars in thousands):

	Year Ended December 31,		
	2008	2007	2006
Number of options exercised	1,022,972	1,797,036	787,149
Cash received from options exercised	\$ 41,936	\$ 58,344	\$ 14,445
Total intrinsic value of options exercised	\$ 58,657	\$ 91,119	\$ 31,367
Tax benefits realized from options exercised	\$ 21,090	\$ 29,604	\$ 10,761

***Options Issued to Non-employees for Services***

We issued options under the EIP to consultants for services performed during 2008, 2007 and 2006. We measure related option grants at fair value and recognize related expense over the period of performance which is typically the vesting term of the options, or one year. A summary of consultant stock option grants is summarized below:

	Number of Options Granted	Weighted Average Grant Price
For the years ended December 31,		
2008	41,000	\$ 99.09
2007	41,000	\$ 53.22
2006	49,437	\$ 66.70

We incurred approximately \$2.4 million, \$1.4 million and \$2.6 million during the years ending December 31, 2008, 2007 and 2006, respectively, in consultant stock-option expense. Pursuant to the terms of the Offer, 24,167 options held by members of our Scientific Advisory Board were submitted for exchange with a weighted average exercise price of \$82.84.

***Treasury Stock Transactions***

On December 18, 2008, we issued 3,150,837 shares of our common stock from the treasury to Eli Lilly & Company (Lilly) in exchange for \$150.0 million. The issuance of treasury shares was made pursuant to a November 2008 stock purchase agreement between Lilly and us (see Note 15 to these consolidated financial statements). The total cost of the treasury stock issued in excess of the aggregate sales price of the transaction was approximately \$14.2 million and has been included in the accumulated deficit on our consolidated balance sheet at December 31, 2008.

In July 2006, we repurchased 766,666 shares of our common stock from Toray Industries, Inc. (Toray), for approximately \$42.2 million pursuant to a stock purchase agreement between us and Toray. The purchase price was the average of the closing price of our common stock for the 30 consecutive trading days ending on July 26, 2006.

The Board approved a stock repurchase program that authorized us to acquire up to 4.0 million shares of our outstanding common stock over a two year period beginning October 17, 2006. Approximately 3.1 million shares were acquired for an aggregate cost of \$182.6 million under the stock repurchase program, which concluded in October 2008. We did not repurchase any shares of our outstanding common stock during 2008.

Table of Contents

## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## 11. Stockholders' Equity (Continued)

*(Loss) Earnings per Share*

The components of basic and diluted (loss) earnings per share were as follows (in thousands, except per share amounts):

	Years ended December 31,		
	2008	2007	2006
Net (loss) income (numerator)	\$ (42,789)	\$ 19,859	\$ 73,965
Shares (denominator):			
Basic weighted-average shares outstanding	22,901	21,224	23,010
Effect of dilutive securities:			
Convertible Senior Notes			
Stock options(1)		1,227	1,128
Diluted weighted-average shares	22,901	22,451	24,138
(Loss) earnings per share			
Basic	\$ (1.87)	\$ 0.94	\$ 3.21
Diluted	\$ (1.87)	\$ 0.88	\$ 3.06
Stock options and warrants excluded from calculation(2)	8,120	4,776	1,588

(1) Calculated using the treasury stock method

(2) Certain stock options and warrants were excluded from the computation of diluted earnings per share because their impact would be antidilutive.

*Shareholder Rights Plan*

On June 30, 2008, we entered into an Amended and Restated Rights Agreement with The Bank of New York, as Rights Agent (the Plan), which amends and restates our original Rights Agreement, dated December 17, 2000. The Plan, as amended and restated, extends the expiration date of the Preferred Share Purchase Rights (Rights) from December 29, 2010, to June 26, 2018, and increases the purchase price of each Right from \$129.50 to \$800.00. Each Right entitles holders to purchase one one-thousandth of a share of our Series A Junior Participating Preferred Stock. Rights are exercisable only upon our acquisition by another company, or commencement of a tender offer that would result in ownership of 15 percent or more of the outstanding shares of our voting stock by a person or group (as defined under the Plan) without our prior express written consent. We have not issued any shares of our Series A Preferred Stock.

*Call Spread Option*

Concurrent with the issuance of the Convertible Senior Notes (see Note 9 in these 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



Table of Contents

**UNITED THERAPEUTICS CORPORATION**

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

**11. Stockholders' Equity (Continued)**

would deliver to Note Holders upon conversion. We must issue shares of our common stock upon conversion of the Convertible Senior Notes once our stock price exceeds \$75.2257 per share. The Call Option will terminate upon the earlier of the maturity date of the Convertible Senior Notes or the first day all of the related Convertible Senior Notes are no longer outstanding due to conversion or otherwise. We paid \$80.8 million for the Call Option which was recorded as a reduction to additional paid-in-capital.

In a separate transaction that took place concurrently with the issuance of the Convertible Senior 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 additional paid-in-capital.

The combination of the Call Option and Warrant effectively reduces the potential dilutive impact of the Convertible Senior Notes. The Call Option has a strike price equal to the initial conversion price of the Convertible Senior Notes and the Warrant has a higher strike price of \$105.689 per share that caps 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 with respect to the Convertible Senior 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, 2008, to effect such settlement.

Deutsche Bank AG London is responsible for providing 100% of the shares of our common stock upon an exercise of the Call Option triggered by a Note Holder's conversion. 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 Issue No. 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock* (EITF 00-19) and SFAS 133, these instruments are both (1) indexed to our common stock and (2) classified as equity; therefore, the Call Option and Warrant qualify for the scope exception under SFAS 133 and are not accounted for as derivative instruments.

Table of Contents

## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

**12. Comprehensive Income (Loss)**

Comprehensive (loss) income comprised the following (in thousands):

	Year ended December 31,		
	2008	2007	2006
Net (loss) income	\$(42,789)	\$ 19,859	\$ 73,965
Other comprehensive income:			
Foreign currency translation (loss) gain	(5,489)	285	336
Marketable investments available-for-sale			
Unrealized holding losses, net of tax	(4,702)	(892)	(2,453)
Reclassification adjustment for other-than-temporary impairment realized in income, net of tax (Note 4)	4,511		
Unrealized (loss) on available-for-sale securities, net	(191)	(892)	(2,453)
Unrecognized prior period service cost, net of tax	(414)	(587)	
Unrecognized actuarial pension (loss) gain, net of tax	(136)	35	
Comprehensive (loss) income	\$(49,019)	\$ 18,700	\$ 71,848

**13. Income Taxes**

Components of income tax benefit consist of the following (in thousands):

	Year Ended December 31,		
	2008	2007	2006
Current:			
Federal	\$	\$ 634	\$
State	1,311	103	868
Foreign	391	78	
Total current	1,702	815	868
Deferred			
Federal	(68,075)	(39,025)	(43,133)
State	(5,311)	(83)	(3,449)
Foreign	(206)		
Total deferred	(73,592)	(39,108)	(46,582)
Other non-current(1)			
Federal	40,406	32,526	10,326
State	1,975	2,491	1,331
Total other	42,381	35,017	11,657
Total income tax benefit	\$(29,509)	\$ (3,276)	\$(34,057)

- (1) Relates primarily to share-based compensation.

