

UNITED THERAPEUTICS Corp  
Form 10-K  
February 24, 2011

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

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**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, 2010**

**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.)

**1040 Spring Street, Silver Spring, MD**  
(Address of Principal Executive Offices)

**20910**  
(Zip Code)

**(301) 608-9292**

Registrant's Telephone Number, Including Area Code

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

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

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

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

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**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 whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). 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       Accelerated filer       Non-accelerated filer       Smaller reporting company   
(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, 2010, as reported by the NASDAQ Global Select Market was approximately \$2,020,812,000.

**The number of shares outstanding of the issuer's common stock, par value \$0.01 per share, as of February 18, 2011, was 57,753,901.**

## DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for the registrant's 2011 annual meeting of shareholders scheduled to be held on June 29, 2011, are incorporated by reference in Part III of this Form 10-K.

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**PART I**

**ITEM 1. BUSINESS**

United Therapeutics Corporation is a biotechnology company focused on the development and commercialization of unique products to address the unmet medical needs of patients with chronic and life-threatening conditions.

Our key therapeutic products and product candidates are:

*Prostacyclin Analogues.* Prostacyclin analogues 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 product is Remodulin® (treprostinil) Injection (Remodulin) to be administered subcutaneously or intravenously for the treatment of pulmonary arterial hypertension (PAH). The United States Food and Drug Administration (FDA) initially approved Remodulin in 2002 for subcutaneous (under the skin) administration. Subsequently, the FDA broadened 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, primarily for subcutaneous use. In July 2009, the FDA approved Tyvaso® (treprostinil) Inhalation Solution (Tyvaso), an inhaled prostacyclin therapy for the treatment of PAH. We commenced commercial sales of Tyvaso in the third quarter of 2009. Our oral tablet of treprostinil diethanolamine is in the later stages of development. Our subsidiary, Lung Rx, LLC (Lung Rx), is separately developing modified release beraprost (beraprost-MR), another type of oral prostacyclin analogue, for the treatment of PAH;

*Phosphodiesterase Type 5 (PDE-5) Inhibitor.* PDE-5 inhibitors 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 PDE-5 inhibitor product is Adcirca® (tadalafil) tablets (Adcirca), a once-daily oral therapy for the treatment of PAH. We acquired certain exclusive commercialization rights to Adcirca from Eli Lilly and Company (Lilly) in 2008. In May 2009, the FDA approved Adcirca for the treatment of PAH. We commenced commercial sales of Adcirca in the third quarter of 2009;

*Monoclonal Antibodies (MAb).* MAb act by targeting tumor-associated antigens on cancer cells to activate a patient's immune system against the cancer cells. We are developing the antibody Ch14.18 MAb for the treatment of neuroblastoma, under an agreement with the National Cancer Institute. We are also developing another antibody, 8H9 MAb, for the treatment of metastatic brain cancer, under an agreement with Memorial Sloan-Kettering Cancer Center; and

*Glycobiology Antiviral Agents.* Glycobiology antiviral agents are a novel class of small, sugar-like molecules that have shown pre-clinical indications of efficacy against a broad range of viruses.

We devote most of our research and development resources to developing these key products and product candidates.

We generate revenues primarily from the sale of Remodulin, Tyvaso and Adcirca (which we refer to as our commercial products). Our sales and marketing staff supports the availability of our commercial products in the countries in which they are approved. These efforts are supplemented by our specialty pharmaceutical distributors in the United States and our other distributors internationally.

United Therapeutics was incorporated in Delaware in June 1996. Our principal executive offices are located at 1040 Spring Street, Silver Spring, Maryland 20910. We also maintain executive offices at 55 T.W. Alexander Drive, Research Triangle Park, North Carolina 27709.

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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 February 15, 2011:

<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*, Argentina, Canada, Chile, Israel, Mexico, Peru, Saudi Arabia and South Korea	Worldwide
Remodulin	Continuous intravenous	Pulmonary arterial hypertension	Commercial in the U.S., Argentina, Canada, Israel, Mexico, Peru, Saudi Arabia, South Korea and Switzerland	Worldwide
Tyvaso	Inhaled	Pulmonary arterial hypertension	Commercial in the U.S.	Worldwide
Adcirca (tadalafil) Tablets	Oral	Pulmonary hypertension	Commercial in the U.S. and Puerto Rico	United States/Puerto Rico
CardioPAL® SAVI and Decipher Monitors**	Telemedicine	Cardiac arrhythmias and ischemic heart disease	Commercial in the U.S.	Worldwide
Oral Treprostinil (UT-15C)	Oral	Pulmonary arterial hypertension	Phase III	Worldwide
Ch14.18 MAb	Intravenous	Neuroblastoma	Phase III	Worldwide
Beraprost-MR	Oral	Pulmonary arterial hypertension	Phase II	North America/Europe
Oral Treprostinil	Oral	Peripheral vascular disease	Phase II	Worldwide
8H9 MAb	Intravenous	Metastatic brain cancer	Phase I	Worldwide
IW001	Oral	Idiopathic pulmonary fibrosis and primary graft dysfunction	Phase I	Worldwide
Miglustat	Oral	Hepatitis C	Pre-Clinical	Worldwide
Other Glycobiology Antiviral Agents	Oral	Broad-spectrum agents against viral infectious diseases	Pre-Clinical	Worldwide

\*

We have obtained approval in 28 member countries of the European Economic Area (EEA), as well as in other European countries that are not members of the EEA. We have received formal approval letters and pricing approval in most of these countries.

\*\*

On February 7, 2011 we entered into an agreement to sell Medicomp, Inc., our telemedicine subsidiary, to a group of private investors, which is expected to close in March or April 2011, assuming timely receipt of regulatory approvals and satisfaction of other closing conditions. For a description of the transaction, see the section below entitled *Products to Provide Telemedicine Services for Cardiac Arrhythmias and Ischemic Heart Disease*.

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**Products to Treat Cardiopulmonary Diseases**

**Pulmonary Arterial Hypertension**

PAH is a life-threatening disease that affects the blood vessels in the lungs and is characterized by increased pressure in the pulmonary arteries, which are the blood vessels leading from the heart to the lungs. The elevated pressure in the pulmonary arteries strains the right side of the heart as it pumps blood to the lungs. This eventually leads to right heart failure and, ultimately, death. PAH is characterized by structural changes in blood vessel walls, aggregation of platelets and alteration of smooth muscle cell 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, due to the rarity of the disease 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.

Currently, treatment of PAH focuses on three distinct molecular pathways that have been implicated in the disease process: the prostacyclin pathway, the nitric oxide (NO) pathway, and the endothelin (ET) pathway. The three classes of drugs that target these three pathways are:

*Prostacyclin Analogues.* 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 the pulmonary vessels. Therefore, drugs that mimic the action of prostacyclin, known as prostacyclin analogues, are established PAH treatments.

*PDE-5 Inhibitors.* 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 causes relaxation of the pulmonary blood vessels. NO produces this effect by increasing intracellular levels of an intermediary known as cyclic guanosine monophosphate (cGMP). Therefore, another established therapeutic approach has been to inhibit the degradation of cGMP, using drugs that are known as PDE-5 inhibitors.

*Endothelin Receptor Antagonists.* PAH patients have also been shown to have elevated levels of endothelin-1, a naturally occurring substance in the body that causes constriction and structural changes of the pulmonary blood vessels. Therefore, another established therapeutic approach has been to block the action of endothelin with drugs that are known as endothelin receptor antagonists (ETRAAs).

Because any or all of the three pathways may be therapeutic targets in a patient, these three classes of drugs are used alone or in combination to treat patients with PAH. We currently market drugs in two of these three classes. Remodulin and Tyvaso are prostacyclin analogues, and Adcirca is a PDE-5 inhibitor.

***Remodulin***

Our lead product for treating PAH is Remodulin (treprostinil) Injection, the main ingredient of which is a prostacyclin analogue known as treprostinil. We sell Remodulin to our specialty pharmaceutical distributors in the United States and to our international distributors at a transfer price set by us. We recognized approximately \$403.6 million, \$331.6 million and \$269.7 million in Remodulin revenues, representing 67%, 90% and 96% of our net revenues for the years ended December 31, 2010, 2009 and 2008, respectively. In May 2002, Remodulin was approved by the FDA as a continuous subcutaneous infusion for the treatment of PAH in patients with New York Heart Association (NYHA) Class II-IV (moderate to severe) symptoms. In November 2004, the FDA expanded its approval to permit continuous intravenous infusion of Remodulin for patients who cannot tolerate subcutaneous

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infusion. In March 2006, the FDA expanded its approval to include transition of patients to Remodulin from Flolan® (epoprostenol), the first FDA-approved prostacyclin therapy for PAH. In January 2007, the results of a prospective, open-label study demonstrated that stable patients with PAH can be safely transitioned from Flolan to intravenous Remodulin using a rapid switch protocol.

Outside of the United States, Remodulin is also approved as a continuous subcutaneous infusion treatment for various forms of PAH in 36 countries and as a continuous intravenous infusion treatment for various forms of PAH in seven countries. Applications for approval of both subcutaneous and intravenous Remodulin are under review in other countries. We continue to work toward commercializing Remodulin in new territories, including Japan and China.

Flolan 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. Generic formulations of Flolan are also available. We believe subcutaneous Remodulin provides patients with a less invasive alternative to Flolan and its equivalents. In contrast to Flolan, Remodulin is stable at room temperature and lasts significantly longer inside the human body. These attributes allow for potentially safer and more convenient drug delivery to patients. Unlike Flolan, Remodulin can be delivered by subcutaneous infusion with a pager-sized miniature pump. 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, the active ingredient in Remodulin, is highly soluble in an aqueous solution, which enables us to manufacture Remodulin in 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 keep the drug cool 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 April 2008, Teva Pharmaceuticals Industries Ltd. (Teva) announced that the FDA approved its version of generic epoprostenol for the treatment of PAH, which has all of the attributes of Flolan discussed above. In June 2008, the FDA approved a generic version of Flolan, developed by GeneraMedix, Inc. (GeneraMedix), which is stable at room temperature but shares all of Flolan's other negative attributes including risk of central venous catheter infection, required hospitalization at the start of treatment, short half-life (which increases risk of rebound PAH), mixing requirements, greater frequency of pump refills and larger pump size. In February 2009, GeneraMedix licensed the commercial rights for its generic epoprostenol to Actelion Pharmaceuticals Ltd (Actelion), marketed as Veletri®. Actelion also markets Tracleer®, an ETRA, and Ventavis®, an inhaled prostacyclin, for the treatment of PAH.

There are noteworthy adverse events associated with Remodulin. When infused subcutaneously, Remodulin causes varying degrees of infusion site pain and reaction (redness and swelling) in most patients. Patients who cannot tolerate the site pain related to use of subcutaneous Remodulin may instead use intravenous Remodulin. Intravenous Remodulin is delivered continuously by an external pump through a surgically implanted central venous catheter, similar to Flolan, Veletri and generic epoprostenol. When delivered intravenously, Remodulin bears the risk of a serious bloodstream infection known as sepsis, as do Flolan, Veletri and generic epoprostenol.

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*FDA Approval of Subcutaneous and Intravenous Remodulin*

In May 2002, the FDA approved Remodulin as a continuous subcutaneous infusion for the treatment of PAH in patients with NYHA class II-IV symptoms to diminish symptoms associated with exercise. Remodulin is approved for all types of PAH and is the only prostacyclin analogue approved for patients with NYHA class II-IV symptoms.

In November 2004, based on data establishing intravenous Remodulin's bioequivalence with commercial subcutaneous Remodulin, the FDA approved intravenous Remodulin for those not able to tolerate subcutaneous infusion.

*International Regulatory Review of Subcutaneous and Intravenous Remodulin*

Remodulin for subcutaneous use is approved in many countries throughout the world. We used the mutual recognition process, described more fully in *Governmental Regulation*, to obtain approval of subcutaneous Remodulin in most countries in the European Union (EU). 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 the Republic of Ireland (Ireland), Spain and the United Kingdom (UK) following a request for additional documentation from these countries, and we intend to resubmit some or all of the applications if and when we achieve EU approval for intravenous Remodulin. A license variation for intravenous Remodulin was resubmitted in mid-2010, once our compulsory five-year renewal application for subcutaneous Remodulin was approved. Our license variation is currently under review by our reference member state, France.

We sell (but do not market) Remodulin under the named-patient system in the EU member countries where Remodulin is not approved. Under the named-patient system, our distributors are permitted to import Remodulin into EU member countries for sale to hospitals for use in treating specifically approved patients.

*Tyvaso*

We commenced commercial sales of Tyvaso in September 2009. We sell Tyvaso at a discount from an average wholesale price recommended by us to the same specialty pharmaceutical distributors in the United States that distribute Remodulin. For the years ended December 31, 2010 and 2009, we recognized approximately \$151.8 million and \$20.3 million in Tyvaso revenues, representing 25% and 5%, respectively of our net revenues. We did not recognize any revenues from Tyvaso in 2008.

Currently, the only other FDA-approved inhaled prostacyclin analogue is Ventavis. Ventavis is marketed by Actelion in the United States and by Bayer Schering Pharma AG in Europe. The active ingredient in Ventavis, iloprost, has a half-life of approximately 20 to 30 minutes and can cause a decrease in systemic blood pressure if the drug is administered at too high a dose. Patients need to inhale Ventavis six to nine times per day via a nebulizer. According to its label, each Ventavis inhalation consists of 4 to 10 minutes of continuous inhalation via the nebulizer.

In contrast to iloprost, treprostinil (the active ingredient in Tyvaso) has a longer half-life and greater selectivity to the lungs. Tyvaso is administered four times a day, by inhaling up to nine breaths during each two-to-three-minute treatment session. Tyvaso is administered using the Tyvaso Inhalation System, an ultra-sonic nebulizer that provides a dose of Tyvaso on a breath-by-breath basis. In addition, a day's supply of Tyvaso is packaged in a single ampoule emptied into the nebulizer once a day. As a result, unlike the Ventavis nebulizer which requires cleaning after each use, the Tyvaso Inhalation System only needs to be cleaned once a day.

Tyvaso has been generally well tolerated in our trials, during which adverse events appeared to be similar to those previously reported for treprostinil or due to administration by inhalation. The most common adverse events were transient cough, headache, nausea, dizziness and flushing. We recently



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completed an open-label study in the United States to investigate the clinical effects of switching patients from Ventavis to Tyvaso, in which improvements in patient quality of life were observed.

*FDA Approval of Tyvaso*

In June 2008, we submitted a New Drug Application (NDA) to obtain FDA approval to market Tyvaso for the treatment of PAH in the United States. On July 30, 2009, the FDA approved Tyvaso for the treatment of PAH using the Tyvaso Inhalation System. Tyvaso is indicated to increase walk distance in patients with NYHA Class III symptoms of PAH, which includes multiple etiologies such as idiopathic and familial PAH, as well as PAH associated with scleroderma and congenital heart disease.

In connection with the Tyvaso approval, we have agreed to a post-marketing requirement (PMR) and certain post-marketing commitments (PMCs). PMRs and PMCs are studies that sponsors conduct after FDA approval to gather additional information about a product's safety, efficacy, or optimal use. PMRs are required studies, whereas a sponsor voluntarily commits to conduct PMCs. We are required to provide the FDA annual updates on our PMR and PMCs. Failure to complete the studies or adhere to the timelines set by the FDA for the PMR could result in penalties, including fines or withdrawal of Tyvaso from the market, unless we are able to demonstrate good cause for not completing the studies or adhering to our timelines.

In accordance with our PMR, we recently commenced patient enrollment in a long-term observational study in the U.S. that will include 1,000 patient years of follow up in patients treated with Tyvaso, and 1,000 patient years of follow up in control patients receiving other PAH treatments. This study will allow us to continue to assess the safety of Tyvaso. We are currently required to submit the results of the study by December 15, 2013, but we have requested an extension of this timeline.

The PMCs require us to modify particular aspects of the Tyvaso Inhalation System. As part of these modifications, we agreed to perform a usability analysis incorporating the evaluation and prioritization of user-related risk followed by a human factors study. We submitted proposed device modifications to the FDA in accordance with the PMCs and completed the related human factors study. The FDA has requested further modifications to the device and a follow-up usability study once these additional modifications are complete. As a result of the request to make further modifications to the device and to perform a follow-up usability study, we have requested an extension to the original October 31, 2010 timeline for completion of the PMCs. Our request is under review by the FDA.

In June 2010, the FDA granted orphan-drug designation for Tyvaso. Such a designation, coupled with an approval of the product for the orphan indication, confers an exclusivity period during which the FDA may not approve any application to market the same drug for the same indication, except in limited circumstances.

We are also working with Medtronic, Inc. on demonstrating the safety of its Synchroned® II implantable infusion pump for intravenous Remodulin, and are planning to begin enrolling a clinical trial in April 2011. In Europe, another manufacturer's implantable pump is occasionally used to deliver intravenous Remodulin.

*International Regulatory Review of Tyvaso*

In April 2004, the European Medicines Agency (EMA) designated Tyvaso an orphan medicinal product for the treatment of both PAH and chronic thromboembolic pulmonary hypertension. The EMA orphan designation confers a ten-year exclusivity period commencing with marketing approval. We filed a Marketing Authorization Application (MAA) in December 2008 for Tyvaso and the Tyvaso Inhalation System with the EMA using the centralized filing process. See *Governmental Regulation* below for further discussion on the centralized filing process for the EU. In February 2010, we withdrew our MAA from consideration by the EMA due to the EMA's major objection related to

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findings of non-compliance with good clinical practice (GCP) at two clinical sites. The EMA stated that these findings would preclude a recommendation for approval of Tyvaso in the EU. The EMA had no major objections at the time of withdrawal related to the safety or efficacy of Tyvaso. We are currently working with the EMA on the design of another study acceptable for filing of an MAA in Europe.

*Adcirca*

We began commercial sales of Adcirca in July 2009. Adcirca is a PDE-5 inhibitor, the active pharmaceutical ingredient of which is tadalafil. Tadalafil is also the active pharmaceutical ingredient in Cialis®, which is marketed by Lilly for the treatment of erectile dysfunction. We acquired the commercial rights to Adcirca for the treatment of PAH in the U.S. from Lilly in November 2008. We sell Adcirca at a discount from an average wholesale price to pharmaceutical wholesalers. For the years ended December 31, 2010 and 2009, we recognized approximately \$36.3 million and \$5.8 million in Adcirca revenues, representing 6% and 2%, respectively, of our net revenues. We did not recognize any revenues from Adcirca in 2008.

Patients with PAH have 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 vascular smooth muscle cells. Impaired blood vessel relaxation in penile tissue is also a cause of erectile dysfunction. NO works to relax pulmonary blood vessels by increasing intracellular levels of an intermediary known as cyclic GMP. Because cyclic GMP is degraded by PDE-5, an established therapeutic approach in the treatment of PAH is to use PDE-5 inhibitors to increase levels of cGMP in blood vessels and improve cardiopulmonary function in PAH patients.

Prior to the approval of Adcirca, Revatio, which is marketed by Pfizer Inc. (Pfizer) was the only PDE-5 inhibitor approved for the treatment of PAH. Sildenafil, the active ingredient in Revatio, is also the active ingredient in Viagra®, which is marketed by Pfizer for the treatment of erectile dysfunction. Revatio is dosed three times daily; in contrast, patients take Adcirca only once daily.

*FDA Approval of Adcirca*

In May 2009, the FDA approved Adcirca, with a recommended dose of 40 mg, making it the first once-daily PDE-5 inhibitor for the treatment of PAH. Adcirca is indicated to improve exercise ability in World Health Organization Group I PAH patients, which encompasses patients with multiple forms of PAH including etiologies such as idiopathic and familial PAH as well as PAH associated with collagen vascular disease and congenital heart disease.

*Commercial Rights to Adcirca*

In December 2008, we completed the transactions contemplated by several agreements we entered into with Lilly and one of its subsidiaries in November 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 Adcirca for the treatment of pulmonary hypertension in the United States and Puerto Rico. Pursuant to the manufacturing and supply agreement, Lilly agreed to manufacture Adcirca and distribute it on our behalf 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, non-refundable, non-creditable 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, Lilly purchased 6,301,674 shares of our common stock (adjusted for our September 2009 two-for-one stock split) for an aggregate purchase price of \$150.0 million. We issued those shares from treasury. See *Strategic Licenses and Relationships* below for more details on these agreements.

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

*Pulmonary Arterial Hypertension*

We are developing a novel salt form of treprostinil for oral administration. We use technology licensed from Supernus Pharmaceuticals, Inc. (Supernus) to provide for sustained release of treprostinil in tablets. The tablet coating technology 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 healthy volunteers demonstrated that the formulation and coating provided sustained blood concentrations of treprostinil for 8 to 10 hours following a single oral dose. This duration may allow for twice daily dosing. In July 2005, the EMA announced that oral treprostinil had been designated an orphan medicinal product for the treatment of PAH.

In December 2006, we commenced two Phase III multi-national, placebo-controlled clinical trials of oral treprostinil in patients with PAH to study both safety and efficacy. The FREEDOM-C trial was a 16-week study of patients on approved background therapy using a PDE-5 inhibitor, such as Revatio, or an ETRA, 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. These trials have been conducted at a total of approximately 60 centers throughout the United States and the rest of the world.

We commenced both trials using a 1 mg tablet, but during the open-label extension trial (and associated pharmacokinetic substudy) we discovered that treprostinil concentrations were higher in PAH patients than in healthy individuals due to the difference in overall absorption, metabolism and excretion of the drug between these two populations. These differences led to a number of discontinuations by patients randomized to receive the 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 and a 0.25 mg tablet in April 2008 to enable more gradual dose titration in order to increase dosing to a tolerable level.

In November 2008, we announced that the FREEDOM-C trial did not meet statistical significance for its primary endpoint. Analysis suggests that the inability to dose titrate was a limiting factor that suppressed the overall treatment effect. Of the 174 patients who received the 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 1 mg or less twice daily. Adverse events that led to discontinuation or inability to dose-escalate included headache, nausea and vomiting. Discontinuations were most common in patients who only had access to the 1 mg tablets during the study, which was the only tablet size available when the trial began. There were no discontinuations among patients who had access to 0.25 mg tablets. Analysis of other secondary efficacy measures demonstrated statistically significant improvements compared to placebo.

Enrollment in FREEDOM-M was initially closed on October 31, 2008, with 171 patients enrolled in the trial. We believe that the results of the FREEDOM-C clinical trial, particularly as they relate to treatment effect and dosing, support our continued development of oral treprostinil. Accordingly, based on our observations from the FREEDOM-C clinical trial relating to patient tolerability and tablet strength, we submitted a protocol amendment to the FDA in February 2009 to add patients to the ongoing FREEDOM-M trial. These additional patients were provided access to a lower-strength tablet (0.25 mg) when they began the trial and their doses were titrated in 0.25 mg increments in order to improve tolerability. In addition, our amendment to the FREEDOM-M protocol specified that the primary statistical analysis of the trial will include only those patients who had access to the 0.25 mg tablet when they started the trial. We hope these protocol amendments will achieve the following objectives: (1) to assess more accurately the effectiveness of oral treprostinil; (2) to improve patient tolerability of oral treprostinil so that an effective maintenance dose can be attained; and (3) to reduce

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the rate of premature discontinuation due to adverse events. We believe the results of the protocol amendment will reflect the benefits of a favorable dosing regimen for oral treprostinil.

On January 31, 2011, we completed enrollment of the FREEDOM-M trial under the amended protocol with 349 patients, compared to target enrollment of 315 patients. We expect to unblind and announce preliminary analysis of the FREEDOM-M trial results in June 2011.

We commenced a second Phase III clinical trial, FREEDOM-C<sup>2</sup>, to continue studying dosage and efficacy of oral treprostinil in PAH patients on an approved background therapy. Enrollment in FREEDOM-C<sup>2</sup> began in June 2009. In FREEDOM-C<sup>2</sup>, patients are provided access to a lower strength tablet (0.25 mg) and doses are being titrated in 0.25 mg to 0.5 mg increments. We estimate that this trial will be fully-enrolled in April 2011, in which case we expect to unblind and announce preliminary analysis of the trial in September 2011.

We have also introduced a 0.125 mg tablet so that if necessary patients can begin treatment on an even lower strength tablet, and titrate doses in smaller increments, for both FREEDOM-C<sup>2</sup> and FREEDOM-M.

Currently, we do not anticipate filing an NDA for oral treprostinil until 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, then patients and physicians may use prostacyclin earlier in the PAH disease continuum, which could increase demand for our PAH therapies.

*Scleroderma*

We are undertaking a Phase II study to investigate the effectiveness of oral treprostinil in reducing the frequency and severity of digital ulcers associated with scleroderma. Enrollment of this Phase II trial has been completed at 148 patients, and we expect to unblind and announce the preliminary results of this trial in the first half of 2011.

***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) 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.

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

**Idiopathic Pulmonary Fibrosis and Primary Graft Dysfunction Collagen Type V**

In February 2010, Lung Rx entered into a Development Agreement with ImmuneWorks, Inc. (ImmuneWorks) to develop IW001, a purified bovine (derived from cows) Type V Collagen oral solution for the treatment of Idiopathic Pulmonary Fibrosis (IPF), a progressive lung disease characterized by abnormal and excessive deposition of fibrotic tissue in the lung, and Primary Graft

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Dysfunction (PGD), a type of organ rejection in patients receiving lung transplant. Human clinical testing of IW001 has commenced and a Phase I clinical trial in patients with IPF is ongoing. In connection with entering into the development program, Lung Rx was granted an option to acquire all of the issued and outstanding capital stock of ImmuneWorks. In November 2009, the FDA granted IW001 orphan drug exclusivity.

**Products to Treat Cancer**

*Ch14.18 Antibody*

In July 2010, we entered into a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI) to collaborate on the late-stage development and regulatory agency submissions of Chimeric Monoclonal Antibody 14.18 (Ch14.18) for children with high-risk neuroblastoma and patients with other cancers. Neuroblastoma is a rare cancer of the sympathetic nervous system mainly affecting children. It is the most common extracranial, outside the skull, solid cancer in children and the most common cancer in infants. There are fewer than 1,000 new cases of neuroblastoma diagnosed each year. Ch14.18 is a chimeric, composed of a combination of mouse and human DNA, monoclonal antibody that induces antibody-dependent cell-mediated cytotoxicity, a mechanism of cell-mediated immunity whereby the immune system actively targets a cell that has been bound by specific antibodies. Under the terms of the CRADA, NCI will conduct a clinical trial in approximately 100 patients to define more clearly the safety and toxicity profile of Ch14.18 immunotherapy in children and we will develop the commercial manufacturing capability for the antibody. As part of developing our commercial manufacturing capability, we will need to demonstrate comparability of our Ch14.18 to the NCI-produced Ch14.18, which typically includes a series of analytical and bioanalytical assays and human pharmacokinetics. The NCI studies, including the previously-conducted Phase III study and all other studies supported by NCI, will be used in support of a Biologics License Application seeking FDA approval of Ch14.18 immunotherapy for the treatment of neuroblastoma.

*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, respectively. The monoclonal antibody 3F8 is a mouse IgG3 MAb, which is currently used in an investigational setting for the treatment of neuroblastoma. In August 2009, we began enrolling patients in a Phase II clinical trial of 3F8 for primary refractory neuroblastoma. However, after we entered into the CRADA relating to the Ch14.18 antibody with the NCI in 2010, we stopped further development of the 3F8 program in the fourth quarter of 2010 and returned the rights to 3F8 to MSKCC.

The monoclonal antibody 8H9 is a mouse IgG1 MAb that 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 for patients with metastatic brain cancers is very poor. In the United States, more than 100,000 cases of metastatic brain cancer are diagnosed each year.

**Products to Treat Infectious Diseases Glycobiology Antiviral Agents**

We have a license agreement with the Glycobiology Institute at the University of Oxford for the exclusive worldwide rights to certain patents relating to novel antiviral compounds. These glycobiology antiviral compounds are small molecules that may be effective as oral therapies for the treatment of hepatitis B and C infections, and may also be effective generally as broad-spectrum antiviral agents. Currently, many of these compounds are undergoing laboratory testing, and new compounds are also being synthesized.

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

*CardioPAL SAVI and Decipher Recorders*

We provide telemedicine monitoring services to detect cardiac arrhythmias and ischemic heart disease through our wholly-owned subsidiary Medicomp, Inc. (Medicomp), which we acquired in December 2000. Medicomp provides cardiac Holter monitoring (a 24-hour continuous test of heart rhythms), event monitoring (a test that typically extends to 30 days and looks for more elusive, intermittent arrhythmias) and other cardiac monitoring services 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. Holter and event services and systems are marketed to physicians, hospitals, and managed care providers directly by Medicomp's sales force.

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, the analysis of which 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. In October 2009, Medicomp received FDA approval for a wireless version of the CardioPAL SAVI event monitor, which was commercially launched in 2010.

On February 7, 2011, we entered into an agreement and plan of merger to sell Medicomp to a group of private investors including Medicomp's current president. As Medicomp does not represent a core component of our business, its sale will allow us to devote more resources to our principal operations. Upon closing of the merger, we will receive aggregate consideration of \$14.9 million, consisting of approximately \$3.0 million in cash and/or shares of United Therapeutics common stock held by the investors, and an \$11.9 million, ten-year promissory note to be issued by Medicomp at closing. The promissory note will bear interest at 5.0 percent per annum. Closing of this transaction is subject to customary closing conditions and regulatory approvals, and assuming timely receipt of these approvals closing will occur in March or April 2011. Upon closing of the sale, we will acquire a 19.9 percent ownership interest in Medicomp in exchange for \$1.0 million in cash and a reduction in the face value of the promissory note by approximately \$2.0 million.

Additionally, we obtained royalty-free license rights to use Medicomp's proprietary detection technology to develop and commercialize a smart-phone based arrhythmia detection application for patients in the individual consumer market.

In connection with entering into the merger agreement, we recognized an impairment charge of \$6.2 million representing the write-off of the carrying value of Medicomp's goodwill as of December 31, 2010. The impairment charge has been included in selling, general and administrative expenses for the year ended December 31, 2010. For further details, see *Note 20 Subsequent Event* to our consolidated financial statements included in this Annual Report on Form 10-K.

We recognized revenues of approximately \$10.9 million, \$11.0 million and \$9.5 million from the sales of telemedicine products and services in 2010, 2009 and 2008, respectively.

**Sales and Marketing**

Our marketing strategy for our commercial products is to use our sales and marketing teams to reach out to the prescriber community to: (1) increase PAH awareness; (2) increase understanding of the progressive nature of PAH; and (3) increase awareness of our commercial products and how they fit into the various stages of disease progression and treatment. The sales and marketing team consisted of approximately 113 employees as of December 31, 2010. We have divided our domestic sales force into two teams. One team sells Remodulin and Tyvaso, while the other team sells Adcirca. The efforts

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of our sales and marketing teams are supplemented in the United States by our specialty pharmaceutical distributors for Remodulin and Tyvaso. Our U.S. 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 distribution agreements for Remodulin covering many territories worldwide. We are working with our current distributors to expand Remodulin sales into other countries in which they have distribution rights.

***Domestic Distribution of Commercial Products***

*Remodulin and Tyvaso*

We have entered into separate, non-exclusive distribution agreements with CuraScript, Inc. (CuraScript), Accredo Health Group, Inc. (Accredo), and CVS Caremark (Caremark), our specialty pharmaceutical distributors in the United States, to market, promote and distribute both Remodulin and Tyvaso. Our Remodulin distribution agreements with Accredo and Caremark include automatic term renewals for additional one-year periods subject to notice of termination. Our Remodulin distribution agreement with CuraScript contains automatic term renewals for additional two-year periods subject to notice of termination. We entered into our distribution agreements for Tyvaso in August 2009. Our Tyvaso distribution agreements have one-year terms and renew automatically for additional one-year periods, unless terminated earlier. We update our distribution agreements from time to time to reflect changes in the regulatory environment. Such 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. For specific services requested by us, we compensate our distributors on a fee-for-service basis as set forth in our distribution agreements. If any of our distribution agreements expire or terminate, we may, under certain circumstances, be required to repurchase any unsold Remodulin or Tyvaso inventory held by our distributors. None of our current agreements grants our distributors the distribution rights for oral tadalafil in the United States.

Our specialty pharmaceutical distributors are responsible for assisting patients with obtaining reimbursement for the cost of Remodulin and Tyvaso and providing other support services. Under our distribution agreements, we sell Remodulin and Tyvaso to our distributors at a discount from an average wholesale price recommended by us. We have also established a patient assistance program in the United States, which provides eligible uninsured or under-insured patients with Remodulin and Tyvaso at no charge for a certain period of time.

In March and April of 2010, we increased the price on all concentrations of Remodulin sold to our U.S.-based and international distributors by 9.6 percent and 13.3 percent, respectively. In addition, we increased the price of Tyvaso by 4.9 percent in November 2010 to offset the increasing cost of manufacture and distribution. Our Remodulin distribution agreements do not allow our distributors to preorder inventory prior to a price increase. The impact of these price increases was a \$25.9 million increase in our revenues, of which, \$25.6 million related to sales of Remodulin for the year ended December 31, 2010.

*Adcirca*

We sell Adcirca to pharmaceutical wholesalers at a discount from an average wholesale price. Under our manufacturing and supply agreement with Lilly, (see *Strategic Licenses and Relationships* below for more details), Lilly has agreed to manufacture Adcirca and distribute it via its wholesaler network, which includes our specialty pharmaceutical distributors, in the same manner that it distributes its own pharmaceutical products. Under the terms of this agreement, we take title to Adcirca upon completion of its manufacture by Lilly. Adcirca is shipped to customers in accordance with purchase orders received by Lilly. When customers take delivery of Adcirca, Lilly sends an invoice and collects

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the amount due from the customer subject to customary discounts and rebates, if any. Although Lilly provides these services on our behalf, we maintain the risk of loss as it pertains to inventory and non-payment of invoices. The manufacturing and supply agreement will continue in effect until expiration or termination of the license agreement. In January 2011, Lilly notified us of its decision to increase the wholesale price of Adcirca by approximately 9.0 percent.

***International Distribution of Remodulin***

We currently sell subcutaneous and intravenous Remodulin outside the United States to five distributors, each of which has exclusive distribution rights in one or more countries within Europe, Israel and the Middle East, Asia and South and Central America. We also distribute Remodulin in Canada through a specialty pharmaceutical wholesaler. In some of the European markets where we are not licensed to market Remodulin, we sell (but do not market) Remodulin under the named-patient system in which therapies are approved for individual patients by a national medical review board on a case-by-case basis. 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 and June 2010, we entered into distribution agreements with Mochida Pharmaceutical Co., Ltd. (Mochida) and Lee's Pharmaceutical (HK) Limited (Lee's Pharma) to obtain approval and exclusively distribute subcutaneous and intravenous Remodulin in Japan and China, respectively. Mochida is conducting an open-label Phase III study to support a New Drug Application for subcutaneous and intravenous Remodulin in Japan, which we anticipate will be filed during 2011. In addition, Grupo Ferrer Internacional, S.A. (Grupo Ferrer) has been actively working toward commencing commercial sales of Remodulin in Taiwan and recently launched Remodulin in South Korea. In order to commercialize Remodulin in certain countries, such as Japan, we may be required to conduct new clinical trials, called bridging studies, to demonstrate the efficacy and safety of a drug in their local patient population prior to approval. Therefore it could take several years before we can commence commercial sales in these countries.

**Strategic Licenses and Relationships**

***Lilly Agreements Related to Adcirca***

In December 2008, we completed the transactions contemplated by several agreements we entered into in November 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, which is more fully described below in *Patents and Proprietary Rights Lilly License*, Lilly granted us an exclusive license for the right to develop, market, promote and commercialize Adcirca for the treatment of pulmonary hypertension in the United States and Puerto Rico.

If in the future Lilly seeks to grant rights to a third party to develop or commercialize Adcirca 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: (1) expiration, lapse, cancellation, abandonment or invalidation of the last claim to expire within a Lilly patent covering the commercialization of Adcirca for the treatment of pulmonary hypertension in the United States and Puerto Rico; or (2) expiration of any government-conferred exclusivity rights to use Adcirca 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. 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.



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*Manufacturing and Supply Agreement.* Under the terms of the manufacturing and supply agreement, Lilly agreed to manufacture Adcirca and distribute it on our behalf via its pharmaceutical wholesaler network, in the same manner that it distributes its own pharmaceutical products. Under the terms of this agreement, we take title to Adcirca upon its manufacture by Lilly. Adcirca is shipped to customers, generally pharmaceutical wholesalers, in accordance with customers' purchase orders received by Lilly. Lilly invoices and collects amounts due from the customer subject to customary discounts and rebates, if any, and remits the collections to us. 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 Adcirca, we made a non-refundable payment to Lilly of \$125.0 million in December 2008, which was expensed. We also agreed to purchase Adcirca at a fixed manufacturing cost. The agreement provides a mechanism, generally related to the increase in the national cost of pharmaceutical manufacturing, in which Lilly may raise the manufacturing cost of Adcirca.

*Stock Purchase Agreement.* Under the terms of the stock purchase agreement, on December 18, 2008, we issued 6,301,674 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 \$23.805 per share (adjusted for our September 2009 stock split), 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 \$26.02 per share. In September 2010, Lilly filed with the SEC a Form 4 (Statement of Changes in Beneficial Ownership) disclosing that it had entered into forward contracts to sell up to an aggregate of approximately 3.1 million shares of United Therapeutics common stock during 2011. According to the Form 4, the settlement dates for these forward contracts are July 7, 2011, October 5, 2011 and December 28, 2011.

***Toray Amended License Agreement***

In June 2000, we licensed from Toray the exclusive right to develop and market in the United States and Canada beraprost-SR, a chemically stable oral prostacyclin analogue in a sustained release formulation, 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 concerning the commercialization of beraprost-MR, a modified release formulation of beraprost. 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 400,000 shares of our common stock to Toray in exchange for the cancellation of Toray's existing right under the original agreement to receive an option grant to purchase 1,000,000 shares of our common stock. Under the terms of the amended agreement, Toray has the right to request that we repurchase the 400,000 shares of our common stock upon 30 days prior written notice at the price of \$27.205 per share (share based numbers and prices are adjusted for our September 2009 two-for-one stock split), which was the average closing price of our common stock between January 11, 2007, and February 23, 2007. In accordance with the provisions of the Financial Accounting Standards Board Accounting Standards Codification (FASB ASC) 815, *Derivatives Hedging*, and Accounting Series Release No. 268, *Presentation in Financial Statements of Redeemable Preferred Stocks* 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 we will reclassify an amount equal to the repurchase price as a liability until the repurchase is completed.

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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. In September 2010, we entered into a supplement to our license agreement with Toray under which we agreed on the timing of two of the milestone payments under our existing agreement, in the amounts of \$4.0 million and \$5.0 million. All conditions relating to these milestone payments were satisfied in the fourth quarter of 2010; accordingly, during the quarter we paid Toray \$4.0 million and recognized a \$5.0 million liability and associated expense relating to the second milestone payment, which will be paid to Toray during the first quarter of 2011. Although the second milestone payment is not due until the first quarter of 2011, we accrued and expensed the payment in 2010 because the contingencies affecting this milestone payment were removed during the fourth quarter of 2010. These milestone payments were expensed as research and development when incurred since beraprost-MR has not demonstrated commercial feasibility.

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

In December 2008, we entered into an agreement with NEBU-TEC, to purchase its line of business relating to the manufacture of the Tyvaso Inhalation System for €5.0 million plus future milestone payments of up to €10.0 million (of which we have already paid €1.0 million). The transaction closed in September 2009 after we received FDA approval for Tyvaso. Under the terms of our agreement, we purchase the device components and manage the manufacturing process for the Tyvaso Inhalation System, and NEBU-TEC supplies the labor to assemble the devices. NEBU-TEC also granted us an option to acquire its next generation inhalation device, the SIM-Neb, which is currently under development.

***ImmuneWorks Development Agreement***

In February 2010, Lung Rx entered into a Development Agreement with ImmuneWorks, Inc. to develop IW001, a purified bovine (derived from cows) Type V Collagen oral solution for the treatment of Idiopathic Pulmonary Fibrosis (IPF), a progressive lung disease characterized by abnormal and excessive deposition of fibrotic tissue in the lung, and Primary Graft Dysfunction (PGD), a type of organ rejection in patients receiving lung transplant. Human clinical testing of IW001 has commenced and a Phase I clinical trial in patients with IPF is ongoing. In connection with entering into the development program, Lung Rx was granted an option to acquire all of the issued and outstanding capital stock of ImmuneWorks. In November 2009, the FDA granted IW001 orphan drug exclusivity.

**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, GlaxoSmithKline PLC (formerly Glaxo Wellcome, Inc.) (Glaxo) assigned to us all rights to the use of the stable prostacyclin analogue now known as treprostinil, the active ingredient in Remodulin, Tyvaso and our oral treprostinil tablet. The patent covering the use of treprostinil for PAH expires in the United States in October 2014 (as extended *see Patent Term Extensions* below) and on various dates from May 2011 to June 2014 in three 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 treprostinil. We filed

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our own patent application for a new synthesis and production method for tadalafil in October 1997 in the United States, Europe and various other countries. This application resulted in the grant of three patents in the United States, all of which expire in October 2017, as well as one patent in Europe and one patent in Japan, both expiring in October 2018. The application remains pending in other countries. 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 tadalafil. We continue to conduct research into new methods to synthesize tadalafil and have two registered patents in the United States that expire in 2021, as well as additional United States and foreign pending patent applications, relating to such methods.

***Lilly License***

In November 2008, we entered into a license agreement with Lilly pursuant to which Lilly granted us the exclusive right to develop, market, promote and commercialize Adcirca for the treatment of pulmonary hypertension in the United States and Puerto Rico.

In exchange for the license, we paid Lilly a non-refundable fee of \$25.0 million in December 2008, which was expensed since Adcirca had not yet received regulatory approval for commercial sales. We also agreed to pay Lilly royalties equal to 5 percent of our net sales of Adcirca 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.

Lilly retained the exclusive rights to develop, manufacture and commercialize pharmaceutical products containing tadalafil, the active pharmaceutical ingredient in Adcirca, 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 Adcirca, including retail pricing, which is expected to be at price parity with Cialis, Lilly's therapy for the treatment of erectile dysfunction, the active ingredient of which is also tadalafil.

If in the future Lilly seeks to grant rights to a third party to develop or commercialize Adcirca 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: (1) expiration, lapse, cancellation, abandonment or invalidation of the last claim to expire within a Lilly patent covering the commercialization of Adcirca for the treatment of pulmonary hypertension in the United States and Puerto Rico; or (2) expiration of any government-conferred exclusivity rights to use Adcirca 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. Either party may terminate upon a material breach by the other party of the license agreement or the manufacturing and supply agreement, described above.

***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 tadalafil tablet. 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 tadalafil and its commercial launch. In addition, the agreement provides that we will pay a royalty to Supernus based on net worldwide sales of the initial product. Any such royalty will be paid for approximately twelve years commencing with the first product sale and is subject to adjustments as specified in the agreement. Additional milestone payments and royalty payments may be due for the development and commercialization of other products developed using the technology granted under this license.