F-40

---



Table of Contents**UNITED THERAPEUTICS CORPORATION****Notes to Consolidated Financial Statements (Continued)****13. Income Taxes (Continued)**

Presented below is a reconciliation of income taxes computed at the statutory federal tax rate to income tax benefit as reported (in thousands):

	<b>Years Ended December 31,</b>		
	<b>2008</b>	<b>2007</b>	<b>2006</b>
Federal tax provision computed at 35%	\$(24,683)	\$ 5,804	\$ 13,877
State tax provision, net of federal tax provision	(1,758)	473	1,908
Change in valuation allowance allocated to tax expense		795	(45,662)
General business credits	(7,101)	(12,849)	(4,358)
Incentive stock option expense	1,288	1,234	1,771
Change in tax rate		903	(1,402)
Nondeductible expenses	2,745	364	(191)
<b>Total income tax (benefit) expense</b>	<b>\$(29,509)</b>	<b>\$ (3,276)</b>	<b>\$(34,057)</b>

Components of the net deferred tax asset are as follows (in thousands):

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
<b>Deferred tax assets:</b>		
Net operating loss carryforwards	\$	\$ 2,296
General business credits	79,265	69,771
Impairment losses on investments	2,813	2,543
Realized losses on marketable investments	2,857	4,635
License fees capitalized for tax purposes	66,060	11,896
Nonqualified stock option	26,098	20,446
State net operating losses	5,777	
Other	13,811	7,876
<b>Total deferred tax assets</b>	<b>196,681</b>	<b>119,463</b>
<b>Deferred tax liabilities:</b>		
Furniture and equipment principally due to differences in depreciation	(4,063)	(2,691)
<b>Net deferred tax asset before valuation allowance</b>	<b>192,618</b>	<b>116,772</b>
Valuation allowance	(11,822)	(7,548)
<b>Net deferred tax assets</b>	<b>\$ 180,796</b>	<b>\$ 109,224</b>

Deferred tax assets are reduced by a valuation allowance when, in the opinion of our management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. In evaluating our ability to realize deferred tax assets, we consider all available positive and negative evidence. Accordingly, we consider past operating results, forecasts of earnings and taxable income, the reversal of temporary differences and any prudent and feasible tax planning strategies. Future increases in the valuation allowance would result in a corresponding charge to earnings in the period such a determination is made. Conversely, future reductions to the valuation allowance would result in either the recognition of a tax benefit or an increase to additional paid-in-capital in the period we conclude a reduction is warranted. The increase in the valuation allowance during the year ended December 31, 2008, related mainly to state net operating losses, that we do not consider realizable.

Table of Contents**UNITED THERAPEUTICS CORPORATION****Notes to Consolidated Financial Statements (Continued)****13. Income Taxes (Continued)**

At December 31, 2008, we had no net operating losses available for federal income tax purposes, and approximately \$8.9 million in state net operating loss carryforwards. In addition, as of December 31, 2008, we had business tax credit carryforwards of approximately \$79.3 million. These carryforwards expire on various dates through 2028. Certain business tax credit carryforwards that were generated at various dates prior to December 2007 may be subject to limitations on their use pursuant to Internal Revenue Code Section 382 (Section 382) as a result of ownership changes as defined by Section 382. However, we do not expect that these business tax credits will expire unused. We are currently reviewing our stock trading history for the year ended December 31, 2007 to ascertain whether any further ownership changes have occurred pursuant to Section 382.

As a result of specific realization requirements of SFAS 123R, certain deferred tax assets at December 31, 2008 and 2007, that relate to tax deductions for the excess of equity compensation over that which was recognized for financial reporting purposes have been excluded from net deferred tax assets as reported above. As a result of the utilization on the net operating losses related to equity compensation, additional paid-in capital increased by \$17.1 million.

We have been and may continue to be subject to federal alternative minimum tax and state income taxes, even though we have existing net operating loss and business credit carryforwards.

A reconciliation of the beginning and ending balances of the total amounts of unrecognized tax benefit for the years indicated is as follows (in thousands):

Unrecognized tax benefit at January 1, 2008	\$2,989
Gross increases tax positions in current period	2,893
Gross decreases tax positions in prior period	
Gross increases tax positions in the current period	
Gross decreases tax positions in current period	
Settlements	
Lapse of statute of limitations	
Unrecognized tax benefit at December 31, 2008	\$5,882
Unrecognized tax benefit at January 1, 2007	\$
Gross increases tax positions in prior period	2,989
Gross decreases tax positions in prior period	
Gross increases tax positions in the current period	
Gross increases tax positions in the current period	
Settlements	
Lapse of statute of limitations	
Unrecognized tax benefit at December 31, 2007	\$2,989

Included in unrecognized tax benefits at December 31, 2008 and 2007, is \$1.8 million of tax benefits that, if recognized, would impact the effective tax rate. For the years ended December 31, 2008 and 2007, we did not accrue for or recognize any interest and penalties related to uncertain tax positions.

Table of Contents

**UNITED THERAPEUTICS CORPORATION**

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

**13. Income Taxes (Continued)**

We are unaware of any positions for which it is reasonably possible that the total amounts of unrecognized tax benefits will significantly increase or decrease within the next 12 months.

We are subject to federal and state taxation in the United States and various foreign jurisdictions. Our tax years beginning with 2005 to 2007 are subject to examination by federal and state tax authorities. We believe that appropriate provisions for all outstanding items have been made for all jurisdictions and open years.

**14. Employee Benefit Plans**

*Supplemental Executive Retirement Plan*

In May 2006, the Compensation Committee approved the United Therapeutics Corporation Supplemental Executive Retirement Plan (SERP). The SERP is administered by the Compensation Committee of our Board of Directors and is open to members of a "select group of management or highly compensated employees" within the meaning of ERISA section 201(2). Participants who retire at age 60 are eligible to receive monthly payments based on an average of their total gross base salary over the last 36 months of active employment, subject to certain adjustments, as defined under the SERP. Related benefit payments will commence on the first day of the sixth month after retirement and will continue through the remainder of the participant's life. Alternatively, participants can elect to receive a lump sum distribution equal to the present value of the estimated monthly payments that would have been received upon retirement. Participants who terminate employment with us for any reason prior to age 60 will not be entitled to any benefits under the SERP.

In connection with the SERP, we established a rabbi trust in December 2007, the assets of which will be contributed by us to pay benefits under the SERP. Participants of the SERP will have no preferred claim on, nor any beneficial ownership interest in, any assets of the rabbi trust. The balance in the rabbi trust was approximately \$5.1 million and \$5.0 million as of December 31, 2008 and 2007, respectively. Investments held in the rabbi trust have been included in restricted marketable investments and cash on our consolidated balance sheets.