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***National Cancer Institute***

In July 2010, we entered into a CRADA with NCI to collaborate on the late-stage development and regulatory agency submissions of Chimeric Monoclonal Antibody 14.18 (Ch14.18) for children with high-risk neuroblastoma and patients with other cancers. Neuroblastoma is a rare cancer of the sympathetic nervous system mainly affecting children. Under the terms of the CRADA, NCI will conduct a clinical trial in approximately 100 patients to define more clearly the safety and toxicity profile of Ch14.18 immunotherapy in children and we will develop the commercial manufacturing capability for the antibody. As part of developing our commercial manufacturing capability, we will need to demonstrate comparability of our Ch14.18 to the NCI-produced Ch14.18, which typically includes a series of analytical and bioanalytical assays and human pharmacokinetics. The NCI studies, including the previously-conducted Phase III study and all other studies supported by NCI will be used in support of a Biologics License Application seeking FDA approval of Ch14.18 immunotherapy for the treatment of neuroblastoma.

***Memorial Sloan Kettering License***

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, respectively. The monoclonal antibody 3F8 is a mouse IgG3 MAb, which is currently used in an investigational setting for the treatment of neuroblastoma. However, after we entered into the CRADA relating to the Ch14.18 antibody with the NCI in 2010, we stopped further development of the 3F8 program in the fourth quarter of 2010 and terminated our license with MSKCC relating to 3F8.

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 the treatment of metastatic brain cancer.

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

***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 and Tyvaso. 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. The FDA has granted Tyvaso an orphan designation, which will result in orphan exclusivity through July 2016.

**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 2010, 2009 and 2008 totaled approximately \$166.8 million, \$122.2 million and \$239.2 million, respectively. See *Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations Major*

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*Research and Development Projects* for additional information regarding expenditures related to major research and development projects.

**Manufacturing and Supply**

We make trestipinil, the active ingredient for Remodulin and Tyvaso, and trestipinil diethanolamine, the active ingredient for oral trestipinil, at our facility in Silver Spring, Maryland. In June 2009, the FDA approved our Silver Spring facility for commercial manufacturing of trestipinil. In November 2009, we also received European regulatory approval to manufacture trestipinil in our Silver Spring facility. In addition, we are currently developing the capacity to manufacture Remodulin and Tyvaso at our Silver Spring facility.

Baxter Healthcare Corporation (Baxter) manufactures Remodulin for us. In April 2009, we amended our agreement with Baxter to extend its term through 2013. In addition, we agreed that Remodulin will be manufactured using a different set of equipment and in larger quantities than the current manufacturing process. Since Baxter will make Remodulin on different equipment and in a larger production batch than the current process, we are required to have the new equipment and process approved by the FDA. We are currently conducting the validation testing for the new equipment and process. If the validation testing is successful, we anticipate filing for FDA approval of the new equipment and process during 2011. Baxter continues to manufacture Remodulin for us according to the process currently approved by the FDA. In January 2011, the FDA approved Hollister-Stier Laboratories, LLC as our second Remodulin manufacturer, in the larger quantities described above.

We are actively working towards obtaining approval to manufacture Remodulin and Tyvaso in our Silver Spring facility. Our goal is to become the primary manufacturer with contracted third-party manufacturers supplementing our manufacturing capacity. Also, although we maintain a three-year inventory of Remodulin and Tyvaso based on expected demand, we believe that having third parties approved to manufacture these products will mitigate some of our manufacturing risks, including the risk that we might not be able to produce sufficient quantities to meet patient demand.

We rely on Catalent Pharma Solutions, Inc. (formerly Cardinal Health, Inc.) (Catalent) to do the following: (1) conduct stability studies on Remodulin, (2) manufacture Tyvaso, (3) serve as a backup manufacturer for oral trestipinil, and (4) analyze other products we develop. We have begun manufacturing oral trestipinil tablets, which are being used in our clinical trials, in our manufacturing facility in Research Triangle Park, North Carolina.

Under our manufacturing and supply agreement with Lilly, Lilly manufactures and distributes Adcirca through its wholesaler network in the same manner that it distributes its own pharmaceutical products. Under the terms of this agreement, we take title to Adcirca upon completion of its manufacture by Lilly. Adcirca is shipped to customers, generally pharmaceutical wholesalers, in accordance with purchase orders received by Lilly. Although Lilly provides these services on our behalf, we maintain the risk of loss as it pertains to inventory and non-payment of invoices.

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We manufacture the nebulizer used in our Tyvaso Inhalation System. While we purchase the components and manage the manufacturing process, NEBU-TEC supplies all the labor to manufacture the nebulizers. In December 2010, Minnetronix, Inc. (Minnetronix) was approved by the FDA as a second manufacturer of the Tyvaso Inhalation System.

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 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, also known as epoprostenol, is a prostacyclin 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). In 2009, Gilead returned the rights to Flolan to Glaxo. 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 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 epoprostenol, which is stable at room temperature. In February 2009, Actelion announced that it had entered into an agreement with GeneraMedix to acquire its epoprostenol product, marketed as Veletri, and began commercial sales in the second half of 2010;

*Ventavis*. Approved in December 2004 in the United States and in September 2003 in Europe, Ventavis is an inhaled prostacyclin analogue. Ventavis was initially marketed by CoTherix, Inc. (CoTherix) in the United States and is marketed by Bayer Schering Pharma AG in Europe as Iloprost. In January 2007, CoTherix was acquired by Actelion, the manufacturer and distributor of Tracleer and distributor of Veletri;

*Tracleer*. The first oral drug to be approved for PAH, Tracleer is also the first drug in its class, known as ETAs. 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. Revatio contains sildenafil, the same active ingredient as Viagra, and is the first PDE-5 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 ETA. In April 2008, Glaxo received marketing authorization from the EMA for Letairis in Europe where it is known as Volibris®; and

*Thelin*®. Approved in August 2006 in the EU, Thelin 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, Thelin is an ETA. In June 2008, Pfizer completed its acquisition of Encysive. During the fourth quarter of 2010, Pfizer discontinued selling Thelin due to safety concerns.

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Due to their ease of use, oral therapies such as Adcirca, Revatio and Tracleer are generally considered first-line therapies for newly diagnosed NYHA Class II PAH patients, although Remodulin is also approved for NYHA Class II PAH patients and patients may improve to NYHA Class II status while on Remodulin even if Remodulin is started by patients in a more serious stage of the disease. Inhaled therapies like Tyvaso and Ventavis are generally used in NYHA Class III patients during the middle stages of the PAH disease treatment cycle, although Remodulin is also approved for NYHA Class III patients and is frequently used within this group. More complex infusion therapies such as Remodulin and Flolan are often used as later-stage therapies for NYHA Class IV patients, although many doctors start patients on these therapies prior to the advanced disease progression associated with NYHA Class IV.

The use of the available oral therapies and Tyvaso, either alone or in combination, could delay the need for infusion therapy for many patients. As a result, the success of other therapies in preventing disease progression affects our commercial products. 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 compete successfully with established and newly developed drugs or products, or the companies that develop and market them.*

We compete with the developers, manufacturers and distributors all of these products 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**

***Pharmaceutical Product Approval Process***

The research, development, testing, manufacture, promotion, marketing, distribution, sampling, storage, recordkeeping, post-approval monitoring and reporting, and import and export of pharmaceutical products (drugs or biological products, hereinafter collectively drugs) are extensively regulated by governmental agencies in the United States and in other countries. Failure to comply with applicable U.S. requirements, pursuant to the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and other federal statutes and regulations, may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending new drug applications (NDAs) or biologics license applications (BLAs), warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

Satisfaction of FDA pre-market approval requirements typically takes many years, and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease. Drugs are subject to rigorous regulation by the FDA in the United States, the EMA 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;

Clinical studies in patients to explore safety, efficacy and dose-response characteristics;

Adequate and well-controlled clinical trials to establish the safety and efficacy of the drug for each indication;

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The submission of an NDA or BLA to the FDA; and

FDA review and approval of the NDA or BLA prior to any commercial sale or shipment of the drug.

Preclinical tests include laboratory evaluation of product chemistry and formulation, as well as animal studies to explore toxicity and for proof-of-concept. The conduct of the preclinical tests must comply with federal regulations and requirements including good laboratory practices. In the United States, the results of preclinical testing are submitted to the FDA as part of an IND, along with other information including information about product chemistry, manufacturing and controls and a proposed clinical trial protocol. A 30-day review period after the filing of each IND is generally required prior to the commencement of clinical testing in humans. If the FDA has not commented on or questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin. 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.

Clinical trials involve the administration of the investigational new drug or biologic to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted in compliance with federal regulations, good clinical practices (GCP) and protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board (IRB) for approval. An IRB may also require the clinical trial at a site to be halted temporarily or permanently for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials in support of an NDA or a BLA 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 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 BLA is typically submitted to the FDA in the United States, and an MAA is typically submitted to the EMA in the EU. FDA approval of the NDA or BLA is required before marketing of the product may begin in the U.S. The NDA or BLA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA or BLA is substantial. Under federal law, the submission of most NDAs and BLAs is additionally subject to a substantial application fee, currently exceeding \$1.5 million, and the manufacturer and/or sponsor of an approved new drug application are also subject to annual product and establishment (manufacturing site) fees, currently exceeding \$86,000 per product



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and \$497,000 per establishment. These fees are typically increased annually. However, the application, product, and establishment fees may be waived for orphan drugs if certain requirements are met.

The FDA has 60 days from its receipt of an NDA or a BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of new drug applications. Most such applications for non-priority drug products are reviewed within ten months while most applications for priority review drugs, that is, drugs that the FDA determines represent a significant improvement over existing therapy, are reviewed in six months. The review process may be extended by the FDA for three additional months to consider certain information or clarification regarding information already provided in the submission. The FDA may also refer applications for novel pharmaceutical products or pharmaceutical products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA or a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with current good manufacturing practices is satisfactory and the NDA or BLA contains data that provide substantial evidence that the pharmaceutical product is safe and effective for the indication studied.

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. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA or BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. To continue marketing our products after approval, applicable regulations require us to maintain a positive risk-benefit profile, maintain regulatory applications through periodic reports to regulatory authorities, fulfill pharmacovigilance requirements, maintain manufacturing facilities according to the FDA's current Good Manufacturing Practices requirements, and successfully complete regulatory agency inspections, among other requirements. Our manufacturing facilities are subject to continual review and periodic inspections. As a condition of NDA or BLA approval, the FDA may require substantial post-approval testing and surveillance to monitor the product's safety or efficacy and may impose other conditions, including labeling restrictions which can materially affect the potential market and profitability of the pharmaceutical product. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

*Orphan Drugs*

Under the Orphan Drug Act, an applicant can request the FDA to designate a product as an "orphan drug" in the United States if the drug is intended to treat an orphan, or rare, disease or condition. A disease or condition is considered orphan if it affects fewer than 200,000 people in the United States. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not shorten the duration of the regulatory review and approval process. The first NDA applicant to receive orphan drug designation and FDA approval of the drug for the designated disease is entitled to a seven-year exclusive marketing period in the U.S. for that product for that indication. During the seven-year

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period, the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA application user fee and product and establishment user fees.

The FDA granted orphan designation for the active ingredient treprostinil for the treatment of PAH as a continuous infusion. However, this designation does not preclude us from seeking orphan drug designation for other formulations or routes of administration, such as oral or inhaled, of treprostinil to treat PAH, or for treprostinil used to treat other orphan diseases. In order for the FDA to grant orphan drug designation for other formulations or routes of administration of treprostinil to treat PAH, we must demonstrate that such new formulation or route of administration is clinically superior to the formulation or route of administration previously granted orphan designation.

***Pediatric Information***

Under the Pediatric Research Equity Act of 2007 (PREA), NDAs, or BLAs and supplements to NDAs or BLAs must contain data to assess the safety and effectiveness of the drug for the claimed indication(s) in all relevant pediatric subpopulations and to support dosing and administration for each such pediatric subpopulation. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan drug designation has been granted. The Best Pharmaceuticals For Children Act, or BPCA, provides sponsors with an additional six-month period of market exclusivity on all forms of the drug containing the active moiety, if the sponsor submits results of pediatric studies specifically requested by the FDA under BPCA. In order to receive the BPCA exclusivity, the drug must have other existing patent or exclusivity protection in effect.

***Hatch-Waxman Act***

The Hatch-Waxman Act was enacted to encourage competition between brand and generic pharmaceutical companies. It created a faster approval process for generic drugs, called the Abbreviated New Drug Application (ANDA), while it provided protection to brand pharmaceuticals by extending their patent protection. Upon approval of a drug through an NDA, applicants are required to submit to the FDA each patent that covers the applicant's product or FDA approved method of using this product. Those patents are then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an ANDA. Generally, an ANDA provides for marketing of a drug product that has the same active ingredients in the same strength(s), route of administration, and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. ANDA applicants are not required to conduct or submit results of pre-clinical or clinical tests to prove the safety or effectiveness of their drug product, other than the requirement for bioequivalence testing. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid is called a Paragraph IV certification. If the applicant does not challenge the listed patents, the ANDA

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application will not be approved until all the listed patents claiming the referenced product have expired. Alternatively, for a patent covering an approved method of use, an ANDA applicant may submit a statement to the FDA that the company is not seeking approval for the covered use.

If the ANDA applicant has submitted a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired. Federal law provides a period of five years following approval of a drug containing no previously approved active moiety, during which ANDAs for generic versions of those drugs cannot be submitted unless the submission contains a Paragraph IV challenge to a listed patent, in which case the submission may be made four years following the original product approval. Federal law provides for an exclusivity period of three years, during which the FDA cannot grant effective approval of an ANDA, following approval of a listed drug that contains previously approved active ingredients but is approved in a new dosage form, route of administration or combination, or for a new condition of use that was required to be supported by new clinical trials conducted by or for the sponsor. Both of the five-year and three-year exclusivity periods, as well as any unexpired patents listed in the Orange Book for the listed drug, can be extended by six months if the FDA grants the NDA sponsor a period of pediatric exclusivity based on studies submitted by the sponsor in response to a written request.

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 a 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 with the maximum patent term extension of five years, and the patent will expire on October 6, 2014.

***Section 505(b)(2) New Drug Applications***

Most drug products (other than biological products) obtain FDA marketing approval pursuant to an NDA or an ANDA. A third alternative is a special type of NDA, commonly referred to as a Section 505(b)(2) NDA, which enables the applicant to rely, in part, on the FDA's finding of safety and efficacy data for an existing product, or published literature, in support of its application.

Section 505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely upon certain preclinical or clinical studies conducted for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all or some of the labeled indications for which the referenced product has been approved, as well as for any new indication for which the Section 505(b)(2) NDA applicant has submitted data.

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To the extent that the Section 505(b)(2) applicant is relying on prior FDA findings of safety and efficacy, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. Thus, approval of a Section 505(b)(2) NDA can be delayed until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) NDA applicant.

***Other Regulatory Requirements***

Once an NDA or a BLA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet.

Pharmaceutical products may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new or supplemental NDA/BLA before the change can be implemented. An NDA/BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing supplements as it does in reviewing NDAs or BLAs.

Adverse event reporting and submission of periodic reports are required following FDA approval of an NDA or a BLA. The FDA also may require post-marketing testing, known as Phase 4 testing, risk minimization action plans, and surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control as well as drug manufacture, packaging, and labeling procedures must continue to conform to current good manufacturing practices (cGMPs) after approval. Manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards or if previously unrecognized problems are subsequently discovered.

***Marketing Pharmaceutical Products Outside the United States***

Outside of the United States, our ability to market our products is also contingent upon receiving marketing authorizations from 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/mutual recognition or a national level process. The centralized procedure is mandatory for the approval of biotechnology products, high technology products and orphan products and is available at the applicant's option for other products. The centralized procedure provides for the grant

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of a single marketing authorization that is valid in all EU member countries. The decentralized/mutual recognition procedure is available for all medicinal products that are not subject to the centralized procedure. The decentralized/mutual recognition 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 usually (depending on the country) 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/mutual recognition 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 some or all of the applications when we achieve approval for intravenous Remodulin since these countries required additional information not required by the other European countries.

To secure European regulatory approval for Tyvaso, we submitted an MAA to the EMA via the centralized process in December 2008. Regulations in Europe have changed since we made our initial filing for Remodulin and all therapies for orphan diseases must now use the centralized process. In February 2010, we withdrew our MAA from consideration by the EMA due to the EMA's major objection related to findings of non-compliance with good clinical practice at two clinical sites. The EMA stated that these findings would preclude a recommendation for approval of Tyvaso in the EU. The EMA had no major objections at the time of withdrawal related to the safety or efficacy of Tyvaso.

*U.S. Regulation of Medical Devices*

Our medical devices are subject to regulation by government agencies, including the FDA. To varying degrees, each government agency requires us to comply with laws and regulations governing the developing, testing, manufacturing, labeling, marketing and distribution of our medical devices. Medical devices, unless expressly exempt by regulation, are required to be manufactured in conformance with the FDA's Quality System Regulations (QSRs). The QSRs are complex regulations that impose methods, procedures, and documentation requirements regarding the manufacturing and quality assurance activities of medical devices, including the design, testing, control, manufacturing, labeling, packaging, storage, and shipping of medical devices. We are also subject to periodic inspections by regulatory agencies to ensure that we meet all regulatory requirements. Upon an inspection, if the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our medical devices may pose unreasonable health risks, the FDA could require us to notify health professionals or others of these risks, order a recall, repair, replacement or refund of such device, or detain or seize adulterated or misbranded medical devices. The FDA may also impose operating restrictions, enjoin or restrain certain conduct resulting in violations of applicable law pertaining to medical devices and assess civil or criminal penalties.

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To maintain approval of the Tyvaso Inhalation System in the United States, we must comply with the QSRs, and the FDA may also require additional patient data to support approval for this device.

Our telemedicine products are manufactured at contract facilities that must comply with the QSRs. These devices are designed and sold by Medicomp and have received marketing clearance from the FDA under Section 510(k) of the Food, Drug and Cosmetic Act.

***Government Reimbursement of Pharmaceutical Products***

In the United States, many independent third-party payers, as well as the Medicare and State Medicaid programs, reimburse buyers of our commercial products. 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 our pharmaceutical commercial products at a rate generally equal to 95% of the published average wholesale price as of October 1, 2003 (the Medicare Part B payment formula for drugs infused through durable medical equipment) or 106% of Average Sales Price (the Medicare Part B payment formula for drugs inhaled through durable medical equipment). The State Medicaid programs also generally provide reimbursement for our commercial products, at reimbursement rates that are below the published average wholesale price and that vary from state to state. In return for including our pharmaceutical commercial products in the Medicare and Medicaid programs, we have agreed to pay a rebate to State Medicaid agencies that provide reimbursement for those products. We have also agreed to sell our commercial products under contracts with the Department of Veterans Affairs, Department of Defense, Public Health Service and numerous other federal agencies as well as certain hospitals that are designated as 340B covered 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 our drugs. We estimate that between 35-50% of Remodulin, Tyvaso and Adcirca sales in the United States are reimbursed under the Medicare and Medicaid programs.

***Anti-Kickback, False Claims Laws and The Prescription Drug Marketing Act***

In addition to FDA restrictions on marketing pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes and false claims statutes. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Violations of the anti-kickback statute are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal healthcare programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. Recently, several pharmaceutical and other

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healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment.

As part of the sales and marketing process, pharmaceutical companies frequently provide samples of approved drugs to physicians. The Prescription Drug Marketing Act (PDMA), imposes requirements and limitations upon the provision of drug samples to physicians, and prohibits states from licensing distributors of prescription drugs unless the state licensing program meets certain federal guidelines that include minimum standards for storage, handling and record keeping. In addition, the PDMA sets forth civil and criminal penalties for violations.

***Patient Protection and Affordable Care Act of 2010***

The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (PPACA) is intended to expand healthcare coverage within the U.S.

Several provisions of the new law, which have varying effective dates, may affect us and will likely increase certain of our costs. For example, an increase in the Medicaid rebate rate from 15.1 percent to 23.1 percent is effective as of January 1, 2010, and the volume of rebated drugs has been expanded to include beneficiaries in Medicaid managed care organizations, effective as of March 23, 2010. The PPACA also imposes an annual fee on pharmaceutical manufacturers beginning in 2011, based on the manufacturer's sale of branded pharmaceuticals and biologics (excluding orphan drugs) to certain U.S. government programs during the preceding year; expands the 340B drug discount program (excluding orphan drugs) including the creation of new penalties for non-compliance; and includes a 50% discount on brand name drugs for Medicare Part D participants in the coverage gap, or "donut hole". The law also revised the definition of "average manufacturer price" for reporting purposes effective October 1, 2010, which could increase the amount of the Medicaid drug rebates paid to states.

The PPACA also created a regulatory pathway for the abbreviated approval of biological products that are demonstrated to be "biosimilar" or "interchangeable" with an FDA-approved biological product. In order to meet the standard of interchangeability, a sponsor must demonstrate that the biosimilar product can be expected to produce the same clinical result as the reference product, and for a product that is administered more than once, that the risk of switching between the reference product and biosimilar product is not greater than the risk of maintaining the patient on the reference product. Such biosimilars would reference biological products approved in the U.S. The law establishes a period of 12 years of data exclusivity for reference products, which protects the data in the original BLA by prohibiting sponsors of biosimilars from gaining FDA approval based in part on reference to data in the original BLA.

In addition, the PPACA imposes new reporting requirements for pharmaceutical and device manufacturers with regard to payments or other transfers of value made to physicians and teaching hospitals, effective March 30, 2013. In addition, pharmaceutical and device manufacturers will be required to report investment interests held by physicians and their immediate family members during the preceding calendar year. Such information is to be made publicly available by the Secretary of Health and Human Services in a searchable format beginning September 30, 2013. Failure to submit

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required information may result in civil monetary penalties of up to \$150,000 per year (and up to \$1 million per year for "knowing failures") for all payments, transfers of value or ownership or investment interests not reported in an annual submission. Further, the PPACA amends the intent requirement of the federal anti-kickback and criminal health care fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims laws.

***State Pharmaceutical and Medical Device Marketing Laws***

If not preempted by the PPACA, several states, such as Maine, Massachusetts, and Vermont, require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to individual physicians in those states. Other states prohibit various other marketing related activities. Still other states require the posting of information relating to clinical studies and their outcomes. In addition, certain states, such as California, Nevada, and Massachusetts, require pharmaceutical companies to implement compliance programs or marketing codes and several other states are considering similar proposals. Compliance with these laws is difficult and time consuming, and companies that do not comply with these state laws face civil penalties.

**Employees**

We had 520 employees as of February 5, 2011. 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 *Segment Information* to our 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 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 1, 2011, 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 shareholders, and until his or her successor is elected and qualified or until his or her earlier resignation or removal. Each executive officer's employment will end pursuant to the terms of his or her employment contract. Each of the employment contracts generally 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.	56	Chairman, Chief Executive Officer and Director
Roger Jeffs, Ph.D.	49	President, Chief Operating Officer and Director
John M. Ferrari	56	Chief Financial Officer and Treasurer
Paul A. Mahon, J.D.	47	Executive Vice President, 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 United Therapeutics, she founded and served as Chairman and CEO of Sirius Satellite Radio. She also 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, 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.

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**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 sufficiency of current and future working capital for planned and unplanned needs including paying the holders of our Senior Convertible Notes the principal due when the Notes mature in October 2011;

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

The value of our common stock;

The maintenance of domestic and international regulatory approvals;

The timing and outcome of clinical studies and regulatory filings, including in particular our FREEDOM-C<sup>2</sup> and FREEDOM-M trials and anticipated filing of an NDA for oral treprostinil;

The expected likelihood and timing of regulatory approvals for drug candidates under development and the timing of related sales;

The outcome of potential future regulatory actions, including audits and inspections, from the FDA and international regulatory agencies;

The expected volume and timing of sales of Remodulin® (treprostinil) Injection (Remodulin), Adcirca® (tadalafil) tablets (Adcirca) and Tyvaso® (treprostinil) Inhalation Solution (Tyvaso) (collectively, referred to as our commercial products);

The impact of competing therapies, including generic products, on sales of our commercial products;

The expectation that we will be able to manufacture sufficient quantities and maintain adequate inventories of our commercial products;

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

The potential impact, if any, of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 on our business;

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

Any statements preceded by, followed by or that include any form of the words "believe," "seek," "expect," "anticipate," "forecast," "project," "intend," "estimate," "should," "could," "may," "will," "plan," or similar expressions; and

Other statements contained or incorporated by reference in this Annual Report on Form 10-K that are not historical facts.

The statements identified as forward-looking statements may exist in *Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations* or elsewhere in this Annual Report on Form 10-K. These statements are subject to risks and uncertainties and our actual results may differ materially from anticipated results. Factors that may cause such differences include, but are

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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.**

We have experienced financial reporting periods in which we incurred net losses. While we believe we develop our annual cash-based operating budgets using reasonable assumptions and targets, unanticipated factors, including factors outside of our control, could affect our profitability and cause uneven quarterly and/or annual operating results.

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

During the twelve months ended December 31, 2010, net Remodulin and Tyvaso sales accounted for 67 percent and 25 percent of our total revenues, respectively. A wide variety of events, many of which are described in other risk factors below, could cause sales of Remodulin and/or Tyvaso to decline. For instance, if regulatory approvals for either of these products were withdrawn, we would be unable to sell the product and our business could be jeopardized. Any substantial change in the prescribing practices or dosing patterns of patients using Remodulin or Tyvaso due to combination therapy, side effects, adverse events, death or any other reasons, could decrease related revenues. In addition, we rely on third parties to produce, market, distribute and sell Remodulin and Tyvaso. The inability of any one of these third parties to perform these functions, or the failure of these parties to perform successfully, could negatively affect our revenues. We are also increasingly internalizing elements of the manufacturing process, and any failure to manage our internal manufacturing processes could result in a decrease in production and an inability to meet demand. Because we are highly dependent on sales of Remodulin and Tyvaso, any reduction in sales of either or both of these products would have a negative and possibly material adverse impact on our operations.

**If our products fail in clinical trials, we will be unable to obtain or maintain FDA and international regulatory approvals and will be unable to sell those products.**

To obtain regulatory approvals from the FDA and international regulatory agencies such as the EMA, we must conduct clinical trials demonstrating that our products are safe and effective. In the past, several of our product candidates failed or were discontinued at various stages in the development process. In addition, we may need to amend ongoing trials or the FDA and/or international regulatory agencies may require us to perform additional trials beyond those we planned. Such occurrences could result in significant delays and additional costs, and related clinical trials may be unsuccessful. In November 2008, we reported that our FREEDOM-C Phase III clinical trial of oral treprostinil did not achieve statistical significance for its primary endpoint. Because we have decided to amend the protocol for our current FREEDOM-M Phase III clinical trial and conduct a new Phase III clinical trial, FREEDOM-C<sup>2</sup>, we have experienced delays in completing our clinical trials for oral treprostinil and do not anticipate filing an NDA prior to 2012. As with all clinical trials, there is a risk that FREEDOM-M and FREEDOM-C<sup>2</sup> may not be successful. Upon filing an NDA, we could be subject to additional delays, if the FDA determines that it cannot approve the NDA as submitted. In such case, the FDA would issue a complete response letter, which would outline the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA would then issue an approval letter. We may fail to address any such deficiencies adequately, in which case we would be unable to obtain FDA approval to market a given product candidate.

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The length of time that it takes for us to complete clinical trials and obtain regulatory approval for marketing varies by product, product use and country. 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 clinical trials may be discontinued, delayed or disqualified 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;

Ongoing or new clinical trials conducted by drug companies in addition to our own clinical trials reduce the number of patients available for our trials;

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 trial sites or our contracted clinical trial administrators may not adhere to trial protocols and required quality controls, particularly as clinical trials expand into new territories;

Our trials do not comply with applicable regulations or guidelines;

We do not pass inspections by regulatory agencies;

Patients die during our trials because of an adverse event related to the trial drug, their disease is too advanced, or they experience medical problems unrelated to the drug being studied;

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

The results of preclinical testing cause delays in our trials.

In addition, the FDA and its international equivalents have substantial discretion over the approval process for pharmaceutical products. As such, these regulatory agencies may not agree that we have demonstrated the requisite level of product safety and efficacy to grant approval.

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

We compete with well-established drug companies for, among other things, funding, licenses, expertise, personnel, clinical trial patients and investigators, consultants and third-party collaborators. We also compete with these companies for market share. Most of these competitors have substantially greater financial, marketing, manufacturing, sales, distribution and technical resources than we do. These competitors also have more experience in areas such as research and development, clinical trials, sales and marketing and regulatory matters than we do.

There are several treatments that compete with our commercial therapies. For the treatment of PAH, we compete with a number of approved products in the United States and worldwide, including the following: Flolan®, Ventavis®, Tracleer®, Revatio®, Letairis®, Veletri® and a generic intravenously administered product containing epoprostenol, the active ingredient in Flolan. Patients and doctors may perceive

these competing products as safer, more effective, more convenient and/or less expensive than our therapies. Alternatively, doctors may reduce the prescribed doses of our products if they prescribe them as combination therapy with our competitors' products. In addition, certain competing products are less invasive than Remodulin and the use of these products may delay or prevent initiation of Remodulin therapy. Any of these circumstances may suppress our sales growth, or cause our revenues to decline.

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Actelion, Gilead and Pfizer presently control the majority of the approved therapies for PAH in the United States. Each of these companies has achieved considerable influence over prescribers through the sales and marketing of their respective therapies and through market dominance in this therapeutic area. Furthermore, the future commercialization and introduction of new PAH therapies into the market could exert downward pressure on the pricing of our products and reduce our market share.

**Discoveries or development of new products or technologies by others may make our products obsolete or seemingly inferior.**

Other companies may discover or introduce new products that render all or some of our technologies and products obsolete or noncompetitive. Our commercial therapies may have to compete with numerous investigational products currently in development. In addition, alternative approaches to treating chronic diseases, such as gene therapy, may make our products obsolete or noncompetitive. Other investigational therapies for PAH could be used in combination with, or as a substitute for, our therapies. If this occurs, doctors may reduce or discontinue the use of our pharmaceutical products for their patients.

**Sales of our products are subject to reimbursement from government agencies and other third parties. Pharmaceutical pricing and reimbursement pressures may cause our sales to suffer.**

The commercial success of our products and services depends, in part, on the availability of reimbursements by governmental payers such as Medicare and Medicaid, and private insurance companies. Accordingly, our commercial success is tied to such third-party payers. In the United States, the European Union and other significant or potentially significant markets for our products, third-party payers are increasingly attempting to limit or regulate the price of medicinal products and services, and are frequently challenging the pricing of new and expensive drugs. Consequently, it may be difficult for our specialty pharmaceutical distributors or wholesalers to obtain reimbursement of our products from third-party payers. Alternatively, third-party payers may reduce the amount of reimbursement for our products based on changes in pricing of other therapies for PAH, including generic formulations of other approved therapies. If third-party payers do not approve our products for reimbursement, or limit reimbursements, patients could choose a competing product that is approved for reimbursement. Presently, most third-party payers, including Medicare and Medicaid, reimburse the cost of our commercial products. Our prostacyclin analogue products, Remodulin and Tyvaso, are expensive therapies. The Medicare Modernization Act (MMA) requires that we negotiate a new price for our commercial products with the Centers for Medicare and Medicaid Services. As a result of the staggered implementation of the MMA, our products have not yet been subject to its pricing provisions; however, future reimbursements could be subject to reduction. Furthermore, 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. We are currently assessing the potential effect of the Patient Protection and Affordable Care Act and the related Health Care and Education Reconciliation Act of 2010 on our business. While we believe the short-term impact on our business of this legislation will not be material, we continue to monitor the developments of this legislation as many of its provisions are not yet effective and are subject to finalization.

In Europe, the success of our commercial products and future products depends largely on obtaining and maintaining government reimbursement. In many European countries patients are unlikely to use prescription drugs that are not reimbursed by their governments. Reimbursement policies may adversely affect our ability to sell our products on a profitable basis. In many markets outside the United States, governments control the prices of prescription pharmaceuticals, including through the implementation of reference pricing, price cuts, rebates, revenue-related taxes and profit

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control, and expect prices of prescription pharmaceuticals to decline over the life of the product or as volumes increase.

**Our manufacturing strategy exposes us to significant risks.**

We must be able to produce sufficient quantities of our commercial products to satisfy demand. The process of manufacturing our products is difficult and complex, and currently involves a number of third parties. We produce treprostinil, the active ingredient in both Remodulin and Tyvaso, in our Silver Spring, Maryland facility using raw materials and advanced intermediate compounds supplied by vendors. Although we produce treprostinil, we outsource the manufacture of Remodulin to Baxter and Hollister-Stier. We also rely on Catalent to manufacture Tyvaso. We are in the process of developing the capability to manufacture Remodulin and Tyvaso at our own facilities. Currently, we manufacture oral treprostinil tablets for use in our clinical trials, but neither we nor our third-party vendors would be able to manufacture oral treprostinil on a commercial scale in the U.S. without FDA approval of a New Drug Application (NDA) for oral treprostinil or for international commercial sales without the corresponding international approvals.

As long as we utilize third-party vendors for significant portions of our manufacturing process, we will remain exposed to the risks described under the risk factor below titled *We rely in part on third parties to perform activities that are critical to our business. Our ability to generate commercial sales or conduct clinical trials could suffer if our third-party suppliers and service providers fail to perform.* In addition, while we expect our efforts to internalize additional manufacturing processes will increase our control over manufacturing, it will also subject us to risks as we engage in complex manufacturing processes for the first time. For example, Remodulin and Tyvaso must be produced in a sterile environment, and we have no experience with sterile manufacturing on a commercial scale.

Some of the products we are developing will involve even more complicated manufacturing processes than our current products. For example, the monoclonal antibodies we are developing are biologic products, which are inherently more difficult to manufacture than our current products and involve increased risk of viral and other contaminations.

Additional risks presented by our manufacturing strategy include:

We and our third-party manufacturers are subject to the FDA's current Good Manufacturing Practices in the United States and similar regulatory standards internationally. While we have significant control over regulatory compliance with respect to our internal manufacturing processes, we do not exercise the same level of control over regulatory compliance by our third-party manufacturers;

As we expand our manufacturing operations to include new elements of the manufacturing process or new products, we will need to design and implement processes and procedures to ensure compliance with applicable regulations;

Even if we and our third-party manufacturers are in compliance with domestic and international drug manufacturing regulations, the sterility and quality of the products being manufactured could be substandard and, therefore, such products would be unavailable for sale or use;

If we have to replace a third-party manufacturer with another manufacturer or our own manufacturing operations, the FDA and its international counterparts would require new testing and compliance inspections. Furthermore, a new manufacturer would have to be familiarized with the processes necessary to manufacture and commercially validate our products, as manufacturing our treprostinil-based products is complex. Any new third-party manufacturers and any new manufacturing process at our own facilities would need to be approved by the FDA and its international counterparts before being used to produce commercial supply of our products;



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We may be unable to contract with needed manufacturers on satisfactory terms or at all; and

The supply of materials and components necessary to manufacture and package our 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 approval from the FDA and international regulatory agencies before they could be sold. The timing of any such regulatory approval is difficult to predict.

Any of these factors could disrupt sales of our commercial products, delay clinical trials or commercialization of new products, result in product liability claims and product recalls, and entail higher costs.

**We rely in part on third parties to perform activities that are critical to our business. Our ability to generate commercial sales or conduct clinical trials could suffer if our third-party suppliers and service providers fail to perform.**

Frequently, we involve third parties to assist us in conducting clinical trials, obtaining regulatory approvals, and marketing and distributing our products, as we do not possess the internal capacity to perform all of these functions. Accordingly, the success of these third parties in performing their contractual obligations is critical to our operations.

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 our clinical trials.

We rely on Baxter to manufacture Remodulin for us, and the FDA recently approved Hollister-Stier as a second manufacturer of Remodulin. We extended our contract with Baxter through 2013 and as part of that contract amendment, we agreed that Baxter will manufacture Remodulin in greater quantities using larger production equipment than under its current manufacturing process. This new manufacturing process and related equipment will require FDA and international approvals. Catalent manufactures Tyvaso for commercial use and also maintains the ability to manufacture oral tadalafil for us. In addition, Catalent conducts stability studies on Remodulin and Tyvaso for us and analyzes other products that we are developing. We are also evaluating alternative supply arrangements, including other third-party production arrangements and the production of Remodulin and Tyvaso in our combination office and laboratory facility in Silver Spring, Maryland. If we are unable to successfully implement these alternatives, we may not have sufficient inventory to meet future demand. Presently, we are producing oral tadalafil for clinical trials at our manufacturing facility in Research Triangle Park, North Carolina. However, our process to manufacture oral tadalafil has not been approved for commercial use by the FDA or international regulatory agencies, and we may encounter unforeseen obstacles in seeking regulatory approval.

NEBU-TEC retains many responsibilities related to the manufacture of the Tyvaso Inhalation System, which includes a nebulizer and related accessories. Although we manage the manufacturing process, NEBU-TEC supplies the labor. We rely on NEBU-TEC, as we do for any third-party contractor, to adhere to and maintain the manufacturing process in accordance with all applicable regulatory requirements. Any regulatory compliance problems encountered by NEBU-TEC related to the manufacture of the Tyvaso Inhalation System could adversely affect the sale of Tyvaso. Until the fourth quarter of 2010, when we received approval for Minnetronix to serve as a second manufacturer of the Tyvaso Inhalation System, the NEBU-TEC facility was the only facility currently approved for the manufacturing of the Tyvaso Inhalation System. If we are unable to manufacture or supply the Tyvaso Inhalation System in the quantities we require or if our suppliers are unable to supply sufficient parts

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to manufacture the Tyvaso Inhalation System, it could delay, disrupt or prevent us from selling Tyvaso, which could impede our business and its projected growth.

We rely on Accredo, CuraScript, and Caremark to market, distribute and sell Remodulin and Tyvaso in the United States. These distributors are also partially responsible for negotiating reimbursements from third-party payers for the cost of our therapies. In March and April of 2010, we increased the price on all concentrations of Remodulin sold to our U.S.-based and international distributors by 9.6 percent and 13.3 percent, respectively. In addition, we increased the price of Tyvaso by 4.9 percent in November 2010. Our price increases may not be fully reimbursed by third-party payers. If our distributors do not achieve acceptable profit margins on our products, they may reduce or discontinue the sale of our products. Furthermore, if our domestic and international distributors devote fewer resources to selling our products or are unsuccessful in their sales efforts, our revenues may decline materially.

We rely on Lilly to manufacture and supply Adcirca for us, and we use Lilly's pharmaceutical wholesaler network to distribute Adcirca in the United States and Puerto Rico. If Lilly is unable to manufacture or supply Adcirca or its distribution network is disrupted, it could delay, disrupt or prevent us from selling Adcirca, which could slow down the growth of our business.

Although most of our current suppliers and service providers could eventually be replaced, a change in suppliers and/or service providers could interrupt the manufacture and distribution of our commercial products and our other products and services, and impede the progress of our clinical trials, commercial launch plans and related revenues. Interruptions in manufacturing could be significant given the length of time and complexity involved in obtaining necessary FDA and other regulatory approvals for alternative arrangements, through either third parties or internal manufacturing processes.

**Our operations must comply with extensive laws and regulations in the U.S. and other countries, including FDA regulations. Failure to obtain approvals on a timely basis or to achieve continued compliance could delay, disrupt or prevent the 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. 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 future product approvals we receive could be accompanied by significant restrictions on the use or marketing of the product. Product candidates may fail to receive marketing approval on a timely basis, or at all. If granted, product approvals can be withdrawn for failure to comply with regulatory requirements, such as the FDA's post-marketing requirement and post-marketing commitments for Tyvaso or upon the occurrence of adverse events subsequent to commercial introduction.

Discovery of previously unknown problems with our marketed products or problems with our manufacturing, regulatory, compliance, marketing or sales activities could result in regulatory restrictions on our products, including withdrawal of our products from the market. For example, in February 2010, we withdrew our MAA for Tyvaso as a result of findings by the EMA that certain of our clinical sites had failed to comply with Good Clinical Practices. If we fail to comply with applicable regulatory requirements, we could be subject to penalties that may consist of fines, suspension of regulatory approvals, product recalls, seizure of our products and/or criminal prosecution. In addition, our reputation could be harmed as a result of any such regulatory restrictions or actions and patients and physicians may not want to use our products even after we have resolved these issues that led to such regulatory action.

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**We are subject to ongoing regulatory review of our currently marketed products.**

After any of our products receive regulatory approval, they remain subject to ongoing regulation, which can impact, among other things, product labeling, manufacturing practices, adverse event reporting, storage, distribution, advertising and promotion, and record keeping. If we do not comply with the applicable regulations, the range of possible sanctions includes issuance of adverse publicity, product recalls or seizures, fines, total or partial suspensions of production and/or distribution, suspension of marketing applications, and enforcement actions, including injunctions and civil or criminal prosecution. The FDA and comparable international regulatory agencies can withdraw a product's approval under some circumstances, such as the failure to comply with regulatory requirements or unexpected safety issues. Further, the FDA often requires post-marketing testing and surveillance to monitor the effects of approved products. The FDA and comparable international regulatory agencies may condition approval of our product candidates on the completion of such post-marketing clinical studies. These post-marketing studies may suggest that a product causes undesirable side effects or may present a risk to the patient. If data we collect from post-marketing studies suggest that one of our approved products may present a risk to safety, the government authorities could withdraw our product approval, suspend production or place other marketing restrictions on our products. If regulatory sanctions are applied or if regulatory approval is delayed or withdrawn, our operating results and the value of our company may be adversely affected. Additionally, if we are unable to generate revenue from the sale of these products, our potential for generating positive cash flow will be diminished and the need for capital necessary to fund our operations will be increased.

**Regulatory approval for our currently marketed products is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated.**

Any regulatory approval of our products is limited to those specific diseases and indications for which our products are deemed to be safe and effective by the FDA. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. If we are not able to obtain FDA approval for any desired future indications for our products, our ability to effectively market and sell our products may be reduced and our business may be adversely affected.

While physicians may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those approved by regulatory authorities (called "off-label" uses), our ability to promote the products is limited to those indications that are specifically approved by the FDA. Although U.S. regulatory authorities generally do not regulate the behavior of physicians, they do restrict communications by companies on the subject of off-label use. If our promotional activities fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines relating to promotion and advertising may cause the FDA to delay or refuse approval for a product, the suspension or withdrawal of an approved product from the market, recalls, fines, disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could harm our business.

**We must comply with various laws around the world that restrict certain marketing practices in the pharmaceutical and medical device industries. Failure to comply with such laws could result in penalties and have a material adverse effect on our business, financial condition and results of operations.**

Various laws around the world, including antikickback and false claims statutes, the Foreign Corrupt Practices Act (FCPA) and the UK Bribery Act, restrict particular marketing practices in the pharmaceutical and medical device industries. Although we have compliance programs and procedures

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in place that we believe are effective, our business activities may be subject to challenge under these laws, and any penalties imposed upon us could have a material adverse effect on our business, financial condition and results of operations. Furthermore, we have significantly expanded our sales and marketing staff recently. Although we train our sales and marketing staff under our corporate compliance programs, any expansion of sales and marketing efforts can have the effect of increasing the risk of noncompliance with these laws.