We account for the SERP in accordance with FASB Statement No. 158, *Employers' Accounting for Defined Benefit Pension and Other Postretirement Plans* (SFAS 158), and related standards. Accordingly, we recognize on our consolidated balance sheet a liability equal to the unfunded status of the SERP (equal to the projected benefit obligation as we do not fund the SERP) and measure our projected benefit obligation as of the end of our fiscal year. Expenses related to the SERP are reported in selling, general and administrative and research and development expenses in the accompanying consolidated statements of operations.

Effective for fiscal years ending after December 15, 2008, SFAS 158 requires financial statement issuers to measure pension plan assets and obligations as of their fiscal year-end. Application of the measurement provisions of SFAS 158 had no impact on the January 1, 2008 balances of retained earnings and the projected benefit obligation since we measure our projected benefit obligation for the twelve months ended December 31<sup>st</sup> of each year.

Table of Contents

## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## 14. Employee Benefit Plans (Continued)

The following table reconciles the beginning and ending balances of the projected benefit obligation (in thousands):

	Year ended December 31,	
	2008	2007
Projected benefit obligation at beginning of year	\$4,899	\$2,598
Service cost	2,664	2,449
Interest cost	386	149
Amendments	1,024	
Actuarial loss (gain)	200	(297)
Projected benefit obligation at end of year	\$9,173	\$4,899
Fair value of plan assets at end of year		
Unfunded at end of year(1)	\$9,173	\$4,899

(1)

Included within other non-current liabilities on our consolidated balance sheets

The accumulated benefit obligation for the SERP, a measure that does not encompass future increases in participant salaries, was approximately \$5.4 million and \$3.0 million at December 31, 2008 and 2007.

Over the course of the next five years we do not expect to make benefit payments under the SERP as no participant will reach retirement age during the succeeding five-year period.

The following weighted-average assumptions were used to measure the SERP obligation:

Years Ended December 31,	2008	2007
Discount Rate	6.35%	6.15%
Salary Increases	5.00%	5.00%

The components of net periodic pension cost recognized on our consolidated statement of operations were composed of the following (in thousands):

Years Ended December 31,	2008	2007	2006
Service cost	\$2,664	\$2,449	\$1,521
Interest cost	386	149	31
Prior period service cost amortization	145	59	20
Total	\$3,195	\$2,657	\$1,572

Table of Contents**UNITED THERAPEUTICS CORPORATION****Notes to Consolidated Financial Statements (Continued)****14. Employee Benefit Plans (Continued)**

Amounts relating to the SERP that have been recognized in other comprehensive (loss)/income are as follows (thousands):

<b>Years Ended December 31,</b>	<b>2008</b>	<b>2007</b>	<b>2006</b>
Net unrecognized actuarial loss (gain)	\$ 200	\$ (296)	\$
Net unrecognized prior service cost	879	(60)	
<b>Total</b>	<b>1,079</b>	<b>(356)</b>	
Tax	(529)	63	
<b>Total, net of tax</b>	<b>\$ 550</b>	<b>\$ (293)</b>	<b>\$</b>

The table below presents amounts included in accumulated other comprehensive (loss)/income that have not yet been recognized as a component of net periodic pension cost on our consolidated statements of operations (thousands):

<b>December 31,</b>	<b>2008</b>	<b>2007</b>	<b>2006</b>
Net unrecognized actuarial loss (gain)	\$ 158	\$ (42)	\$
Net unrecognized prior service cost	1,591	712	
<b>Total</b>	<b>1,749</b>	<b>670</b>	
Tax	(647)	(118)	
<b>Total, net of tax</b>	<b>\$ 1,102</b>	<b>\$ 552</b>	<b>\$</b>

Of the amounts included in accumulated other comprehensive loss/income as of December 31, 2008 above, we expect to recognize \$146,000 in net periodic pension cost relating to net prior service cost during the year ended December 31, 2009. Net unrecognized actuarial gains/losses will not be recognized through amortization until they exceed 10% of the beginning projected benefit obligation balance as of a given year.

***Employee Retirement Plan***

We maintain a salary reduction 401(k) plan adopted in January 1999 (the 401(k) Plan) which is open to all eligible full-time employees. Under the 401(k) Plan, eligible employees can make pre-tax contributions up to statutory limits. We make discretionary matching contributions to the 401(k) Plan currently equal to 20% of a participant's salary deferral. Matching contributions vest over a three-year period. Expenses related to the Plan were \$407,000, \$375,000 and \$295,000 for the years ended December 31, 2008, 2007 and 2006, respectively.

**15. License Agreements*****Glaxo SmithKline PLC***

In January 1997, GlaxoSmithKline PLC (Glaxo) assigned to us patents and patent applications for the use of the stable prostacyclin analogue UT-15 (now known as Remodulin) for the treatment of PAH and congestive heart failure. Under the agreement, Glaxo is entitled to receive royalties from us on sales exceeding a specified threshold for a period of ten years following the date of the first commercial sale of any product containing Remodulin. The terms of the agreement provide Glaxo

Table of Contents

**UNITED THERAPEUTICS CORPORATION**

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

**15. License Agreements (Continued)**

rights to negotiate a license with us if we license any part of the marketing rights under the agreement to a third party. Additionally, if we grant any third-party license rights to Remodulin, Glaxo would be entitled to a percentage of all related fees that we would receive on such arrangements.

*Pfizer Inc.*

Pursuant to a December 1996 license agreement, Pfizer Inc. (Pfizer) exclusively licensed to us patents and a patent application for the composition and production of treprostinil. Under the license agreement, as amended in 2002, we pay royalties to Pfizer equal to 4% of annual net sales of Remodulin in excess of \$25.0 million. Related royalties are reduced by up to 50% in the event that we pay royalties to a third party in order to market or develop treprostinil. Pfizer is entitled to these royalties for a period of ten years from the date of the first commercial sale of any product containing treprostinil.

*Eli Lilly and Company*

In November 2008, we entered into the following agreements with Eli Lilly and Company (Lilly): a license agreement, a manufacturing and supply agreement and a stock purchase agreement. These agreements became effective in December 2008 and are described below.

*License Agreement.* Lilly granted us an exclusive right to develop, market, promote and commercialize tadalafil for the treatment of pulmonary hypertension in the United States and Puerto Rico. In connection with these license rights, we made a one-time, upfront payment to Lilly of \$25.0 million. Additionally, we agreed to pay Lilly royalties of 5% of our net sales of tadalafil as a pass through of Lilly's third-party royalty obligations for as long as Lilly is required to make such royalty payments. The term of the license agreement will continue generally until the later of (1) the expiration or lapse of the last to expire claim within a Lilly patent covering commercialization of tadalafil, or (2) expiration of any government conferred exclusivity rights to tadalafil. In addition, at Lilly's discretion the license agreement may be terminated in the event that a separate brand name for tadalafil is not approved by the FDA or we undergo a change in control. If this were to occur, Lilly would refund our \$25.0 million payment.