In the United States, the federal health care program antikickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce, or in return for, purchasing, leasing, ordering, or arranging for the purchase, lease, or order of any health care item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers and prescribers, purchasers, and formulary managers. Although a number of statutory exemptions and regulatory safe harbors exist to protect certain common activities from prosecution, the exemptions and safe harbors are narrow, and practices that involve remuneration intended to induce prescriptions, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Although we seek to comply with the conditions for reliance on these exemptions and safe harbors, our practices may not always meet all of the criteria for safe harbor protection from anti-kickback liability.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Several pharmaceutical and health care companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the company's marketing of the product for unapproved, and thus non-reimbursable, uses. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment.

The PPACA imposes new reporting requirements for pharmaceutical and device manufacturers with regard to payments or other transfers of value made to physicians and teaching hospitals, effective March 30, 2013. In addition, pharmaceutical and device manufacturers will be required to report and disclose investment interests held by physicians and their immediate family members during the preceding calendar year. Such information is to be made publicly available by the Secretary of Health and Human Services in a searchable format beginning September 30, 2013.

Failure to submit required information may result in civil monetary penalties of up to \$150,000 per year (and up to \$1 million per year for "knowing failures") for all payments, transfers of value or ownership or investment interests not reported in an annual submission. Further, the PPACA amends the intent requirement of the federal anti-kickback and criminal health care fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims laws.

If not preempted by this federal law, several states require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to individual physicians in those states. Other states prohibit various other marketing related activities. Still other states require the posting of information relating to clinical studies and their

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outcomes. In addition, certain states, such as California, Nevada, and Massachusetts, require pharmaceutical companies to implement compliance programs or marketing codes and several other states are considering similar proposals. Compliance with these laws is difficult and time consuming, and companies that do not comply with these state laws face civil penalties.

**Government health care reform could increase our costs, which would adversely affect our revenue and results of operations.**

Our industry is highly regulated and changes in law may adversely impact our business, operations or financial results. The PPACA is a sweeping measure intended to expand healthcare coverage within the United States, primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. The reforms imposed by the new law will significantly impact the pharmaceutical industry; however, the full effects of the PPACA cannot be known until these provisions are implemented and the Centers for Medicare & Medicaid Services and other federal and state agencies issue applicable regulations or guidance. Moreover, in the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our products or product candidates. We will continue to evaluate the PPACA, as amended, the implementation of regulations or guidance related to various provisions of the PPACA by federal agencies, as well as trends and changes that may be encouraged by the legislation and that may potentially have an impact on our business over time.

**Reports of actual or perceived side effects and adverse events associated with our products, such as sepsis, could cause physicians and patients to avoid or discontinue use of our products in favor of alternative treatments.**

Reports of side effects and adverse events associated with our products could have a significant adverse impact on the sale of our products. An example of a known risk associated with intravenous Remodulin is sepsis, which is a serious and potentially life-threatening infection of the bloodstream caused by a wide variety of bacteria. Intravenous prostacyclins, such as intravenous Remodulin and Flolan, are infused continuously through a catheter placed in a large vein in the patient's chest, and sepsis is a known risk associated with this type of delivery. As a result, sepsis is included as a risk in both the Remodulin and Flolan package inserts. Although a discussion of the risk of sepsis is currently included on 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.

**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, which are constantly evolving. These regulations are subject to frequent revisions that often introduce more stringent requirements. While we believe we have developed and instituted adequate corporate compliance programs, we cannot ensure that we 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 receive approval of 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.

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**If the licenses, assignments and alliance agreements we depend on are breached or terminated, we could lose our right to develop and sell 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. Under our product license agreements, we receive certain rights to existing intellectual property owned by others subject to the terms of each license agreement. Under agreements assigning intellectual property rights to us, the assignor transfers all right, title and interest in and to the intellectual property to us, which are subject to the terms of such agreements. In addition, we may be required to obtain licenses to other third-party technologies to commercialize our early stage products. This dependence on technology developed by others involves 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 related products;

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

If a licensor or assignor fails to maintain the intellectual property licensed or assigned to us as required by most of our license and assignment agreements, we may lose our rights to develop and market some or all of our products. 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.

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

When we license or are assigned rights to drugs and other products that have been discovered and initially developed by others, our rights are frequently limited. For instance, our rights to market Adcirca are geographically limited to the United States and Puerto Rico; however, we would have an opportunity to negotiate with Lilly for the rights to market Adcirca in other territories in the event that Lilly decides not to market Adcirca in a particular territory. Furthermore, we cannot undertake any additional investigational work with respect to Adcirca in other indications of pulmonary hypertension without Lilly's prior approval. Lilly also has authority over all regulatory activities and has the right to determine the retail price for Adcirca and the wholesale price at which Lilly sells Adcirca to us.

Provisions in our license and assignment agreements may impose other restrictions that affect our ability to develop and market related products. For example, Glaxo retained 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 and Tyvaso anywhere in the world. Similarly, our amended license agreement with Toray includes a conditional non-compete clause that grants Toray the right to be our exclusive provider of beraprost-MR. Moreover, we must also meet certain minimum annual sales to maintain our exclusive rights to beraprost-MR.

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

The period under which our commercial and developmental therapies are protected by our patent rights is limited. Our U.S. patent for the method of treating PAH with Remodulin will expire in October 2014. Our three U.S. patents covering our current methods of synthesizing and producing treprostinil, the active ingredient in both Remodulin and Tyvaso, expire in October 2017. We also have

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been granted one patent in the EU and one patent in Japan, each of which covers our treprostiniil synthesis and production methods and will expire in October 2018. The patent for Adcirca for the treatment of pulmonary hypertension will expire in 2017 and our patents for Tyvaso will expire in the United States and in various countries throughout the EU in 2018 and 2020, respectively.

We continue to conduct research into new methods to synthesize treprostiniil and have two registered patents in the United States that expire in 2021, as well as, additional U.S. and international pending patent applications, relating to such methods. However, we cannot be sure that these additional patents will successfully deter competitors, or that additional patent applications will result in grants of patents. Upon the expiration of our patents, competitors may develop generic versions of our products and market those generic versions to compete with our products. Competitors may also seek to design around our patents prior to their expiration to develop competing products.

The scope of any patent may be insufficient to deter competitors and patent laws of international jurisdictions may not protect our rights to the same extent as the patent laws of the United States. Furthermore, our suppliers' intellectual property protections may not be adequate. Consequently, competitors may attempt to invalidate our existing patents before they expire. 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.

To the extent 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. Moreover, 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 would be unable to market related products and services.

We may initiate litigation to enforce or defend our patents or proprietary rights; however, litigation can be time-consuming and costly and may not conclude favorably. If we are unsuccessful with respect to any future legal action in the defense of our patents and our patents are invalidated or canceled, our business could be negatively impacted. Furthermore, any licensed rights, patents or other intellectual property we possess may be challenged, invalidated, canceled, infringed or circumvented and, therefore, may not provide us with any competitive advantage.

**We may not maintain adequate insurance coverage to protect us against significant product liability claims.**

The testing, manufacturing, marketing, and sale of drugs and diagnostics involve product liability risks. Although we currently maintain product liability insurance, 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.

**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 chemicals and hazardous substances and we are expanding these activities in both scale and location. In addition, patients may dispose of our products using means we do not control. Such activities subject us to numerous federal, state, and local environmental and safety laws and regulations that govern the management, storage and disposal of hazardous materials. Compliance with current or future environmental laws and regulations can require significant costs; furthermore, we can be subject to substantial fines and penalties in the event of noncompliance. While we believe we comply with laws

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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 facilities, 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.

**We may encounter substantial difficulties managing our growth relative to product demand.**

We have spent considerable resources building our laboratories and manufacturing facilities, and we are currently seeking regulatory approvals for some of these laboratories and all of our manufacturing facilities. These facilities may be insufficient to meet future demand for our products. Alternatively, we may have excess capacity at these facilities if future demand falls short of our expectations, or if we do not receive regulatory approvals for the products we intend to produce at these facilities. Constructing our facilities was expensive and our ability to recover our investment satisfactorily will depend on sales of the products manufactured at these facilities in sufficient volume. If we do experience substantial sales growth, we may have difficulty managing inventory levels as marketing new therapies is complicated, and gauging future demand can be difficult and uncertain. We intend to increase our internal manufacturing activities and reduce reliance on third-party suppliers, but we may not be successful in doing so. As our manufacturing capabilities and sales forces grow, we will be faced with increasing regulatory risks and will need to develop appropriate processes and compliance programs to manage such risks.

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

We may be required to seek additional sources of financing to meet unplanned or planned expenditures. 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 trials. We may also face unexpected costs in preparing products for commercial sale, or in maintaining sales levels of our currently marketed therapeutic products. If we are unable to obtain additional funding on commercially reasonable terms or at all, 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.

We may require additional financing to meet significant future obligations. For example, upon the maturity of our Convertible Senior Notes in October 2011, we must repay our investors in cash up to the principal balance of approximately \$250.0 million. In addition, awards granted under our Share Tracking Awards Plan (STAP) entitle participants to receive in cash an amount equal to the appreciation in the price of our common stock, which is calculated as the positive difference between the closing price of our common stock on the date of exercise and the date of grant. Consequently, the STAP will likely require significant future cash payments to participants to the extent the price of our common stock continues to appreciate and the number of vested STAP awards increases over time. If we do not have sufficient funds to meet such contractual obligations or the ability to secure alternative sources of financing, we could be in default, face litigation and/or lose key employees.



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**Risks Related to Our Common Stock**

**The price of our common stock can be highly volatile and may decline.**

The price of common stock can be highly volatile within the pharmaceutical and biotechnology sector. Consequently, there can be significant price and volume fluctuations in the market that may not always relate to operating performance. 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, 2010	December 31, 2010	\$ 64.24	\$ 46.22
January 1, 2009	December 31, 2009	\$ 52.88	\$ 27.86
January 1, 2008	December 31, 2008	\$ 57.99	\$ 24.51

The price of our common stock could decline sharply due to the following factors, among others:

Quarterly and annual financial and operating results;

Failure to meet estimates or expectations of securities analysts;

The timing of enrollment and results of our clinical trials, including our ongoing studies of oral treprostinil for PAH;

Physician, patient, investor or public concerns regarding 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, our therapeutic products 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;

Interference in patent or other proprietary rights;

Substantial sales of our common stock by us or our existing shareholders;

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

Rumors among or incorrect statements by investors and/or analysts concerning our company, our products, or operations;

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

Discovery of previously unknown problems with our marketed products or problems with our manufacturing, regulatory, compliance, promotional, marketing or sales activities that result in regulatory restrictions on our products, including withdrawal of our products from the market;

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Failure to obtain or maintain regulatory approvals from the FDA and international regulatory agencies;

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

Timing and outcome of additional regulatory submissions and approvals; and

General market conditions.

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

Many securities analysts publish independently developed quarterly and annual projections of our revenues and profits. Such estimates are inherently subject to uncertainty. As a result, actual revenues and profits may differ from these projections, and even small variations in reported revenues and profits compared to securities analysts' expectations could have a significant impact on the price of our common stock.

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

The price of our common stock could decline if: (1) we issue common stock to raise capital or to acquire a license or business; (2) our shareholders transfer ownership of our common stock, or sell substantial amounts in the public market; or (3) our investors become concerned that substantial sales of our common stock may occur. For example, Lilly has announced that they intend to sell a significant portion of our common stock they currently hold in 2011. A decrease in the price of our common stock could make it difficult for us to raise capital or fund acquisitions through the issuance of our stock.

The conversion of some or all of the Convertible Senior Notes when the price of our common stock exceeds \$52.85 per share would dilute the ownership interests of our existing shareholders. Any sales 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.

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

We may be required to repurchase the Convertible Senior Notes from their holders in the event of a fundamental change, which includes a change-of-control of our company. This may delay or prevent a change-of-control of our company that would otherwise be beneficial to our shareholders.

**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 shareholders.**

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/or

the replacement or removal of current management by our shareholders.

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 shareholders to replace 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-competition and all other restrictive covenants in most of our employment agreements will terminate upon a change of control that is not approved by our Board.

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, 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

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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 of control. If our counterparties to these agreements withhold their consent, related agreements could be terminated and we would lose related license rights. For example, both Lilly and Toray have the right to terminate our license agreements relating to Adcirca and beraprost-MR, respectively, in the event of certain change of control transactions. These restrictive change-of-control provisions could impede or prevent mergers that could benefit our shareholders.

**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 shareholder approval.**

Our directors and executive officers beneficially owned approximately 7.9 percent of our outstanding common stock as of December 31, 2010. Shares beneficially owned include stock options that could be exercised by those directors and executive officers within 60 days of December 31, 2010. Accordingly, these shareholders as a group may be able to influence the outcome of matters requiring shareholder approval, including the election of our directors. Such shareholder influence could delay or prevent a change of control that could benefit our shareholders.

**Because we do not intend to pay cash dividends, our shareholders must rely on stock appreciation for any return on their investment in us.**

We have never declared or paid cash dividends on our common stock. Furthermore, we do not intend to pay cash dividends in the future. As a result, the return on an investment in our common stock will depend entirely upon the future appreciation in the price of our common stock. There can be no assurances that our common stock will provide a return to investors.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

**ITEM 2. PROPERTIES**

**Maryland** We own a 147,000 square foot combination laboratory and office building in Silver Spring, Maryland that serves as our corporate headquarters and is used for the synthesis of treprostiniil-based compounds and monoclonal antibodies. We plan to use this facility to produce Remodulin, Tyvaso and monoclonal antibodies for commercial use. Our previous corporate headquarters and the buildings adjacent to it were demolished for the construction of a new office building which began in the third quarter of 2010 and is expected to be complete in late 2011. We also own two other buildings in Silver Spring used principally for office space and we lease space at a warehouse near Silver Spring.

**Florida** We own an office building in Satellite Beach, Florida. Our Lung Rx and Medicomp subsidiaries lease office space in Melbourne, Florida.

**North Carolina** We own a 200,000 square foot combination manufacturing facility and office building in Research Triangle Park, North Carolina, which is occupied by our clinical research and development and commercialization staffs. We warehouse and distribute Tyvaso and manufacture oral treprostiniil at this location. In March 2011, we plan to begin construction of an approximately 180,000 square foot expansion of this facility to meet our anticipated future needs for additional warehouse, packaging and office space. The expansion is expected to be completed in mid-2012.

**Europe** We own a 24,000 square foot building near London, England which serves as our European headquarters. We also own a building in Oxford, England. In Germany, we lease office and production space from NEBU-TEC for production of the Tyvaso Inhalation System.

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We believe that these facilities, along with various other owned and leased office facilities in the United States and Canada, are adequate for our current operations and that additional land and facilities for future expansion are reasonably available.

All our properties and leased facilities, except for the lease space for Medicomp, are used in our pharmaceutical segment.

**ITEM 3. LEGAL PROCEEDINGS**

As previously disclosed in each of our Quarterly Reports on Form 10-Q beginning with the quarter ended September 30, 2009, as well as in our Annual Report on Form 10-K for the year ended December 31, 2009, purported shareholders filed derivative lawsuits in the Court of Chancery for the State of Delaware against certain of our directors and named executive officers relating to the adoption of our STAP, the modification of awards granted under the STAP, the exchange of certain stock options granted under our Amended and Restated Equity Incentive Plan, and certain stock options awarded to our Chief Executive Officer. The parties entered into a stipulation to settle these lawsuits, and the Court entered an order approving the stipulation and settlement on January 21, 2011. The period for appealing that order expired on February 22, 2011. The derivative lawsuits are, therefore, resolved.

From time to time, we may be involved in other lawsuits and proceedings incidental to the conduct of our business. We are not a party to any other lawsuit or proceeding that, in the opinion of our management, is likely to have a material adverse effect on our financial position or results of operations.

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, as adjusted for the two-for-one split of our common stock on September 22, 2009:

		2010		2009	
		High	Low	High	Low
January 1	March 31	\$ 61.46	\$ 53.27	\$ 36.64	\$ 29.60
April 1	June 30	\$ 58.52	\$ 48.81	\$ 42.93	\$ 27.86
July 1	September 30	\$ 56.07	\$ 46.22	\$ 50.30	\$ 39.32
October 1	December 31	\$ 64.24	\$ 54.26	\$ 52.88	\$ 40.63

As of February 18, 2011, there were 42 holders of record of our common stock.

**Dividend Policy**

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

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**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 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.

	For Years Ended December 31,				
	2010	2009	2008	2007	2006
<b>Consolidated Statements of Operations Data:</b>					
Revenues	\$ 603,831	\$ 369,848	\$ 281,497	\$ 210,943	\$ 159,632
Operating expenses:					
Research and development	166,761	122,188	239,181	83,352	57,570
Selling, general and administrative	199,600	176,338	94,306	99,027	56,052
Cost of sales	73,465	45,321	30,066	22,261	17,028
Total operating expenses	439,826	343,847	363,553	204,640	130,650
Income (loss) from operations	164,005	26,001	(82,056)	6,303	28,982
Other income (expense):					
Interest income	2,939	5,146	11,025	13,602	10,700
Interest expense	(19,714)	(12,875)	(11,439)	(14,281)	(2,417)
Equity loss in affiliate	(160)	(141)	(226)	(321)	(491)
Other, net	769	636	(1,025)	(826)	1,199
Total other income (expense), net	(16,166)	(7,234)	(1,665)	(1,826)	8,991
Income (loss) before income tax	147,839	18,767	(83,721)	4,477	37,973
Income tax (expense) benefit	(41,923)	695	34,394	7,876	34,623
Net income (loss)	\$ 105,916	\$ 19,462	\$ (49,327)	\$ 12,353	\$ 72,596
Net income (loss) per common share:					
Basic(1)	\$ 1.89	\$ 0.37	\$ (1.08)	\$ 0.29	\$ 1.58
Diluted(1)	\$ 1.78	\$ 0.35	\$ (1.08)	\$ 0.28	\$ 1.50
Weighted average number of common shares outstanding:					
Basic(1)	56,142	53,314	45,802	42,448	46,020
Diluted(1)	59,516	56,133	45,802	44,902	48,276

	Year Ended December 31,				
	2010	2009	2008	2007	2006
<b>Consolidated Balance Sheet Data:</b>					
Cash, cash equivalents and marketable investments(2)	\$ 759,932	\$ 378,120	\$ 336,318	\$ 299,792	\$ 264,163
Total assets	1,431,635	1,051,544	874,534	585,247	476,317
Debt	304,897	250,599	234,952	192,172	179,604
Retained earnings (deficit)	31,170	(74,746)	(93,927)	(30,375)	(42,729)
Total stockholders' equity	883,886	653,009	555,334	352,131	272,559

- (1) See Note 11 *Stockholders' Equity* to our consolidated financial statements included 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.



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**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 *Part I, Item 1A Risk Factors Forward Looking Statements* appearing 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 Securities and Exchange Commission. We undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise.

**Overview**

United Therapeutics Corporation is a biotechnology company focused on the development and commercialization of unique products to address the unmet medical needs of patients with chronic and life-threatening conditions.

Our key therapeutic products and product candidates include:

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

*Phosphodiesterase type 5 (PDE-5) inhibitor (Adcirca®):* a molecule that acts to inhibit the degradation of cyclic guanosine monophosphate (cGMP) in cells. cGMP is activated by nitric oxide, a naturally occurring substance in the body that mediates the relaxation of vascular smooth muscle;

*Monoclonal antibodies (Ch14.18 MAb and 8H9 MAb):* antibodies that treat cancer by activating the immune system; and

*Glycobiology antiviral agents (Miglustat and other agents):* a novel class of small, sugar-like molecules that have shown antiviral activity in a range of pre-clinical settings.

We concentrate substantially all of our research and development efforts on these key therapeutic programs. Our lead product is Remodulin (treprostinil) Injection (Remodulin) for the treatment of pulmonary arterial hypertension (PAH). The United States Food and Drug Administration (FDA) initially approved Remodulin in 2002 for subcutaneous (under the skin) administration. Subsequently, the FDA broadened its approval of Remodulin for intravenous (in the vein) use and for the treatment of patients who require transition from Flolan®, the first drug approved by the FDA for the treatment of PAH. In addition to the United States, Remodulin is approved in many other countries, primarily for subcutaneous use. In May 2009, the FDA approved Adcirca (tadalafil) tablets (Adcirca), an orally administered therapy for the treatment of PAH to which we acquired certain exclusive commercialization rights from Eli Lilly and Company (Lilly). In July 2009, the FDA approved Tyvaso (treprostinil) Inhalation Solution (Tyvaso), an inhaled therapy for the treatment of PAH. We launched both Adcirca and Tyvaso for commercial sale during the third quarter of 2009. With the introduction of these two new therapies, we now offer treatments to a broader range of patients who suffer from PAH. In addition, we are continuing to develop oral formulations of treprostinil and beraprost, both for the treatment of PAH.

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***Revenues***

Sales of Remodulin comprise the largest share of our revenues. Other sources of pharmaceutical revenues include sales of our recently approved therapies, Tyvaso and Adcirca. Since their commercial introduction in 2009, sales of Tyvaso and Adcirca have continued to grow, as each of these therapies has gained broader market acceptance. We sell Remodulin and Tyvaso in the United States to our specialty pharmaceutical distributors: Accredo Health Group, Inc., CuraScript, Inc., and CVS Caremark. Adcirca is sold to pharmaceutical wholesalers that are part of Lilly's pharmaceutical wholesaler network. We also sell Remodulin to distributors outside of the United States.

We require our distributors to maintain reasonable levels of contingent inventory, with a minimum of a 30-day supply, at all times, as the interruption of Remodulin or Tyvaso therapy can be life threatening. Consequently, sales of these therapies in any given quarter may not precisely reflect patient demand. Our distributors typically place one bulk order per month based on estimates of future demand and considerations of contractual minimum inventory requirements. As a result, the sales volume of Remodulin and Tyvaso can vary, depending on the timing and magnitude of these orders.