*Manufacturing and Supply Agreement.* Terms of the manufacturing and supply agreement provide that Lilly will manufacture tadalafil and distribute it via its wholesaler network in the same manner that it distributes its own pharmaceutical products. We agreed to purchase tadalafil from Lilly at a fixed cost, which is subject to adjustment by Lilly from time to time. Under the terms of the manufacturing and supply agreement we made a one-time, upfront payment to Lilly of \$125.0 million. This payment is nonrefundable unless the FDA rejects Lilly's application for registration of a separate Lilly brand name for tadalafil or we undergo a change in control. The manufacturing and supply agreement will continue in effect until expiration or termination of the license agreement.

*Stock Purchase Agreement.* On December 18, 2008, we issued 3,150,837 shares of our common stock from treasury to Lilly in exchange for \$150.0 million. The price per share was equal to 90% of the average closing price of our common stock quoted on the NASDAQ Global Select Market during the five trading day period commencing on (and including) November 17, 2008. Upon the completion of the sale of our common stock to Lilly, the license and manufacturing and distribution agreements discussed above became effective.

Table of Contents

**UNITED THERAPEUTICS CORPORATION**

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

**15. License Agreements (Continued)**

We expensed to research and development all one-time fees paid to Lilly totaling \$150.0 million during the fourth quarter of 2008, as tadalafil has not received regulatory approval; therefore, it has not yet demonstrated commercial feasibility.

***Toray Industries, Inc.***

In June 2000, we entered into an agreement with Toray for the exclusive right to develop and market beraprost, a chemically stable oral prostacyclin analogue, in a sustained release formulation (beraprost-SR) in the United States and Canada for the treatment of all cardiovascular indications. In March 2007, the June 2000 agreement was amended to expand our rights to commercialize modified release formulations of beraprost (beraprost-MR). In accordance with the terms of the amended agreement, we issued 200,000 shares of our common stock to Toray in March 2007. The terms of the amended agreement give Toray the right to request that we repurchase the shares we issued to them at the price of \$54.41 per share. The fair value of the stock issued, which amounted to approximately \$11.0 million, was expensed as research and development during the year ended December 31, 2007, as beraprost-MR had not yet received regulatory approval for marketing. In accordance with the provisions set forth under SFAS 133, EITF 00-19, and EITF Topic No. D-98, *Classification and Measurement of Redeemable Securities*, the value of the shares issued has been included within mezzanine equity as common stock subject to repurchase. If Toray requests that we repurchase these shares, we will reclassify the repurchase price of the shares as a liability until settlement occurs. The amended agreement also requires that we make certain milestone payments to Toray during the development period and upon receipt of United States or European Union regulatory approval. Milestone payments made prior to the receipt of regulatory approval will be expensed as incurred.

***Supernus Pharmaceutical***

In June 2006, we entered into an exclusive license agreement with Supernus Pharmaceuticals, Inc. (Supernus) for use of certain technologies developed by Supernus in our sustained release oral treprostini formulation. The agreement requires us to make milestone payments to Supernus in connection with the development of oral treprostini and its commercial launch. Additionally, we will pay a royalty to Supernus based on net worldwide sales of the initial product. Royalties will be paid for approximately twelve years commencing with the first product sale subject to adjustments. Additional milestone and royalty payments may be due for the development and commercialization of other products developed using the technology granted under this license.

***Aradigm Corporation***

In August 2007, we entered into an exclusive license, development and commercialization agreement with Aradigm Corporation (Aradigm) for the rights to manufacture, develop and commercialize the AERx Essence® pulmonary drug delivery system, for use as a next-generation metered-dose inhaler with our investigational inhaled treprostini product for patients with PAH and other conditions. The terms of the agreement include various payments to be made to Aradigm including those related to the completion of certain milestones and license fees over the course of the development period. In addition, we will fund the costs to develop, commercialize and manufacture inhaled treprostini for use with AERx Essence. During the years ended December 31, 2008 and 2007, payments to Aradigm under the agreement totaled approximately \$3.5 million and \$440,000, respectively.

Table of Contents

**UNITED THERAPEUTICS CORPORATION**

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

**15. License Agreements (Continued)**

*Northern Therapeutics, Inc.*

In October 2006, we entered into an exclusive license agreement with Northern to obtain the developmental and commercial rights to Northern's cell-based gene transfer technology for the treatment of PAH in the United States. Under the terms of the agreement, we would assume the development activities of this technology upon the successful completion of the current PHACeT Phase I trial being conducted by Northern in Canada. In addition, we will pay Northern certain milestone payments during the PHACeT trial, totaling approximately \$1.5 million, if the trial is successful. During the year ended December 31, 2008, we did not incur any expenses related to this agreement. We incurred expenses totaling \$150,000 and \$500,000 during the years ended December 31, 2007 and 2006, respectively. Upon successful commercial launch of a product using this technology, royalties would be due to Northern at various rates from 5% to 10% depending on the level of sales.

*Other*

We are party to various other license agreements relating to our key therapeutic platforms. These license agreements require us to make royalty payments based on a percentage of sales of related products (1.0% to 12.0%) and may require other payments upon the achievement of certain milestones.

**16. Related Party Transaction**

In May 2007, we entered into a technical services agreement with Kurzweil Technologies Inc. (KTI), a company controlled by Raymond Kurzweil, a non-independent, non-executive member of our Board of Directors. Pursuant to this agreement, we agreed to pay KTI consulting fees of up to \$12,000 monthly. We also agreed to reimburse KTI on a monthly basis for all necessary, reasonable and direct out of pocket expenses incurred in connection with his services. Under the agreement, we could pay KTI up to a 5% royalty on sales of certain products reasonably attributed to and dependent upon certain technology developed by KTI. We incurred approximately \$145,000 and \$84,000 in expenses during the years ended December 31, 2008 and 2007, respectively under this agreement. As of December 31, 2008 and 2007, no amounts were owed to KTI.

**17. Distribution Agreement**

In March 2007, we entered into an exclusive agreement with Mochida Pharmaceutical Co., Ltd. (Mochida) to distribute subcutaneous and intravenous Remodulin in Japan. Mochida is responsible, with our assistance, for obtaining Japanese marketing authorization for Remodulin, including conducting necessary studies. We will supply the drug used in these studies at no charge to Mochida. Commercial activities in Japan are not expected to begin until late 2011. Upon receipt of marketing authorization and pricing approval, Mochida will purchase Remodulin from us at an agreed-upon transfer price. To date, we have received \$8.0 million in related payments from Mochida pursuant to the distribution agreement. Future payments required to be made to us under the agreement include the following: \$2.0 million upon filing a New Drug Application (NDA) in Japan and \$2.0 million upon the receipt of marketing approval in Japan. We recognize revenue on fees received on this arrangement through the filing of the NDA ratably from the period related fees are payable through the expected date of regulatory approval.



Table of Contents

**UNITED THERAPEUTICS CORPORATION**

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

**18. Acquisition of Assets**

We maintain a Clinical and Commercial Supply Agreement, as amended (Supply Agreement), with NEBU-TEC International Med Products Eike Kern GmbH (NEBU-TEC). Under the Supply Agreement, NEBU-TEC produces for us the Optineb® nebulizer and related supplies used to administer inhaled treprostinil for our clinical and commercial purposes. The term of the Supply Agreement ends on the first anniversary of the receipt of either FDA or European Union approval of inhaled treprostinil, whichever occurs first. We also agreed to amend the supply agreement to provide for an advance order of Optineb devices and related supplies in support of our NDA filing, which is currently under FDA review. The Supply Agreement, as amended, also clarifies certain regulatory obligations of each party and provides NEBU-TEC with the first opportunity to sell the Optineb devices in Europe for so long as NEBU-TEC is able to meet market demand. NEBU-TEC is currently our sole producer of the Optineb device and we are NEBU-TEC's largest customer. The Agreement of Sale and Transfer discussed below provides that the Supply Agreement will continue to remain in full force and effect.

On December 15, 2008, we executed an Agreement of Sale and Transfer and related agreements (collectively the Agreement) with NEBU-TEC to acquire the Optineb business and all of the assets, properties and rights used in the Optineb business (Acquired Assets). We entered into the Agreement to reduce our dependency on NEBU-TEC and obtain control over the production of the Optineb nebulizer.

The purchase price consists of the following:

€2.5 million at December 15, 2008;

€2.5 million within 15 days following the date inhaled treprostinil is approved by the FDA for use with the Optineb nebulizer; and

Future consideration of up to €10.0 million depending on the occurrence of specific events.

Pursuant to the Agreement, the Acquired Assets will not transfer to us until inhaled treprostinil has received FDA approval for use with the Optineb nebulizer. Accordingly, the acquisition date for accounting purposes will fall within the effective date of SFAS 141R. Furthermore, we believe the Acquired Assets constitute a business as defined under SFAS 141R, and as such, the transaction will be accounted for as a business combination. We are in the process of determining the fair value of the assets acquired and do not expect the impact of the acquisition to be significant to our consolidated financial statements.

In connection with the Agreement of Sale and Transfer, we will lease a portion of NEBU-TEC's facilities for use as office and warehouse space and production facilities. NEBU-TEC is obligated to build out the leased premises for us. The lease term begins January 1, 2009, and ends January 1, 2014. Rent will not be due until NEBU-TEC completes the build out and is subject to future contingent reductions.

**19. Segment Information**

We have two reportable business segments: pharmaceutical and telemedicine. The pharmaceutical segment includes all activities associated with the research, development, manufacturing and commercialization of our therapeutic products. The telemedicine segment includes all activities associated with the development and manufacturing of patient cardiac monitoring products and

Table of Contents

## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## 19. Segment Information (Continued)

services. The telemedicine segment is managed separately because diagnostic services require different technology and marketing strategies than therapeutic products.

Segment information as of and for the year ended December 31, 2008, is presented below (in thousands):

	Pharmaceutical	Telemedicine	Consolidated Totals
Revenues from external customers	\$ 272,012	\$ 9,485	\$ 281,497
Net income (losses)	(43,459)	670	(42,789)
Interest income	11,025		11,025
Interest expense	(16)		(16)
Income tax benefit	29,509		29,509
Depreciation and amortization	(4,026)	(510)	(4,536)
Equity loss in affiliate	(226)		(226)
Investments in equity method investees	1,021		1,021
Expenditures for long-lived assets	(122,992)	(1,423)	(124,415)
Goodwill, net	1,287	6,178	7,465
Total assets	853,735	17,584	871,319

Segment information as of and for the year ended December 31, 2007, is presented below (in thousands):

	Pharmaceutical	Telemedicine	Consolidated Totals
Revenues from external customers	\$ 203,218	\$ 7,725	\$ 210,943
Net income (losses)	19,816	43	19,859
Interest income	13,595	7	13,602
Interest expense	(2,165)	(10)	(2,175)
Depreciation and amortization	(3,037)	(390)	(3,427)
Equity loss in affiliate	(321)		(321)
Investments in equity method investees	1,247		1,247
Expenditures for long-lived assets	(37,601)	(1,057)	(38,658)
Goodwill, net	1,287	6,178	7,465
Total assets	555,036	31,982	587,018

Table of Contents

## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## 19. Segment Information (Continued)

Segment information as of and for the year ended December 31, 2006, is presented below (in thousands):

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

The preceding segment disclosures agree to consolidated totals when combined. There were no inter-segment transactions during any of the years presented.

Geographic revenues are determined based on the country in which our customers (distributors) are located. Net revenues to external customers by geographic area are as follows (thousands):

Year Ended December 31,	2008	2007	2006
United States	\$ 249,209	\$ 183,523	\$ 143,368
Rest-of-World(1)	32,288	27,420	16,264
Total	\$ 281,497	\$ 210,943	\$ 159,632

(1)

Sales primarily to countries located in Europe

For the years ended December 31, 2008, 2007 and 2006, sales to one customer within our pharmaceutical segment comprised 66%, 60% and 59%, respectively, of total consolidated net revenues.

Long-lived assets (principally property, plant and equipment) located by geographic area are as follows (thousands):

Year Ended December 31,	2008	2007	2006
United States	\$ 207,927	\$ 68,879	\$ 34,191
Rest-of-World(1)	13,139	475	490
Total	\$ 221,066	\$ 69,354	\$ 34,681

(1)

Long-lived assets as of December 31, 2008, consisted of facilities acquired during 2008 and are primarily located in the United Kingdom.



Table of Contents

## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

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

The following presents summarized quarterly financial information for each of the years ended December 31, 2008 and 2007 (in thousands, except per share amounts):

	Quarter Ended			
	December 31, 2008	September 30, 2008	June 30, 2008	March 31, 2008
Net sales	\$ 75,862	\$ 75,032	\$68,556	\$ 62,047
Gross profit	67,414	66,732	60,558	54,494
Net (loss) income(1)	(81,146)	12,623	14,331	11,403
(Loss) income per share basic	\$ (3.42)	\$ 0.55	\$ 0.63	\$ 0.51
(Loss) income per share diluted	\$ (3.42)	\$ 0.50	\$ 0.59	\$ 0.47

(1)

During the three months ended December 31, 2008, research and development expenses included a charge of \$150.0 million relating to a one-time upfront fee paid to Lilly in connection with the acquisition of certain license rights to tadalafil (Note 15).

	Quarter Ended			
	December 31, 2007	September 30, 2007	June 30, 2007	March 31, 2007
Net sales	\$ 59,898	\$ 59,045	\$51,831	\$ 40,169
Gross profit	52,714	52,213	45,822	35,773
Net income (loss)(2)	1,986	14,848	5,806	(2,781)
Income (loss) per share basic	\$ 0.09	\$ 0.70	\$ 0.28	\$ (0.13)
Income (loss) per share diluted	\$ 0.08	\$ 0.66	\$ 0.26	\$ (0.13)

(2)

During the three months ended December 31, 2007, we recognized approximately \$20.3 million in share-based compensation expense related to the year-end stock option grant to our Chief Executive Officer in accordance with her employment agreement.