In March and April of 2010, we increased the price on all concentrations of Remodulin sold to our U.S.-based and international distributors by 9.6 percent and 13.3 percent, respectively. In addition, we increased the price of Tyvaso by 4.9 percent in November 2010 to offset the increasing cost of manufacture and distribution. In January 2011, Lilly notified us that it was increasing the wholesale price of Adcirca by 9.0 percent.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the Acts). The Acts contain broad provisions that will be implemented over the next several years. We are currently evaluating the impact of the Acts on our business; however, our evaluation is dependent upon the issuance of final regulations and the impact this legislation will have on insurance companies and their relationships with drug manufacturers. We were not materially impacted by the Acts during the year ended December 31, 2010. However, the potential future impact of the Acts on our business is inherently difficult to project as many of the details regarding the implementation of this legislation are yet to be determined. Presently, we have not yet identified any provisions that could materially impact our business, but will continue to monitor future developments of this legislation.

Effective January 1, 2010, the Acts increased the minimum rate for rebates pharmaceutical companies must provide to Medicaid on certain pharmaceutical products from 15.1 percent to 23.1 percent. This increase applies to rebates for Remodulin, Tyvaso and Adcirca. Based on our evaluation of Medicare rebates for the year ended December 31, 2010, the increase in the rate for Medicaid rebates decreased our net revenues by less than one percent. Furthermore, over the last three years, less than ten percent of prescriptions for our drugs have been reimbursed by Medicaid. As such, we do not expect this provision of the Acts to materially impact our future revenues.

Total revenues are reported net of: (1) estimated rebates and other reimbursements; (2) prompt pay discounts; (3) service fees to our distributors; and (4) allowances for product returns or exchanges. Estimates of our liability for rebates and reimbursements are derived from an analysis of historical levels of rebates/reimbursements to both state Medicaid agencies and third-party payers by product relative to sales of each product. Prompt pay discounts are provided on sales of our commercial products if the related invoices are paid in full within a specific time period. We estimate our liability for prompt pay discounts based on observed customer payment behavior. Fees paid to our distributors for services are estimated based on contractual rates for specific services applied to the estimated units of service provided for the period. The allowance for sales returns for Adcirca is estimated based on published industry data related to specialty pharmaceuticals, which is the segment most relevant to Adcirca. The allowance for exchanges for Remodulin is based on the historical rate of product exchanges, which has been too immaterial to record. In addition, because Tyvaso is distributed in the

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same manner and under similar contractual arrangements as Remodulin, the level of product exchanges for Tyvaso has been comparable to that of Remodulin and we anticipate minimal exchange activity in the future for both products.

During the fourth quarter of 2010, we increased our sales and marketing department by approximately 50 personnel. This initiative was designed to increase demand for our products through greater exposure and interaction with prescribers.

In addition to our pharmaceutical revenues, other sources of revenue consist primarily of sales of telemedicine products and services in the United States. Our telemedicine products and services are designed to detect cardiac arrhythmias and ischemic heart disease. On February 7, 2011, we entered into a merger agreement with a group of private investors to sell Medicomp, our telemedicine subsidiary. We expect this transaction to close in March or April 2011, assuming the timely receipt of required regulatory approvals. For further details, see Note 20 *Subsequent Event* to our consolidated financial statements included in this Annual Report on Form 10-K.

***Expenses***

Since our inception, we have devoted substantial resources to our various research and development initiatives. Accordingly, we incur considerable costs related to our clinical trials and research, conducted both internally and by third parties, on a variety of projects to develop pharmaceutical products. We also seek to license or acquire promising technologies and/or compounds to be incorporated into our development pipeline.

Our operating expenses can be materially impacted by the recognition of share-based compensation relating to our Share Tracking Awards Plan (STAP) and any awards of stock option grants. STAP awards are required to be measured at fair value at the end of each reporting period using inputs and assumptions that can materially impact the amount of compensation expense for a given period. Additionally, some, or all of the following factors, among others, can cause substantial variability in the amount of share-based compensation recognized period to period: (1) changes in the price of our common stock; (2) changes in the number of outstanding awards; and (3) changes in both the number of vested awards and the time awards have accrued toward vesting. For further details, see Note 8 *Share Tracking Awards Plan* to our consolidated financial statements included in this Annual Report on Form 10-K. Generally, our stock option grants are measured at fair value at the date of grant. The fair value of stock option grants is recognized as compensation expense over the service period, which typically coincides with the vesting period of related options. We recognize all compensation expense immediately for grants that are fully vested at the date of grant. For further details on stock options, see Note 11 *Stockholders' Equity* to our consolidated financial statements included in this Annual Report on Form 10-K.

**Major Research and Development Projects**

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

***Cardiopulmonary Disease Projects***

*Tyvaso*

Upon receiving FDA approval of Tyvaso for the treatment of PAH in July 2009, we launched the product for commercial sale in September 2009. In connection with the Tyvaso approval, we agreed to a post-marketing requirement (PMR) and certain post-marketing commitments (PMCs). PMRs and PMCs often obligate sponsors to conduct studies after FDA approval to gather additional information

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about a product's safety, efficacy, or optimal use. PMRs are required studies, whereas PMCs are voluntary commitments. We are required to provide the FDA annual updates on our PMR and PMCs. Failure to complete or adhere to the timelines set forth by the FDA for the PMR could result in penalties, including fines or withdrawal of Tyvaso from the market, unless we are able to demonstrate good cause for the failure or delay.

In accordance with our PMR, we recently commenced patient enrollment in a long-term observational study in the U.S. that will include 1,000 patient years of follow-up in patients treated with Tyvaso, and 1,000 patient years of follow up in control patients receiving other PAH treatments. This study will allow us to continue to assess the safety of Tyvaso. We are currently required to submit the results of the study by December 15, 2013, but we have requested an extension to this timeline.

The PMCs require us to modify particular aspects of the Tyvaso Inhalation System. As part of these modifications, we agreed to perform a usability analysis incorporating the evaluation and prioritization of user-related risk followed by a human factors study. We submitted proposed modifications to the device to the FDA in accordance with the PMCs and completed the related human factors study. The FDA has requested further modifications to the device and a follow-up usability study once these additional modifications are complete. As a result of the further modifications and follow-up usability study, we have requested an extension to the original October 31, 2010 timeline for completion of the PMCs. Our request is under review by the FDA.

In June 2010, the FDA granted orphan-drug designation for Tyvaso. Such a designation confers an exclusivity period during which the FDA may not approve any application to market the same drug for the same indication, except in limited circumstances.

In December 2008, we began enrolling patients in an open-label study in the United States to investigate the effects of switching patients on Ventavis®, another inhaled prostacyclin analogue, to Tyvaso. We recently completed the study, in which improvements in patient quality of life were observed. Final data is being prepared for presentation at scientific symposia.

*Oral treprostinil*

In December 2006, we initiated two Phase III clinical trials, FREEDOM-C and FREEDOM-M, to evaluate the safety and efficacy of oral treprostinil in patients with PAH.

FREEDOM-C was a study of patients currently on approved background therapy using a PDE-5 inhibitor, such as Revatio®, or an endothelin receptor antagonist, such as Tracleer®, or a combination of both. We completed enrollment for FREEDOM-C in May 2008 and in November 2008 announced that FREEDOM-C failed to achieve statistical significance for the primary endpoint of six-minute walk distance. Preliminary analysis of the data revealed that the initial dose of 1.0 mg was too high, which contributed to an inability to dose titrate (increase the dose to tolerability), prevented the attainment of optimal dosing levels and led to higher dropout rates than we anticipated. Consequently, the overall treatment effect of the therapy was muted. We believe, however, that the results of the FREEDOM-C clinical trial, particularly as they relate to treatment effect and dosing, warrant our continued development of oral treprostinil. Accordingly, we commenced an additional Phase III clinical trial, FREEDOM-C<sup>2</sup>, to continue studying dosage and efficacy of oral treprostinil in PAH patients on an approved background therapy. Enrollment in FREEDOM-C<sup>2</sup> began in June 2009. In the FREEDOM-C<sup>2</sup> study, patients are provided access to a lower strength tablet (0.25 mg) and doses are being titrated in 0.25 mg to 0.5 mg increments. We estimate that this trial will be fully-enrolled in April 2011, in which case we expect to unblind and announce preliminary analysis of the trial in September 2011.

FREEDOM-M is a 12-week study of newly diagnosed PAH patients not currently on any background therapy. Based on our observations from the FREEDOM-C clinical trial relating to patient

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tolerability and tablet strength, we submitted a protocol amendment to the FDA in February 2009 to add patients to the ongoing FREEDOM-M trial. These additional patients were provided a lower strength tablet (0.25 mg) when beginning the trial and doses were titrated in 0.25 mg to 0.5 mg increments, which we believe improved tolerability. In addition, we submitted an amendment to our statistical analysis plan, specifying that the primary statistical analysis of the trial will include only those patients who started the trial using the 0.25 mg tablet. By amending the protocol for FREEDOM-M we hope to: (1) assess more accurately the effectiveness of oral treprostini; (2) improve patient tolerability of oral treprostini so that an effective maintenance dose can be attained; and (3) reduce the rate of premature discontinuation due to adverse events. The statistical assumptions of the amended protocol provide for 90 percent power (confidence rate) to observe a 45-meter treatment benefit in six-minute walk distance at the significance level of 0.01. On January 31, 2011 we completed enrollment of FREEDOM-M with 349 patients, compared to target enrollment of 315 patients, and expect to unblind and announce preliminary analysis of the results of the clinical trial in June 2011.

We have also introduced a 0.125 mg tablet, which allows us to start patients on an even lower strength tablet, and titrate doses in smaller increments for both FREEDOM-C<sup>2</sup> and FREEDOM-M, if needed.

*Beraprost-MR*

Pursuant to our license agreement with Toray Industries, Inc. (Toray), we are developing a modified release formulation of beraprost-MR, an oral prostacyclin analogue, for the treatment of PAH. In October 2007, beraprost-MR received regulatory approval in Japan for the treatment of PAH. We have completed enrollment of a Phase II clinical trial of beraprost to explore multiple-dose tolerability in patients with PAH and we have begun a second Phase II clinical trial. In September 2010, we entered into a supplement to our license agreement with Toray under which we agreed on the timing of two milestone payments provided for under our existing agreement, in the amounts of \$4.0 million and \$5.0 million. All conditions relating to these milestone payments were satisfied in the fourth quarter of 2010; accordingly, during the quarter we paid Toray \$4.0 million and recognized a \$5.0 million liability and associated expense relating to the second milestone payment, which will be paid to Toray during the first quarter of 2011. Although the second milestone payment is not due until the first quarter 2011, we accrued and expensed the payment in 2010 because the contingencies affecting this milestone payment were satisfied during the fourth quarter of 2010. These milestone payments were expensed as incurred since beraprost-MR has not demonstrated commercial feasibility.

*Collagen Type V*

Pursuant to our February 2010 development agreement with ImmuneWorks, Inc., Lung Rx is developing a purified bovine Type V Collagen oral solution called IW001 for the treatment of idiopathic pulmonary fibrosis (IPF), a progressive lung disease characterized by abnormal and excessive fibrotic tissue in the lungs, and primary graft dysfunction, a type of organ rejection that can occur in lung transplants. Human clinical testing of IW001 has commenced, and a Phase I clinical trial in patients with IPF is ongoing.

From inception to December 31, 2010, we have spent \$601.6 million on our cardiopulmonary disease programs.

*Cancer Disease Projects*

*Ch14.18 Antibody*

In July 2010, we entered into a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI) to collaborate on the late-stage development and regulatory agency submissions of Chimeric Monoclonal Antibody 14.18 (Ch14.18) for children with high-risk

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neuroblastoma and patients with other forms of cancer. Ch14.18 is an antibody that has shown potential in the treatment of certain types of cancer by targeting GD2, a glycolipid on the surface of tumor cells. Under the terms of the CRADA, NCI will conduct a clinical trial in approximately 100 patients to define more clearly the safety and toxicity profile of Ch14.18 immunotherapy in children and we will develop the commercial manufacturing capability for the antibody. As part of developing our commercial manufacturing capability, we will need to demonstrate comparability of our Ch14.18 to the NCI-produced Ch14.18, which typically includes a series of analytical and bioanalytical assays and human pharmacokinetics. The NCI studies, including a previously conducted related Phase III clinical trial and all other necessary studies supported by NCI will be used as the basis for a Biologics License Application seeking FDA approval of Ch14.18 immunotherapy for the treatment of neuroblastoma.

*3F8 and 8H9 Antibodies*

In December 2007, we entered into two agreements with Memorial Sloan-Kettering Cancer Center to license certain rights to two investigational monoclonal antibodies 3F8 for the treatment of neuroblastoma and 8H9 for the treatment of metastatic brain cancer. We terminated our license to 3F8 during the fourth quarter of 2010 given the overlap between this program and the Ch14.18 program.

We have spent \$66.0 million from inception to December 31, 2010, on our cancer programs.

*Infectious Disease Projects*

Pursuant to our research agreement with the University of Oxford (Oxford), we have the exclusive right to commercialize a platform of glycobiology antiviral drug candidates in various preclinical and clinical stages of testing for the treatment of a wide variety of viruses. Through our research agreement with Oxford, we are also supporting research into new glycobiology antiviral drug candidates and technologies. We are currently testing many of these compounds in preclinical studies and Oxford continues to synthesize new agents for us to test.

We have spent \$47.0 million from inception to December 31, 2010, on our infectious disease programs.

**Cost of Product Sales**

Cost of product sales comprises costs to manufacture and acquire products sold to customers, and royalty payments under license agreements granting us rights to sell related products. We manufacture forms of treprostinil using advanced intermediate compounds purchased in bulk from several third-party vendors that have the capacity to produce greater quantities of these compounds more cost effectively than we do. In 2009, we received regulatory approval in both the United States and the European Union to produce treprostinil in our facility in Silver Spring, Maryland. Our manufacturing process has been designed to give us the flexibility to produce the forms of treprostinil used in Remodulin, Tyvaso, and our oral tablet, based on forecasted demand for each of these products. The approved shelf lives for both Remodulin and Tyvaso are 36 months. To ensure sufficient availability of Remodulin and Tyvaso at all times, we maintain inventories of these products equivalent to approximately three years of expected demand.

We acquired the rights to the Tyvaso Inhalation System from NEBU-TEC in September 2009. Tyvaso is generally sold as a starter kit for new patients and as a resupply kit for monthly prescription refills. The Tyvaso starter kits consist of the Tyvaso Inhalation System, which includes two nebulizers and a twenty-eight day supply of Tyvaso. The monthly resupply kits contain a twenty-eight day supply of Tyvaso and daily supplies only. Because the starter kits contain two nebulizers, the cost of product sales for the starter kits is higher than the resupply kit. We currently manufacture the Tyvaso Inhalation System in Germany using labor supplied by NEBU-TEC. In addition, we received FDA approval in December 2010 for Minnetronix, Inc. to manufacture the Tyvaso Inhalation System and for Quality

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Tech Services, Inc. to package daily supplies. Catalent Pharma Solutions, Inc. (Catalent) continues to manufacture Tyvaso.

In 2009, we amended our contract with our Remodulin manufacturer, Baxter Pharmaceutical Solutions, LLC (Baxter), to extend the contract term through 2013. As part of that contract amendment, we agreed that Baxter will manufacture Remodulin in greater quantities using larger capacity production equipment. This new manufacturing process and related equipment will require FDA and international regulatory approvals. We are currently conducting validation testing for the new equipment and process. Until FDA approval of the new process and equipment, Baxter continues to manufacture Remodulin using the approved process and equipment. In January 2011, we received FDA approval of Hollister-Stier Laboratories LLC as a second manufacturer for Remodulin in the larger quantities discussed above.

We are actively working to obtain approval for the commercial manufacture Remodulin and Tyvaso in our Silver Spring facility. Our goal is to become the primary manufacturer with contracted third-party manufacturers supplementing our manufacturing capacity.

Lilly manufactures and distributes Adcirca through its wholesaler network in the same manner that it distributes its own pharmaceutical products. Under the terms of this agreement, we take title to Adcirca upon completion of its manufacture by Lilly. Adcirca is shipped to customers, generally pharmaceutical wholesalers, in accordance with purchase orders received by Lilly. Although Lilly provides these services on our behalf, we maintain the risk of loss as it pertains to inventory and non-payment of invoices.

We acquired the rights to sell our commercial products through license and assignment agreements with the developers of these products, as described in the section entitled *Item 1 Business Patents and Proprietary Rights*. These agreements obligate us to pay royalties generally on the net revenues from the products. While the royalties vary by agreement, we pay royalties on our current commercial products at a rate of 1% to 10% of net revenues.

**Future Prospects**

Because PAH remains a progressive disease without a cure, we expect continued growth in the demand for our commercial products as viable alternatives or complements to other approved therapies. Furthermore, the commercial introduction of Tyvaso and Adcirca allows us to offer products to more patients along the full continuum of the disease. Since 2002, we have experienced annual revenue growth in excess of 30 percent and one of our principal objectives is to sustain industry-leading revenue growth. The continued achievement of this objective will depend in large part upon the successful commercial development of products within our pipeline. To this end, we continue to develop oral treprostinil and beraprost and seek to expand the use of our therapies to treat patients at earlier stages in the PAH disease progression and to treat other conditions.

We believe the outcome of our FREEDOM-M and FREEDOM-C<sup>2</sup> Phase III clinical trials of oral treprostinil will be successful. Furthermore, we anticipate that the products developed under these clinical trials will generate future sources of revenue. However, prior to FDA approval of oral treprostinil for marketing, we could be required to perform additional studies. This could cause unexpected delays in the commercialization of oral treprostinil and could impede our anticipated revenue growth. Our future growth and profitability will depend on many factors including, among others: (1) the timing and outcome of clinical trials and regulatory approvals, including those relating to oral treprostinil and the PMCs and PMR relating to the FDA's approval of Tyvaso; (2) the timing of the commercial launch of Remodulin and Tyvaso in new markets and of new products; (3) the pricing of and demand for our products and services; (4) reimbursement of our products by public and private insurance organizations; and (5) the competition we face within our industry.

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We operate in a highly competitive market in which a small number of pharmaceutical companies control a majority of the currently approved PAH therapies. These pharmaceutical companies not only possess greater visibility in the market, but also greater financial, technical and marketing resources than we do. In addition, there are a number of investigational products in development that, if approved, may erode the market share of our existing commercial therapies and make market acceptance more difficult to achieve for any therapies we market in the future.

**Financial Position**

Cash, cash equivalents and marketable investments (excluding all restricted amounts) at December 31, 2010, were \$759.9 million, compared to approximately \$378.1 million as of December 31, 2009. The increase in cash and marketable investments of \$381.8 million was driven mainly by: (1) significant sales growth of \$234.0 million and related cash receipts from sales of Remodulin and the launch of Adcirca and Tyvaso; (2) \$70.0 million in proceeds received from a mortgage loan which closed on December 27, 2010 (See Note 9 *Debt Mortgage Financing* to the consolidated financial statements included in this Annual Report on Form 10-K); and (3) \$52.5 million in net proceeds received from the exercise of stock options less cash paid upon the exercise of awards granted under our Share Tracking Awards Plan (STAP) during the twelve-month period ended December 31, 2010.

Restricted cash and marketable investments decreased by \$34.9 million as amounts securing our synthetic lease arrangement related to our Phase I Laboratory were released upon the termination of the lease in connection with the closing of our mortgage loan. At December 31, 2010 restricted cash and marketable investments was composed of \$5.1 million placed in the United Therapeutics Corporation Supplemental Executive Retirement Plan Rabbi Trust Document (Rabbi Trust).

Accounts receivable at December 31, 2010, was \$73.7 million, compared to \$50.6 million at December 31, 2009. The \$23.1 million increase reflected the increase in our sales of pharmaceutical products, particularly sales during the quarter ended December 31, 2010, compared to the quarter ended December 31, 2009.

The increase in inventory of \$9.2 million at December 31, 2010, from \$26.4 million to \$35.5 million, coincided largely with our efforts to increase our inventories of Remodulin, Tyvaso and tadalafil to a three-year supply based on sales trends and growth expectations.

Goodwill and other intangible assets decreased by approximately \$8.6 million, from \$18.4 million at December 31, 2009, to \$9.9 million at December 31, 2010. The decrease includes a \$6.2 million impairment charge related to Medicomp, our telemedicine subsidiary. On February 7, 2011, we entered into an agreement to sell Medicomp to a group of private investors for approximately \$14.9 million. At December 31, 2010, the carrying value of Medicomp was greater than the fair value of the purchase price which resulted in the goodwill impairment charge. For additional details, refer to Note 2 *Summary of Significant Accounting Policies Goodwill and Other Intangible Assets* and Note 20 *Subsequent Event*, included in this Annual Report on Form 10-K.

Accrued expenses at December 31, 2010 were \$50.3 million, compared to \$29.8 million at December 31, 2009. The increase in accrued expenses of \$20.5 million comprised mainly of increases in accrued royalties and rebates of \$11.6 million and accrued research-related costs of \$6.0 million, which included a \$5.0 million milestone payment due to Toray in the first quarter of 2011.

Other current liabilities increased by \$64.9 million from \$61.4 million at December 31, 2009, to \$126.3 million at December 31, 2010. The liability for the STAP increased by \$61.4 million from December 31, 2009 to December 31, 2010 as a result of the appreciation in the price of our common stock and increases in both the number of outstanding awards and the period such awards had accrued toward vesting.



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Notes payable current increased by \$15.7 million from \$220.3 million at December 31, 2009 to \$236.0 million at December 31, 2010. This increase resulted from the amortization of the debt discount relating to our Convertible Senior Notes for the year ended December 31, 2010.

Mortgage payable noncurrent at December 31, 2010 increased by \$68.9 million from none at December 31, 2009. The increase related to a \$70.0 million mortgage loan funded in December 2010. Amounts due within one year from December 31, 2010 have been included under the caption, "Other current liabilities" on our consolidated balance sheet at December 31, 2010.