Table of Contents

## United Therapeutics Corporation

## Schedule II Valuation and Qualifying Accounts

Years Ended December 31, 2008, 2007, and 2006

(In thousands)

	Valuation Allowance on Deferred Tax Assets			
	Balance at Beginning of Year	Additions Charged to Expense	Deductions	Balance at End of Year
Year ended December 31, 2008	\$ 7,548	\$ 6,414	\$ (2,140)	\$ 11,882
Year ended December 31, 2007	\$ 6,754	\$ 794	\$	\$ 7,548
Year ended December 31, 2006	\$46,926	\$	\$ (40,172)	\$ 6,754

	Reserve for Inventory Obsolescence			
	Balance at Beginning of Year	Additions Charged to Expense	Deductions	Balance at End of Year
Year ended December 31, 2008	\$ 508	\$ 183	\$ (280)	\$ 411
Year ended December 31, 2007	\$ 440	\$ 570	\$ (502)	\$ 508
Year ended December 31, 2006	\$ 570	\$ 472	\$ (602)	\$ 440

	Allowance for Doubtful Accounts Receivable			
	Balance at Beginning of Year	Additions Charged to Expense	Deductions	Balance at End of Year
Year ended December 31, 2008	\$	\$	\$	\$
Year ended December 31, 2007	\$ 1		\$ (1)	
Year ended December 31, 2006	\$ 15	\$ 1	\$ (15)	\$ 1

F-53

Table of Contents

**ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

**ITEM 9A. CONTROLS AND PROCEDURES**

*Evaluation of Disclosure Controls and Procedures*

Our management, with participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as of December 31, 2008. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2008.

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

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

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2008, based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control Integrated Framework*. Management's assessment included an evaluation of the design of our internal control over financial reporting and testing of the operational effectiveness of our internal control over financial reporting. Based on this assessment, our management concluded that, as of December 31, 2008, our internal control over financial reporting was effective.

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

*Attestation of Independent Registered Public Accounting Firm*

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

*Changes in Internal Control over Financial Reporting*

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2008 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

**ITEM 9B. OTHER INFORMATION**

None.

Table of Contents

**PART III**

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

Information required by Item 10 regarding nominees and directors appearing under *Election of Directors* in our definitive proxy statement for our 2009 annual meeting of shareholders scheduled for June 26, 2009 (the 2009 Proxy Statement) is hereby incorporated herein by this reference. Information regarding our executive officers appears in Part I, Item I of this Annual Report on Form 10-K under the heading *Executive Officers of the Registrant*. Information regarding the Audit Committee and the Audit Committee's financial expert appearing under the heading *Board Meetings and Committees Audit Committee* in our 2009 Proxy Statement is hereby incorporated herein by this reference.

Information appearing under the heading *Section 16(a) Beneficial Ownership Reporting Compliance* in our 2009 Proxy Statement is hereby incorporated herein by this reference.

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

**ITEM 11. EXECUTIVE COMPENSATION**

Information concerning executive compensation required by Item 11 appears under the heading *Compensation Disclosure and Analysis* in our 2009 Proxy Statement and is hereby incorporated herein by this reference.

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

The information regarding beneficial ownership of our common stock required by Item 12 appears under *Security Ownership of Certain Beneficial Owners and Management* in our 2009 Proxy Statement and is hereby incorporated herein by this reference.



Table of Contents**Securities Authorized for Issuance Under Equity Compensation Plans**

The following table presents information as of December 31, 2008, regarding our securities authorized for issuance under equity compensation plans:

<b>Plan category</b>	<b>Number of securities to be issued upon exercise of outstanding options (a)</b>	<b>Weighted average exercise price of outstanding options (b)</b>	<b>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a) (c)</b>
Equity compensation plan approved by security holders	4,378,058	\$ 62.50	6,149,663
Equity compensation plans not approved by security holders	247,170	21.96	N/A
<b>Total</b>	<b>4,625,228</b>	<b>\$ 60.39</b>	<b>6,149,663</b>

We have one equity incentive plan approved by security holders in 1997. In addition, prior to 2005, we granted options to employees and consultants outside of the plan approved by security holders (non-plan options). Information regarding the security holder approved plan and the non-plan options is contained in Note 11 to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K. We do not have any warrants or rights that are outstanding or available for issuance as described in Regulation S-K Item 201(d). Securities issued pursuant to the non-plan awards were made under standard agreements generally consistent with the form contained in Exhibits 10.22 and 10.38.

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

Information concerning related party transactions and director independence required by Item 13 appears under the heading *Certain Relationships and Related Transactions Director Independence and Board Committees* in our 2009 Proxy Statement and is hereby incorporated herein by this reference.

**ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

Information required by this item, concerning the principal accounting fees paid by the Registrant and the Audit Committee's pre-approval policies and procedures, is incorporated by reference to the information under the heading *Independent Auditors* in our 2009 Proxy Statement and is hereby incorporated herein by this reference.

Table of Contents**PART IV****ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES**

In reviewing the agreements included or incorporated by reference as exhibits to this Annual Report on Form 10-K, it is important to note that they are included to provide investors with information regarding their terms, and are not intended to provide any other factual or disclosure information about United Therapeutics or the other parties to the agreements. The agreements contain representations and warranties made by each of the parties to the applicable agreement. These representations and warranties have been made solely for the benefit of the other parties to the applicable agreement, and: should not be treated as categorical statements of fact, but rather as a way of allocating risk between the parties; have in some cases been qualified by disclosures that were made to the other party in connection with the negotiation of the applicable agreement, which disclosures are not necessarily reflected in the agreement; may apply standards of materiality in a way that is different from what may be material to investors; and were made only as of the date of the applicable agreement or such other date or dates as may be specified in the agreement and are subject to more recent developments.

Accordingly, these representations and warranties may not describe the actual state of affairs as of the date they were made or at any other time. Additional information about United Therapeutics may be found elsewhere in this Annual Report on Form 10-K and our other public filings, which are available without charge through the SEC's website at <http://www.sec.gov>.

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

**Certain exhibits to this report have been included only with the copies of this report filed with the Securities and Exchange Commission. Copies of individual exhibits will be furnished to stockholders upon written request to United Therapeutics and payment of a reasonable fee (covering the expense of furnishing copies). Stockholders may request exhibit copies by contacting: United Therapeutics Corporation, Attn: Investor Relations, 1110 Spring Street, Silver Spring, Maryland 20910.**

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
3.2	Second Amended and Restated By-laws of the Registrant, incorporated by reference to Exhibit 3.2 of the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2008.
3.3	Form of Certificate of Designations, Preferences and Rights of Series A Junior Participating Preferred Stock, incorporated by reference to Exhibit A to Exhibit 4 to the Registrant's Current Report on Form 8-K, filed December 18, 2000.
4.1	Reference is made to Exhibits 3.1 and 3.2.
4.2	Form of Purchase Agreement dated as of December 22, 1999, incorporated by reference to Exhibit 4.7 of the Registrant's Registration Statement on form S-1 (Registration No. 333-93853).