The reduction in the lease obligation from \$30.3 million at December 31, 2009 to none at December 31, 2010 resulted from the termination of our synthetic lease agreement relating to our Phase I Laboratory, which was the first completed building in our Silver Spring headquarters campus. We terminated the synthetic lease and acquired title to the Phase I Laboratory to secure our \$70.0 million mortgage loan.

Other noncurrent liabilities at December 31, 2010, were \$39.3 million compared to \$27.1 million at December 31, 2009. The \$12.1 million increase was largely due to an \$11.9 million increase in the projected benefit obligation related to our Supplemental Executive Retirement Plan (SERP) as a result of the addition of two new participants during the year ended December 31, 2010.

Stockholders' equity was \$883.9 million at December 31, 2010, compared to \$653.0 million at December 31, 2009. The increase of \$230.9 million consisted primarily of the following: (1) net income of \$105.9 million; (2) net proceeds and related tax benefits from the exercise of stock options of \$83.3 million and \$23.8 million, respectively; and (3) the recognition of \$22.7 million in share-based compensation.

### **Results of Operations**

#### *Years ended December 31, 2010 and 2009*

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

	For Years Ended December 31,		Percentage Change
	2010	2009	
Cardiopulmonary products:			
Remodulin	\$ 403,598	\$ 331,579	21.7%
Tyvaso	151,797	20,268	648.9%
Adcirca	36,307	5,789	527.2%
Telemedicine services and products	10,932	10,968	(0.3)%
License fees	1,197	1,244	(3.8)%
<b>Total revenues</b>	<b>\$ 603,831</b>	<b>\$ 369,848</b>	<b>63.3%</b>

The growth in revenues experienced during 2010 resulted in large part from the increase in the number of patients being prescribed our products. In addition, in March and April of 2010, we increased the price of Remodulin sold to our U.S. and international distributors, respectively, and in November 2010, increased the price of Tyvaso by 4.9%. The impact of these price increases for the year ended December 31, 2010, was \$25.9 million, of which, \$25.6 million related to sales of Remodulin. For the years ended December 31, 2010 and 2009, approximately 86% and 88%, respectively, of net Remodulin revenues were earned from our three distributors located in the United States. In addition, all of our Tyvaso revenues were earned from the same three distributors. Adcirca revenues are earned from sales to national and regional pharmaceutical wholesalers.

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The table below presents a reconciliation of the liability accounts associated with estimated rebates and reimbursements, sales discounts, distributor fees and sales allowances and the net reductions to revenues related to these items (dollars in thousands):

	For Years Ended December 31,	
	2010	2009
Liability accounts, at beginning of period	\$ 6,639	\$ 4,096
Additions to liability attributed to sales in:		
Current period	44,166	21,338
Prior period	232	
Payments or reductions attributed to sales in:		
Current period	(32,829)	(13,979)
Prior period	(5,032)	(4,816)
Liability accounts, at end of period	\$ 13,176	\$ 6,639
Net reductions to revenues	\$ 44,398	\$ 21,338

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

	For Years Ended December 31,		Percentage Change
	2010	2009	
<b>Project and non-project:</b>			
Cardiopulmonary	\$ 86,161	\$ 61,574	39.9%
Share-based compensation	45,878	36,294	26.4%
Other	34,722	24,320	42.8%
Total research and development expense	\$ 166,761	\$ 122,188	36.5%

*Cardiopulmonary.* The increase in cardiopulmonary expenses of \$24.6 million for the year ended December 31, 2010, compared to the year ended December 31, 2009 was driven largely by the following: (1) an increase of \$12.8 million in expenses incurred in connection with our FREEDOM-M and FREEDOM-C<sup>2</sup> Phase III clinical trials; (2) an increase of \$13.8 million in expenses related to our development of beraprost-MR, which includes \$9.0 million in milestone related expenses; and (3) an increase of \$4.9 million, including \$3.0 million in milestone payments to ImmuneWorks, Inc. for the development of a Type V Collagen oral solution which began in 2010. These increases were offset, in part, by a \$5.9 million decrease in expenditures related to our inhaled treprostinil program.

*Share-based compensation.* The increase in share-based compensation expense of \$9.6 million for the year ended December 31, 2010, compared to the year ended December 31, 2009, can be attributed to our STAP awards.

*Other.* The increase of \$10.4 million in other research and development expenses of during the year ended December 31, 2010, compared to those for the year ended December 31, 2009, corresponded mainly to an increase of \$10.2 million in personnel, depreciation and overhead costs supporting our research mainly because 2010 was the first full year of operations of our new facilities in North Carolina and Maryland. Research and development expenses for our individual disease platforms include only direct labor and related direct costs.

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

Category:	For Years Ended December 31,		Percentage Change
	2010	2009	
General and administrative	\$ 83,077	\$ 68,606	21.1%
Sales and marketing	49,332	43,593	13.2%
Share-based compensation	67,191	64,139	4.8%
<b>Total selling, general and administrative expense</b>	<b>\$ 199,600</b>	<b>\$ 176,338</b>	<b>13.2%</b>

*General and administrative.* During the year ended December 31, 2010, general and administrative expense increased \$14.5 million compared to the year ended December 31, 2009, for the following reasons: (1) increases of \$4.5 million and \$3.9 million in personnel and depreciation, respectively, relating to the operations of our facilities in Maryland and North Carolina, which were in operation for a full year for the first time in 2010; and (2) an increase of \$5.3 million in grants to unaffiliated, not-for-profit organizations that provide therapy-related financial assistance and programs to patients suffering from PAH.

*Sales and marketing.* The increase in sales and marketing expenses of \$5.7 million for the year ended December 31, 2010, compared to the year ended December 31, 2009, related primarily to increases of \$4.6 million in payroll-related expenses as a result of the growth of our sales force and marketing staff and \$1.1 million in marketing consultant fees incurred in connection with the recent commercialization of Tyvaso and Adcirca.

*Share-based compensation.* The increase in share-based compensation of \$3.1 million for the year ended December 31, 2010, compared to the year ended December 31, 2009, can be attributed to our STAP awards.

*Income Tax Expense.* The provision for income taxes was \$41.9 million for the year ended December 31, 2010. For the year ended December 31, 2009, we recognized an income tax benefit of \$695,000 as a result of the business tax credits generated from our drug-related research and development activities.

### *Years ended December 31, 2009 and 2008*

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

	For Years Ended December 31,		Percentage Change
	2009	2008	
Cardiopulmonary products:			
Remodulin	\$ 331,579	\$ 269,718	22.9%
Tyvaso	20,268		100.0%
Adcirca	5,789		100.0%
Telemedicine services and products	10,968	9,485	15.6%
License fees	\$ 1,244	\$ 2,294	(45.8)%
<b>Total revenues</b>	<b>\$ 369,848</b>	<b>\$ 281,497</b>	<b>31.4%</b>

The growth in revenues experienced during 2009 resulted in large part from the increase in the number of patients prescribed Remodulin and the commercial launches of both Tyvaso and Adcirca.

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For the years ended December 31, 2009 and 2008, approximately 88% and 89%, respectively, of net Remodulin revenues were earned from our three distributors located in the United States. 100% of our Tyvaso revenues were earned from the same three distributors. Adcirca revenues are earned from sales to national and regional pharmaceutical wholesalers.

The table below presents a reconciliation of the liability accounts associated with estimated government and third-party rebates, prompt pay discounts, fees due to our distributors for services, allowances for sales returns, and the net reductions to revenues related to these items (in thousands):

	For Years Ended December 31,	
	2009	2008
Liability accounts, at beginning of period	\$ 4,096	\$ 2,879
Additions to liability attributed to sales in:		
Current period	21,338	14,498
Prior period		129
Payments or reductions attributed to sales in:		
Current period	(13,979)	(10,725)
Prior period	(4,816)	(2,685)
Liability accounts, at end of period	\$ 6,639	\$ 4,096
Net reductions to revenues	\$ 21,338	\$ 14,627

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

	For Years Ended December 31,		Percentage Change
	2009	2008	
<b>Project and non-project:</b>			
Cardiopulmonary	\$ 61,574	\$ 60,549	1.7%
License fees Adcirca		150,000	(100.0)%
Share-based compensation	36,294	16,200	124.0%
Other	24,320	12,432	95.6%
Total research and development expense	\$ 122,188	\$ 239,181	(48.9)%

*Cardiopulmonary license fees-Adcirca.* During the year ended December 31, 2008, we expensed \$150.0 million of upfront fees that we paid to Lilly in connection with the licensing and commercialization of Adcirca. There were no comparable transactions entered into during the year ended December 31, 2009.

*Share-based compensation.* The increase in share-based compensation expense of \$20.1 million for the year ended December 31, 2009, compared to the year ended December 31, 2008, can be attributed to our STAP awards.

*Other.* The increase in other research and development expenses of approximately \$11.9 million during the year ended December 31, 2009, compared to those for the year ended December 31, 2008, corresponded mainly to an increase in expenditures related to our investigational projects, including those within our monoclonal antibody and glycobiology antiviral agent therapeutic platforms, and an increase in personnel and overhead costs related to supporting research and development. Research and development expenses for our individual disease platforms includes only direct labor and out-of-pocket expenses, and excludes overhead and indirect personnel costs.

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

Category:	For Years Ended December 31,		Percentage Change
	2009	2008	
General and administrative	\$ 68,606	\$ 41,284	66.2%
Sales and marketing	43,593	32,899	32.5%
Share-based compensation	64,139	20,123	218.7%
<b>Total selling, general and administrative expense</b>	<b>\$ 176,338</b>	<b>\$ 94,306</b>	<b>87.0%</b>

*General and administrative.* During the year ended December 31, 2009, general and administrative expense increased \$27.3 million as compared to the year ended December 31, 2008, for the following reasons: (1) an impairment charge of \$4.2 million recognized on three of our Silver Spring, Maryland, properties that were demolished in 2010 in connection with commencement of construction on the last phase of our Silver Spring headquarters campus; (2) increases in professional fees of approximately \$4.2 million for the year ended December 31, 2009, related to our ongoing litigation, review of potential acquisitions, entering new license agreements, and other matters; (3) \$3.7 million of expenses for validation work to manufacture Remodulin using a larger batch size and on different equipment; and (4) an increase in general operating expenses of \$13.7 million resulting from our overall growth.

*Sales and marketing.* The increases in sales and marketing expenses of approximately \$10.7 million for the year ended December 31, 2009, compared to the year ended December 31, 2008, related primarily to increased expenses for the commercialization of our two new products, Tyvaso and Adcirca.

*Share-based compensation.* For the year ended December 31, 2009, share-based compensation increased by \$44.0 million over the same period in 2008. During the quarter ended December 31, 2008, we reversed approximately \$6.4 million in estimated compensation expense that had been accrued through September 30, 2008, for a potential year-end stock option grant to our Chief Executive Officer, which is based on a formula set forth in her employment agreement. Our Chief Executive Officer did not receive a stock option grant for the year ended December 31, 2008. At the end of 2009, our Chief Executive Officer received a year-end stock option grant in accordance with the formula in her employment agreement, and we recognized approximately \$14.5 million in share-based compensation expense for the year ended December 31, 2009. The remainder of the increase in share-based compensation expense can be attributed to our STAP awards.

*Income Tax Benefit.* As a result of the net losses we incurred before income taxes, we recognized income tax benefits of \$34.4 million for the year ended December 31, 2008. For the year ended December 31, 2009, we recognized income tax benefits of approximately \$695,000 from the business tax credits we generated from our orphan drug-related research and development activities.

### **Liquidity and Capital Resources**

Since FDA approval of Remodulin in 2002, funding for our operations has been derived principally from sales of Remodulin. Sales of Tyvaso and Adcirca, which were commercially launched in the third quarter of 2009, have supplemented our revenues. We believe that our current liquidity is sufficient to repay amounts that will become due in October 2011 relating to our Convertible Senior Notes and that existing revenues and related collections will be adequate to fund our ongoing operations as demand for our commercial products is expected to grow. Furthermore, our customer base remains stable and, we believe, presents minimal credit risk; however, any projections of future cash flows are inherently subject to uncertainty. To compensate for such uncertainty, we may seek other sources of funding and

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believe we have 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 revenues or profits.*

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

Net cash provided by operating activities was \$211.5 million for the year ended December 31, 2010, compared to \$99.7 million in net cash provided by operating activities for the year ended December 31, 2009. The increase in net cash provided by operating activities was driven largely by increases in net income of \$86.5 million and deferred taxes of \$43.0 million, offset partly by an increase in tax benefits recognized in connection with stock option exercises of \$19.4 million.

At December 31, 2010, we had working capital of \$335.8 million, compared to working capital deficit of \$5.7 million at December 31, 2009. The increase in working capital at December 31, 2010 of \$341.5 million reflected increases in cash and cash equivalents and marketable investments of \$397.6 million as a result of (1) increases in sales of pharmaceutical products of \$234.1 million and related collections; (2) proceeds received upon the closing of \$70.0 million mortgage financing arrangement in December 2010; and (3) \$52.5 million in proceeds received from the exercise of stock options less payments for the exercise of awards granted under the STAP.

We have not entered into any short-term borrowing arrangements to fund our working capital requirements and have no current plans to do so. Debt that has been classified as current includes (1) the Senior Convertible Notes (maturing in October 2011) and (2) the current portion of our four-year, \$70.0 million mortgage facility which we entered into in December 2010.

In addition, at December 31, 2010, we had approximately \$132.5 million of long-term (meaning the security will mature more than one year from December 31, 2010) marketable securities that could be liquidated if necessary to fund our operations.

Lastly, there were approximately 5.8 million shares of vested stock options outstanding at December 31, 2010, with a weighted average exercise price of \$35.68 per share. These vested stock options, if exercised, would provide us with additional liquidity.

***Construction Projects***

Our facility in Research Triangle Park, North Carolina (RTP Facility) consists of approximately 200,000 square feet of space and includes manufacturing, warehouse and office space. Currently, we plan to begin construction in the first half of 2011 to expand the RTP Facility to provide additional warehousing, packaging and office space to accommodate projected future growth. We expect to complete the approximately 180,000 square foot expansion of our RTP Facility by mid-2012 at an anticipated cost of approximately \$74.0 million, which includes construction, equipment and other related costs.

Our previous corporate headquarters and two adjoining buildings that were located adjacent to our Silver Spring facility were demolished in September 2010 to begin the construction of a new office building to serve as part of our corporate headquarters campus. We anticipate total construction costs of approximately \$58.0 million and expect to complete this office facility during the fourth quarter of 2011.

During the year ended December 31, 2010, we spent \$5.7 million related to these construction projects.

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***Share Tracking Awards Plan***

Awards granted under the STAP entitle participants to receive in cash the appreciation in our common stock, which is calculated as the increase in the closing price of our common stock on the date of grant and the date of exercise. Depending on the future price movements of our common stock, cash requirements associated with the exercise of awards could be significant. We incorporate anticipated cash outlays relating to the STAP in our operating budgets and have modified the metrics used in determining the number of awards to be granted in order to decrease the size of related grants. In addition, since November 2009, we have increased the vesting period for awards granted from three years to four years. During the first quarter of 2011, we expect to increase the pool of available STAP awards by approximately 2.0 million awards, primarily to accommodate anticipated grants under our long-term incentive bonus and compensation plan.

***Mortgage Financing***

On December 27, 2010, we entered into a Credit Agreement with Wells Fargo Bank, National Association (Wells Fargo) and Bank of America, N.A., pursuant to which we obtained \$70.0 million in debt financing. Proceeds from the loan were used to pay off the synthetic lease arrangement with Wachovia (discussed below) and will also be used to help fund working capital requirements. The Credit Agreement has a forty-eight month term maturing in December 2014 and is secured by a first mortgage lien on our RTP Facility and our Silver Spring facility. Annual principal payments will be based on a twenty-five year amortization schedule using a fixed rate of interest of 7.0 percent; accordingly, a principal balance of approximately \$66.6 million will be due at maturity. Outstanding debt will bear a floating rate of interest per annum based on the one month London Interbank Offer Rate (LIBOR), plus a credit spread of 3.75 percent, or approximately 4.0 percent as of December 31, 2010. Alternatively, we have the option to change the rate of interest charged on the loan to 2.75 percent plus the greater of: (1) Wells Fargo's prime rate, or (2) the federal funds effective rate plus 0.05 percent, or (3) LIBOR plus 1.0 percent. The Credit Agreement also permits prepayment of the outstanding loan balance in its entirety at specified intervals. The prepayment premium is initially 1.5 percent if the debt is prepaid within the first six-months of the term and declines in 0.5 percent increments at each successive six-month interval such that there is no premium if the loan is prepaid after December 2012.

The Credit Agreement subjects us to the following financial covenants: (1) a maximum consolidated leverage ratio of 2.5:1.00, calculated as the ratio of our consolidated indebtedness to "Consolidated EBITDA", which is defined as consolidated net income, adjusted for the following as applicable: (i) interest expense; (ii) income taxes; (iii) non-cash license fees; (iv) depreciation and amortization; (v) impairment charges; and (vi) share-based compensation (stock option and share tracking award expense), to be measured as of the last day of each fiscal quarter on a rolling four quarter basis; and (2) minimum liquidity of no less than \$150.0 million. Under the Credit Agreement, minimum liquidity is defined as the sum of our cash and cash equivalents, plus the fair value of our marketable investments as of the last day of a fiscal quarter less the sum of indebtedness that matures within the next twelve months and the liability related to vested STAP Awards in excess of \$50.0 million. In addition, the Credit Agreement subjects us to various customary negative covenants. As of December 31, 2010, we were in compliance with the preceding covenants.

***Lease Obligation***

Until December 2010, we leased our Phase I Laboratory, the first completed building in our current Silver Spring facility, pursuant to a synthetic lease arrangement entered into in June 2004 with Wachovia Development Corporation and its affiliates (Wachovia), now an affiliate of Wells Fargo. Under the lease, Wachovia funded \$32.0 million toward the construction of the Phase I Laboratory on land that we own. After completing construction in May 2006, Wachovia leased the Phase I Laboratory

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to us. The base term of the lease was scheduled to end in May 2011, at which time we had planned to exercise our option to purchase the Phase I Laboratory for approximately \$32.0 million. However, in order to secure the Credit Agreement, we terminated the lease and acquired title to the Phase I Laboratory for \$32.0 million in December 2010. Upon termination of the lease, \$35.1 million of cash and marketable investments held as collateral under the lease was released.

***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 semi-annually on April 15 and October 15 of each year. The Convertible Senior Notes are unsecured, unsubordinated debt obligations that rank equally with all of our other unsecured and unsubordinated indebtedness.

Conversion can occur: (1) any time after July 15, 2011; (2) during any calendar quarter that follows a calendar quarter in which the price of our common stock exceeded 120% of the conversion price for at least 20 days during the 30 consecutive trading-day period ending on the last trading day of the quarter; (3) 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 number of shares underlying the Convertible Senior Notes; (4) upon specified distributions to our shareholders; (5) in connection with corporate transactions; or (6) in the event that our common stock ceases to be listed on the NASDAQ Global Select Market and is not listed for trading on another U.S. national or regional securities exchange.

Upon conversion, a holder of our Convertible Senior Notes will receive: (1) 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 (2) to the extent the conversion value exceeds the principal amount of the Convertible Senior Notes, 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, holders can require us to purchase from them all or a portion of their Convertible Senior Notes for 100% of the principal value plus any accrued and unpaid interest.

Because the Convertible Senior Notes include contingent conversion provisions, Note Holders may be able to convert their Convertible Senior Notes prior to October 2011. As of December 31, 2010, the Convertible Senior Notes were convertible at the election of their holders as the closing price of our common stock satisfied quarterly contingent conversion requirements.

***Common Stock Subject to Repurchase***

Pursuant to a March 2007 amendment to our June 2000 agreement with Toray, we issued 400,000 shares of our common stock to Toray in March 2007. The terms of our amended agreement expand our rights to develop beraprost-MR and give Toray the right to request that we repurchase these shares at their issuance price of \$27.21 per share upon 30 days prior written notice. To date, Toray has not notified us that it intends to ask us to repurchase these shares.

***License Fees***

Under our existing license agreements, we are obligated to make royalty payments on net sales of Remodulin and Tyvaso at a rate of ten percent of net sales, as defined under the agreements, once the annual combined net sales exceed \$25.0 million. In addition, we pay Lilly a five percent royalty on net sales of Adcirca.

***Off-Balance Sheet Arrangements***

We do not have any off-balance sheet arrangements within the meaning of Item 303(a)(4) of Regulation S-K.



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#### Contractual Obligations

At December 31, 2010, we had the following contractual obligations (in thousands):

	Total	Payments Due by Period			More than 5 Years
		Less than 1 year	1-3 Years	3-5 Years	
Convertible Senior Notes(1)	\$ 250,000	\$ 250,000	\$	\$	\$
Mortgage Loan(2)	70,000	1,100	2,400	66,500	
Obligations under construction commitments(3)	133,900	87,700	46,200		
Operating lease obligations	17,800	4,400	5,000	3,600	4,800
Obligations under the STAP(4)	165,300	129,800	31,000	4,500	
Obligations under the SERP(5)	24,200			24,200	
Purchase commitments	20,800	20,800			
Milestone payments(6)	17,800	2,700	5,200	3,600	6,300
<b>Total(7)</b>	<b>\$ 699,800</b>	<b>\$ 496,500</b>	<b>\$ 89,800</b>	<b>\$ 102,400</b>	<b>\$ 11,100</b>

- 
- (1) The principal balance of the Convertible Senior Notes is to be repaid in cash.
- (2) Principal payments are based on the assumption that we will not elect to exercise our prepayment option during the forty-eight month term of the loan. Refer to Note 9 *Debt* to our consolidated financial statements included in this Annual Report on Form 10-K for details on this arrangement.
- (3) Represents amounts budgeted for our construction projects, although these amounts are not contractually committed at December 31, 2010.
- (4) We estimated the obligation based on the intrinsic value of outstanding STAP awards expected to vest as of December 31, 2010 assuming that awards will be exercised immediately upon vesting. Refer to Note 8 *Share Tracking Awards Plan* to our consolidated financial statements included in this Annual Report on Form 10-K for further details.
- (5) Obligations under the SERP are actuarially derived and represent the estimated future payouts of benefits to certain members of our management team. Refer to Note 14 *Employee Benefit Plans* to our consolidated financial statements included in this Annual Report on Form 10-K for comprehensive disclosures relating to the SERP.
- (6) We license certain rights to products from other companies under various license arrangements. These arrangements require that we make specified cash payments upon the achievement of certain product development and commercialization milestones. The timing and amounts of related milestone payments have been estimated based on: (1) when we believe milestones will be achieved; and (2) a

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probability-weighted assumption, based on industry standards, that the milestones established within these license agreements will be successfully attained.