## Edgar Filing: UNITED THERAPEUTICS CORP - Form 10-K

### Table of Contents

<b>Exhibit No.</b>	<b>Description</b>
4.3	Registration Rights Agreement, dated as of June 27, 2000 by and between the Registrant and Toray Industries, Inc., incorporated by reference to Exhibit 4.7 of the Registrant's Registration Statement on Form S-3 (Registration No. 333-40598).
4.4	Form of Stock Purchase Agreement dated July 13, 2000 incorporated by reference to Exhibit 99.2 of the Registrant's Current Report on Form 8-K filed July 14, 2000.
4.5	First Amended and Restated Rights Agreement, incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on July 3, 2008.
4.6	Indenture, dated October 30, 2006, between Registrant and The Bank of New York, as trustee (including form of 0.50% Convertible Senior Note due October 15, 2011), incorporated by reference to Exhibit 4.1 of Registrant's Current Report on Form 8-K filed October 30, 2006.
4.7	Resale Registration Rights Agreement, dated October 30, 2006, between Registrant and Deutsche Bank Securities Inc., as the initial purchaser, incorporated by reference to Exhibit 4.2 of Registrant's Current Report on Form 8-K filed October 30, 2006.
10.1**	Amended and Restated Equity Incentive Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
10.2**	Executive Employment Agreement (as amended) dated as of April 2, 1999, between the Registrant and Martine A. Rothblatt, incorporated by reference to Exhibit 10.3 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
10.3**	Amendment dated December 21, 2000 to the Employment Agreement between the Registrant and Martine A. Rothblatt, incorporated by reference to Exhibit 10.5 of the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2002.
10.4**	Employment Agreement dated June 16, 2001 between the Registrant and Paul A. Mahon, incorporated by reference to Exhibit 10.4 of the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2002.
10.5*	Exclusive License Agreement dated as of December 3, 1996, between the Registrant and an affiliate of Pharmacia & Upjohn Company, incorporated by reference to Exhibit 10.8 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
10.6*	Assignment Agreement dated as of January 31, 1997, between the Registrant and affiliates of Glaxo Wellcome Inc., incorporated by reference to Exhibit 10.9 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
10.7*	Exclusive License Agreement dated as of September 24, 1998, between the Registrant and Toray Industries, Inc., incorporated by reference to Exhibit 10.11 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
10.8*	Exclusive License Agreement dated as of March 15, 1999, between the Registrant and Toray Industries, Inc., incorporated by reference to Exhibit 10.14 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
10.9**	Employment Agreement dated November 29, 2000 between the Registrant and Roger Jeffs, incorporated by reference to Exhibit 10.9 of the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2002.
10.10	Form of Indemnification Agreement between the Registrant and each of its Directors, incorporated by reference to Exhibit 10.18 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
10.11	Exclusive License Agreement dated as of June 23, 2000 between the Registrant and Toray Industries, Inc., incorporated by reference to Exhibit 10.1 of the Registrant's Registration Statement on Form S-3 (Registration No. 333-40598).
10.12	Asset Purchase Agreement dated as of December 15, 2000 among the Registrant, UP Subsidiary Corporation, and Cooke Pharma, Inc., incorporated by reference to Exhibit 2.1 of the Registrant's Form 8-K/A dated February 1, 2001.

## Edgar Filing: UNITED THERAPEUTICS CORP - Form 10-K

### Table of Contents

<b>Exhibit No.</b>	<b>Description</b>
10.13	Amendment No. 1 to Exclusive License Agreement, effective as of December 3, 1996, made as of October 1, 2002 by and between Pharmacia & Upjohn Company and the Registrant, incorporated by reference to Exhibit 10.25 to Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2002.
10.14	Technical Services Agreement dated August 27, 2002 between the Registrant and Kurzweil Technologies, Inc., which appears as Exhibit 10.26 to Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2002, which exhibit is incorporated herein by reference.
10.15***	Exclusive License Agreement dated April 17, 2002 between AltaRex Corp. and Unither Pharmaceuticals, a subsidiary of the Registrant, incorporated by reference to Exhibit 10.12 of the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2002.
10.16**	Standard Non-plan Option Award Agreement used by Registrant, incorporated by reference to Exhibit 10.39 of the Registrant's Form 10-K for the year ended December 31, 2002.
10.17**	Amendment to Employment Agreement dated December 11, 2002 between the Registrant and Roger Jeffs, incorporated by reference to Exhibit 10.31 of the Registrant's Form 10-K for the year ended December 31, 2002.
10.18**	Amendment to Employment Agreement dated December 11, 2002 between the Registrant and Paul Mahon, incorporated by reference to Exhibit 10.33 to the Registrant's Form 10-K for the year ended December 31, 2002.
10.19	Real Estate Purchase Agreement dated October 31, 2003 by and between Unither Pharmaceuticals, Inc. and Montgomery County, incorporated by reference to Exhibit 10.34 to the Registrant's Form 10-K for the year ended December 31, 2003.
10.20**	United Therapeutics Corporation Amended and Restated Equity Incentive Plan, as amended effective as of September 24, 2004 incorporated by reference to Exhibit 10.1 to the Registrant's Form 10-Q for the quarter ended September 30, 2004.
10.21	Lease Agreement dated as of June 28, 2004, by and among United Therapeutics Corporation and Wachovia Development Corporation, incorporated by reference to Exhibit 99.1 of the Registrant's Form 8-K filed on July 6, 2004.
10.22	Assignment of Liquid Collateral Account dated June 28, 2004, by and among United Therapeutics Corporation and Wachovia Development Corporation, incorporated by reference to Exhibit 99.2 of the Registrant's Form 8-K filed on July 6, 2004.
10.23	Ground Lease dated June 28, 2004, by and among United Therapeutics Corporation and Wachovia Development Corporation, incorporated by reference to Exhibit 99.3 of the Registrant's Form 8-K filed on July 6, 2004.
10.24	Participation Agreement dated June 28, 2004, by and among United Therapeutics Corporation, Wachovia Development Corporation, Various Other Banks and Financial Institutions and Wachovia Bank, NA, incorporated by reference to Exhibit 99.4 of the Registrant's Form 8-K filed on July 6, 2004.
10.25	Agency Agreement dated June 28, 2004, by and among United Therapeutics Corporation and Wachovia Development Corporation, incorporated by reference to Exhibit 99.5 of the Registrant's Form 8-K filed on July 6, 2004.
10.26**	Amendment to Executive Employment Agreement between Martine A. Rothblatt and United Therapeutics Corporation, dated April 2, 1999, as previously amended, incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K filed on December 29, 2004.
10.27**	Amendment to Employment Agreement between Roger Jeffs, Ph.D. and United Therapeutics Corporation dated November 29, 2000, as previously amended, incorporated by reference to Exhibit 10.2 of the Registrant's Form 8-K filed on December 29, 2004.

## Edgar Filing: UNITED THERAPEUTICS CORP - Form 10-K

### Table of Contents

<b>Exhibit No.</b>	<b>Description</b>
10.28**	Amendment to Employment Agreement between Paul A. Mahon and United Therapeutics Corporation dated June 16, 2001, as previously amended, incorporated by reference to Exhibit 10.4 of the Registrant's Form 8-K filed on December 29, 2004.
10.29**	Form of Employee Stock Option Award Agreement, incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K filed on December 17, 2004.
10.30**	Form of Non-Employee Stock Option Award Agreement, incorporated by reference to Exhibit 10.2 of the Registrant's Form 8-K filed on December 17, 2004.
10.31	Turner Construction Contract, incorporated by reference to Exhibits 99.1 and 99.2 of Registrant's Current Report on Form 8-K filed March 17, 2005.
10.32**	United Therapeutics Corporation Supplemental Executive Retirement Plan, incorporated by reference to Exhibit 10.1 of Registrant's Current Report on Form 8-K filed May 4, 2006.
10.33	Stock Purchase Agreement, dated as of July 27, 2006, between Registrant and Toray Industries, Inc., incorporated by reference to Exhibit 10.1 of Registrant's Current Report on Form 8-K filed July 27, 2006.
10.34**	Employment Agreement, dated August 2, 2006, between John Ferrari and Registrant, incorporated by reference to Exhibit 10.1 of Registrant's Current Report on Form 8-K filed August 4, 2006.
10.35**	Amendment, dated July 31, 2006, to amended Employment Agreement, dated November 29, 2000, between Roger Jeffs, Ph.D. and Registrant, incorporated by reference to Exhibit 10.2 of Registrant's Current Report on Form 8-K filed August 4, 2006.
10.36**	Amendment, dated July 31, 2006, to amended Employment Agreement, dated June 16, 2001, between Paul A. Mahon and Registrant, incorporated by reference to Exhibit 10.3 of Registrant's Current Report on Form 8-K filed August 4, 2006.
10.37	First Amendment to Certain Operative Agreements, dated May 16, 2006, between Wachovia Development Corporation and Registrant, incorporated by reference to Exhibit 10.1 of Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2006.
10.38	Confirmation, dated October 24, 2006, between Deutsche Bank AG London and Registrant, incorporated by reference to Exhibit 10.1 of Registrant's Current Report on Form 8-K filed October 30, 2006.
10.39	Confirmation, dated October 24, 2006, between Deutsche Bank AG London and Registrant, incorporated by reference to Exhibit 10.2 of Registrant's Current Report on Form 8-K filed October 30, 2006.
10.40**	Amendment, dated December 28, 2006, to Employment Agreement, dated August 2, 2006, between John Ferrari and Registrant, incorporated by reference to Exhibit 10.1 of Registrant's Current Report on Form 8-K filed on December 29, 2006.
10.41	United Therapeutics Corporation Supplemental Executive Retirement Plan Rabbi Trust Document entered into December 28, 2007, by and between the Registrant and Wilmington Trust Company, as trustee, incorporated by reference to Exhibit 10.1 of Registrant's Current Report on Form 8-K filed on December 28, 2007.
10.42	Standard form of agreement between the Registrant and DPR Construction, Inc., dated March 9, 2007, as amended by Amendment No. 1, dated April 19, 2007, incorporated by reference to Exhibit 10.1 of Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2007.
10.43****	Distribution Agreement dated March 20, 2000, between Registrant and Accredo Therapeutics, Inc., as amended and incorporated by reference to Exhibit 10.45 of Registrants Annual Report Form 10-K for the fiscal year ended December 31, 2007.
10.44****	Agreement between the Registrant and the Whiting-Turner Contracting Company, dated November 5, 2007, as amended by Amendment No. 1, dated November 21, 2008.

## Edgar Filing: UNITED THERAPEUTICS CORP - Form 10-K

### Table of Contents

<b>Exhibit No.</b>	<b>Description</b>
10.45**	Form of United Therapeutics Corporation Share Tracking Awards Plan, incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2008.
10.46**	Terms and conditions for Non-Employees issued by Registrant under the Share Tracking Awards Plan, incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2008.
10.47**	Form of terms and conditions for Employees used by Registrant under the Share Tracking Awards Plan, incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2008.
10.48**	Form of Grant Letter used by Registrant under the Share Tracking Awards Plan, incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2008.
10.49	Stock Purchase Agreement, dated as of November 14, 2008, between United Therapeutics Corporation and Eli Lilly and Company, incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on December 24, 2008.
10.50****	License Agreement, dated as of November 14, 2008, by and between Eli Lilly and Company and United Therapeutics Corporation, incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on December 24, 2008.
10.51****	Manufacturing and Supply Agreement, dated as of November 14, 2008, by and between Eli Lilly and Company, Lilly del Caribe, Inc. and United Therapeutics Corporation, incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed on December 24, 2008.
12.1	Computation of Earnings to Fixed Charges.
21	Subsidiaries of the Registrant.
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

---

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

\*\* Designates management contracts and compensation plans.

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

\*\*\*\* Confidential treatment has been requested for portions of this document. The omitted portions of this document have been filed with the Securities and Exchange Commission.

Table of Contents**SIGNATURES**

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

## UNITED THERAPEUTICS CORPORATION

February 26, 2009

By:           /s/ MARTINE A. ROTHBLATT

Martine A. Rothblatt, Ph.D.

*Chairman of the Board and Chief Executive Officer*

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

Signatures	Title	Date
<u>          /s/ MARTINE A. ROTHBLATT</u> Martine A. Rothblatt	Chairman of the Board and Chief Executive Officer (Principal Executive Officer)	February 26, 2008
<u>          /s/ JOHN M. FERRARI</u> John M. Ferrari	Chief Financial Officer and Treasurer (Principal Financial Officer and Principal Accounting Officer)	February 26, 2008
<u>          /s/ ROGER A. JEFFS</u> Roger A. Jeffs	President, Chief Operating Officer and Director	February 26, 2008
<u>          /s/ CHRISTOPHER CAUSEY</u> Christopher Causey	Director	February 26, 2008
<u>          /s/ RAYMOND DWEK</u> Raymond Dwek	Director	February 26, 2008
<u>          /s/ R. PAUL GRAY</u> R. Paul Gray	Director	February 26, 2008
<u>          /s/ RAYMOND KURZWEIL</u> Raymond Kurzweil	Director	February 26, 2008
<u>          /s/ CHRISTOPHER PATUSKY</u> Christopher Patusky	Director	February 26, 2008
<u>          /s/ LOUIS W. SULLIVAN</u> Louis W. Sullivan	Director	February 26, 2008