(7)

As of December 31, 2010, we had \$7.4 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.

### **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

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estimation in their application. We consider these policies to be critical because of the degree of judgment that is inherent in their application.

***Revenue Recognition***

*Remodulin and Tyvaso*

We sell both Remodulin and Tyvaso to our specialty pharmaceutical distributors under similar contractual arrangements. Sales of Remodulin and Tyvaso are recognized when title and risk of ownership pass to our distributors upon satisfactory delivery to our distributors' facilities i.e., when all of our performance obligations under these distributor arrangements have been satisfied. We record sales of Remodulin and Tyvaso net of various product sales allowances in the period that associated revenues are recognized. These sales allowances include estimated rebates and other reimbursements, prompt payment discounts and service fees to our distributors. Calculating these sales allowances involves the use of significant estimates and judgments and information from external sources.

Estimates for accruals and related revenue reductions for rebates and reimbursements are derived from an analysis of historical levels of rebates/reimbursements to both state Medicaid agencies and third-party payers by product, relative to sales of each product. In formulating our estimates, we also consider the impact of anticipated changes in product sales trends and government rebate programs, particularly as they relate to eligibility requirements and/or rebate pricing. We analyze rebate data separately for Remodulin and Tyvaso, as these therapies have been developed to treat PAH patients at different stages in the disease continuum and therefore, rebate eligibility and pricing requirements can differ for each therapy.

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.

We pay our distributors for contractual services rendered. 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. The shelf life of Remodulin and Tyvaso is three years from the date of manufacture. The number of product exchanges requested by our distributors has been minimal because we sell Remodulin and Tyvaso with a shelf life generally in excess of one year before their expiration and our distributors typically carry a 30- to 60-day inventory supply of our products. In addition, we do not require, nor do we provide incentives for our distributors to assume inventory levels of Remodulin or Tyvaso beyond what would be considered reasonable and customary in the ordinary course of business and we closely track inventory levels in the distribution channels. Accordingly, exchanges for expired product have been minimal. In addition, exchanges for damaged product are highly infrequent. When Remodulin or Tyvaso has been damaged during shipment and we have been promptly notified as required under our distributor arrangements, we do not recognize revenue on that shipment until the damaged product has been replaced, generally within several days after we are notified of the damage.

The financial effects of exchange rights for Remodulin have been immaterial and we expect the volume of exchanges to be consistent with historical levels. Obsolescence due to dating expiration has also been minimal given the fast pace at which Remodulin moves through the distribution channel. Specifically, Remodulin exchanges have comprised substantially less than one percent of the volume of vials that we sell. Because historical and anticipated future exchanges of Remodulin have been, and are expected to be, immaterial, we do not record a reserve for estimated exchange rights in the period of sale. Furthermore, because Tyvaso is distributed in the same manner and under similar contractual arrangements as Remodulin, the level of product exchanges for Tyvaso has been, and is expected to

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remain, comparable to that for Remodulin. Since its commercial launch, there have not been any Tyvaso exchanges. Accordingly, we have not recognized a reserve for anticipated future exchanges of Tyvaso. Lastly, we closely monitor exchange data for both of these therapies to ensure that our assumptions continue to be reasonable, appropriate and current.

*Adcirca*

Adcirca is manufactured for us by Lilly and distributed through Lilly's pharmaceutical wholesaler network. Specifically, Lilly handles all of the administrative functions associated with the sale of Adcirca on our behalf, including the receipt and processing of customer purchase orders, shipment of Adcirca to customers, and the invoicing and collection of customer payments. In addition, sales terms for Adcirca include return rights that extend throughout the distribution channel. We recognize sales of Adcirca on a gross basis (net of allowances) upon delivery to customers due to the following factors: (1) we are responsible for the acceptability of the product purchased by wholesalers; (2) we bear all inventory risk, as title and risk of loss pass to us at the shipping point from Lilly's manufacturing facility; (3) we assume credit risk if Lilly is unable to collect amounts due from customers; and (4) we assume the risk and cost of a product recall, if required.

Adcirca revenues are recognized net of the following sales allowances: reserves for product returns, rebates for Medicaid and third-party payers, prompt pay discounts and wholesaler fees. Calculation of these allowances involves the use of significant judgment and estimates. Until we have sufficient historical data to base estimates for product returns, we have based initial estimates for returns on published industry data related to specialty pharmaceuticals, which is the segment most relevant to Adcirca. In addition, we compare patient prescription data to sales on a quarterly basis to ensure a reasonable relationship between prescription and sales patterns. Allowances for Medicaid and other third-party payer rebates are derived from an analysis of historical levels of rebates/reimbursements to both state Medicaid agencies and third-party payers. Prompt pay discounts are based on contractual terms with distributors, and they typically have taken advantage of such discounts. Lastly, wholesaler fees are based on the contractual fee percentage for each wholesaler relative to sales to that wholesaler.

*Share-based Compensation*

Our share-based awards are classified as either equity (stock options) or as liabilities (STAP awards), and we recognize related share-based compensation expense based on the fair value of awards. We estimate the fair value of all share-based 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.

*Marketable Investments*

Substantially all of our marketable securities are classified as held-to-maturity. For marketable investments whose fair value is lower than their book value, we are required to periodically review whether the decline in the value of these securities are other than temporary. This review requires us to make judgments, particularly as they relate to: (1) the extent and duration of a decline in the fair value of a security; (2) the probability, extent and timing of a recovery of a security's value; (3) our assessment as to whether it is more likely than not that we will be required to sell a security prior to recovery of its amortized cost; and (4) our estimation of the present value of the cash flows we would expect to collect that are attributable to an impaired debt security to determine whether a credit loss exists. The scope of this evaluation requires forward-looking assessments pertaining to a security and

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the relevant financial markets, an issuer's financial condition and business outlook, and our estimation of the value of cash flows we would expect to collect from an issuer upon maturity of an impaired security. Accordingly, we must make assessments regarding current conditions and future events, which involve a considerable degree of uncertainty and judgment. When we determine that the decline in value of a security is other than temporary, we are required to recognize the credit loss portion as a charge within our consolidated statement of operations.

In addition, 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 debt securities that mature within two years.

***Fair Value Measurements***

We are required to disclose assets and liabilities subject to fair value measurements within a specified fair value hierarchy. The fair value 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 fair value hierarchy, in their entirety, based on the lowest level input that is significant to the related fair value measurement. Determining where a particular asset or liability should be disclosed within the hierarchy involves judgment regarding the significance of inputs relative to a fair value measurement and where such inputs lie within the hierarchy. Furthermore, assets and liabilities that are not actively traded may have little or no price transparency. As such, estimating the fair value of Level 3 assets and liabilities involves the use of significant subjective assumptions that we believe market participants would consider in pricing. We often employ a discounted cash flow model to help us estimate the fair value of our Level 3 assets and liabilities. Inputs to the model that involve a significant degree of judgment include estimating the amounts and timing of expected cash flows and determining a suitable discount rate.

***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 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, 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. 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 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

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assets requires us to make significant judgments and forward-looking assessments regarding the amounts and availability of future taxable income.

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. Accounting for uncertain tax positions 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 and Intangible Assets***

We are required 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 often use a discounted cash flow model to test goodwill for impairment, which involves the use of significant and subjective inputs. Inputs requiring our judgment include, among others, the estimation of the amounts and timing of future cash flows and future growth rates and profitability of a reporting unit. 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 implied estimated fair value.

We also test our intangible assets for impairment annually or more frequently if impairment indicators exist. Evaluating intangible assets for impairment requires judgment particularly as it relates to determining the fair value of the license or business to which the intangible asset relates. We must project cash flows to test an intangible asset for impairment, which involves the use of significant and subjective inputs. Related inputs, among others, requiring our judgment include the estimation of the amounts and timing of future cash flows and future growth rates and profitability of business activity. 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 extent that undiscounted cash flows are less than the carrying value of an intangible asset.

***Pension Benefit Obligation***

Accounting for our SERP requires that 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 judgment 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. With the overall economic downturn and the tightening of the credit markets that began in 2008, interest rates, in general, have declined. We must consider these economic factors when determining an appropriate discount rate to employ. Consequently, the discount rate we use to measure our obligation has decreased over each of the years ended December 31, 2010 and 2009. Changes in the discount rate can significantly decrease or increase our SERP obligation. For instance, a reduction in the discount rate would increase our projected benefit obligation, result in an actuarial loss and possibly cause additional pension expense to be recognized in future financial reporting periods on our consolidated statements of operations if certain thresholds have been met as of the beginning of a given financial reporting period. Other actuarial assumptions include participant demographics such as the expected rate of salary increases and withdrawal rates, among other factors. Actual experience may differ from actuarial

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assumptions. Changes in any of these assumptions can also affect the measurement of the SERP obligation.

**Recently Issued Accounting Standards**

In December 2010, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2010-28, *Intangibles - Goodwill and Other (Topic 350) When to Perform Step 2 of the Goodwill Impairment Test for Reporting Units with Zero or Negative Carrying Amounts* (ASU 2010-28). ASU 2010-28 modifies the first step of the goodwill impairment test for reporting units with zero or negative carrying amounts. If the carrying amount of a reporting unit is zero or negative, the second step of the impairment test must be performed to measure the amount of impairment loss, if any, when it is more likely than not that a goodwill impairment exists. In considering whether it is more likely than not that a goodwill impairment exists, an entity shall evaluate whether any adverse qualitative factors exist. ASU No. 2010-28 is effective for fiscal years and interim periods within those years beginning after December 15, 2010. We are currently assessing what, if any, impact the adoption of ASU 2010-28 will have on our consolidated financial statements.

In April 2010, the FASB issued ASU No. 2010-17, *Revenue Recognition - Milestone Method* (ASU No. 2010-17). ASU No. 2010-17 sets forth guidance on the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate for research and development arrangements. Specifically, consideration that is contingent upon the completion of a milestone may be recognized in its entirety as revenue in the period that the milestone has been achieved if the milestone, in its entirety, meets all of the criteria to be considered substantive at the inception of a research and development arrangement. ASU No. 2010-17 is effective prospectively for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010 and applies to research or development deliverables under which the performance obligation is satisfied over a period of time and a portion, or all, of the consideration is contingent upon uncertain future events or circumstances. A reporting entity's decision to use the milestone method of revenue recognition is a policy election. ASU No. 2010-17 will be effective for us January 1, 2011 and adoption of this standard will not have any impact on our consolidated financial statements.

In January 2010, the FASB issued ASU No. 2010-06, *Fair Value Measurements and Disclosures (Topic 820) Improving Disclosures about Fair Value Measurements* (ASU No. 2010-06). ASU No. 2010-06 requires: (1) fair value disclosures of assets and liabilities by class; (2) disclosures about significant transfers in and out of Levels 1 and 2 on the fair value hierarchy, in addition to Level 3; (3) purchases, sales, issuances and settlements be disclosed on a gross basis on the reconciliation of beginning and ending balances of Level 3 assets and liabilities; and (4) disclosures about valuation methods and inputs used to measure the fair value of Level 2 assets and liabilities. ASU No. 2010-06 became effective for the first financial reporting period beginning after December 15, 2009, except for disclosures about purchases, sales, issuances and settlements of Level 3 assets and liabilities, which will be effective for fiscal years beginning after December 15, 2010. Adoption of the currently effective provisions of ASU No. 2010-06 had no impact on our consolidated financial statements. Level 3 disclosure requirements regarding gross presentation of purchases, sales, issuances and settlements are not expected to impact our consolidated financial statements.

In December 2009, the FASB issued ASU No. 2009-17, *Consolidations (Topic 810) Improvements to Financial Reporting By Enterprises Involved with Variable Interest Entities* (ASU No. 2009-17). ASU 2009-17 requires a qualitative approach for determining the primary beneficiary of a variable interest entity and replaces the quantitative evaluation previously set forth under FASB Interpretation No. 46 (revised December 2003), *Consolidation of Variable Interest Entities*. This approach is focused on identifying the reporting entity that has the ability to direct the activities of a variable interest entity that most significantly affects the entity's economic performance and has the obligation to absorb the entity's losses or has the right to receive benefits from the entity. ASU No. 2009-17, among other

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things, will require enhanced disclosures about a reporting entity's involvement in variable interest entities. The guidance under ASU No. 2009-17 became effective for the first annual period beginning after November 15, 2009, and interim periods within that first annual period. Adoption of ASU 2009-17 did not have a material impact on our consolidated financial statements.

In October 2009, the FASB issued ASU No. 2009-13, *Revenue Recognition (Topic 605) Multiple-Deliverable Revenue Arrangements: a consensus of the FASB Emerging Issues Task Force* (ASU 2009-13). ASU 2009-13 establishes a selling-price hierarchy for determining the selling price of each element within a multiple-deliverable arrangement. Specifically, the selling price assigned to each deliverable is to be based on vendor-specific objective evidence (VSOE) if available, third-party evidence if VSOE is unavailable, and estimated selling prices if neither VSOE or third-party evidence is available. In addition, ASU 2009-13 eliminates the residual method of allocating arrangement consideration and instead requires allocation using the relative selling price method. ASU 2009-13 will be effective prospectively for multiple-deliverable revenue arrangements entered into, or materially modified, in fiscal years beginning on or after June 15, 2010. ASU 2009-13 will be effective for us on January 1, 2011 and adoption of this standard will not have any impact on our consolidated financial statements.

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

As of December 31, 2010, we have invested \$507.4 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. Conversely, as rates decrease, the market value of a debt investment would be expected to increase. To address market risk, we invest in debt securities that mature within two years and intend to hold these investments to maturity so that they can be redeemed at their stated or face value. At December 31, 2010, our investments in debt securities issued by corporations and federally-sponsored agencies had a weighted average stated interest rate of approximately 0.44 percent. These investments mature at various times through 2012 and many are callable annually.

There has been an extended period of instability in the financial markets. Such periods of uncertainty in the financial markets expose us to additional investment risk. The value and liquidity of the securities in which we invest could deteriorate and the issuers of such securities could be subject to credit rating downgrades. In light of these 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 exclusively in highly rated securities with relatively short maturities. While we believe we take prudent measures to mitigate investment related risks, such risks cannot be fully eliminated, as circumstances can occur that are beyond our control.



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**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, 2010 and 2009</u>	<u>F-4</u>
<u>Consolidated Statements of Operations for the years ended December 31, 2010, 2009 and 2008</u>	<u>F-5</u>
<u>Consolidated Statements of Stockholders' Equity for the years ended December 31, 2010, 2009 and 2008</u>	<u>F-6</u>
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2010, 2009 and 2008</u>	<u>F-7</u>
<u>Notes to Consolidated Financial Statements</u>	<u>F-8</u>

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**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Shareholders  
United Therapeutics Corporation

We have audited the accompanying consolidated balance sheets of United Therapeutics Corporation as of December 31, 2010 and 2009, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2010. 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, 2010 and 2009, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2010, 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.

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, 2010, 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 24, 2011 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

McLean, Virginia  
February 24, 2011

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**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, 2010, 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 a material 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, 2010, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2010 consolidated financial statements of United Therapeutics Corporation, and our report dated February 24, 2011, expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

McLean, Virginia  
February 24, 2011

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

	<b>December 31,</b>	
	<b>2010</b>	<b>2009</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 252,162	\$ 100,352
Marketable investments	374,921	129,140
Accounts receivable, net of allowance of none for 2010 and 2009	73,707	50,626
Other current assets	6,840	2,638
Prepaid expenses	8,752	8,199
Inventories, net	35,520	26,360
Deferred tax assets	12,585	7,192
Total current assets	764,487	324,507
Marketable investments	132,849	148,628
Marketable investments and cash restricted	5,122	39,976
Goodwill and other intangible assets, net	9,861	18,418
Property, plant, and equipment, net	306,044	303,859
Deferred tax assets, net	202,135	200,969
Other assets (None and \$6,741, respectively, measured under the fair value option)	11,137	15,187
Total assets	\$ 1,431,635	\$ 1,051,544
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 16,146	\$ 18,750
Accrued expenses	50,280	29,764
Convertible notes	235,968	220,272
Other current liabilities	126,292	61,401
Total current liabilities	428,686	330,187
Mortgage payable non current	68,929	
Lease obligation		30,327
Other liabilities	39,252	27,139
Total liabilities	536,867	387,653
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, 245,000,000 and 100,000,000 shares authorized, 60,017,546 and 56,682,369 shares issued, and 57,555,893 and 54,220,779 shares outstanding at December 31, 2010 and 2009, respectively	600	567
Additional paid-in capital	928,690	798,897
Accumulated other comprehensive loss	(9,175)	(4,314)
Treasury stock at cost, 2,461,653 and 2,461,590 shares at December 31, 2010 and 2009, respectively	(67,399)	(67,395)
Retained earnings (deficit)	31,170	(74,746)

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Total stockholders' equity	883,886	653,009
Total liabilities and stockholders' equity	\$ 1,431,635	\$ 1,051,544

See accompanying notes to consolidated financial statements.

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

	For Years Ended December 31,		
	2010	2009	2008
<b>Revenues:</b>			
Net product sales	\$ 591,881	\$ 357,870	\$ 270,005
Service sales	10,753	10,751	9,258
License fees	1,197	1,227	2,234
<b>Total revenue</b>	<b>603,831</b>	<b>369,848</b>	<b>281,497</b>
<b>Operating expenses:</b>			
Research and development	166,761	122,188	239,181
Selling, general and administrative	199,600	176,338	94,306
Cost of product sales	67,716	40,890	26,957
Cost of service sales	5,749	4,431	3,109
<b>Total operating expenses</b>	<b>439,826</b>	<b>343,847</b>	<b>363,553</b>
Income (loss) from operations	164,005	26,001	(82,056)
<b>Other income (expense):</b>			
Interest income	2,939	5,146	11,025
Interest expense	(19,714)	(12,875)	(11,439)
Equity loss in affiliate	(160)	(141)	(226)
Other, net	769	636	(1,025)
<b>Total other income (expense), net</b>	<b>(16,166)</b>	<b>(7,234)</b>	<b>(1,665)</b>
Income (loss) before income tax	147,839	18,767	(83,721)
Income tax (expense) benefit	(41,923)	695	34,394
<b>Net income (loss)</b>	<b>\$ 105,916</b>	<b>\$ 19,462</b>	<b>\$ (49,327)</b>
<b>Net income (loss) per common share:</b>			
Basic	\$ 1.89	\$ 0.37	\$ (1.08)
Diluted	\$ 1.78	\$ 0.35	\$ (1.08)
<b>Weighted average number of common shares outstanding:</b>			
Basic	56,142	53,314	45,802
Diluted	59,516	56,133	45,802

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/(Loss)	Treasury Stock	Retained Earnings (Deficit)	Total
	Shares	Amount					
Balance, December 31, 2007	26,629,189	\$ 266	\$ 613,543	\$ 317	\$ (231,619)	\$ (30,376)	\$ 352,131
Net loss						(49,327)	(49,327)
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)		(49,327)	(55,557)
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			38,356				38,356
Share-based compensation			28,468				28,468
Balance, December 31, 2008	27,662,151	276	722,293	(5,913)	(67,395)	(93,927)	555,334
Net income						19,462	19,462
Foreign currency translation adjustments				2,802			2,802
Unrealized gain on available-for-sale securities				44			44
Unrealized loss on pension liability				(1,247)			(1,247)
Total other comprehensive income				1,599		19,462	21,061
Issuance of stock dividend	28,064,279	281				(281)	
Exercise of stock options	955,939	10	32,061				32,071
Tax benefit from exercises of non-qualified stock options			4,406				4,406
Share-based compensation			40,137				40,137
Balance, December 31, 2009	56,682,369	567	798,897	(4,314)	(67,395)	(74,746)	653,009
Net income						105,916	105,916
Foreign currency translation adjustments				(642)			(642)
Unrealized gain on available-for-sale securities				134			134
Unrealized loss on pension liability				(4,353)			(4,353)
Total other comprehensive income				(4,861)		105,916	101,055
Exercise of stock options	3,335,114	33	83,313				83,346
Stock issued in connection with conversion of	63		3		(4)		(1)

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Convertible Senior Notes		
Tax benefit from exercises of non-qualified stock options	23,826	23,826
Share-based compensation	22,651	22,651
Balance, December 31, 2010	60,017,546 \$ 600 \$ 928,690 \$ (9,175) \$ (67,399) \$ 31,170 \$ 883,886	

See accompanying notes to consolidated financial statements.

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Table of Contents**UNITED THERAPEUTICS CORPORATION****Consolidated Statements of Cash Flows****(In thousands)****For Years Ended December 31,**

	<b>2010</b>	<b>2009</b>	<b>2008</b>
<b>Cash flows from operating activities:</b>			
Net income (loss)	\$ 105,916	\$ 19,462	\$ (49,327)
Adjustments to reconcile net income (loss) to net cash provided by, (used in), operating activities:			
Depreciation and amortization	17,920	11,394	4,536
Provisions for bad debt and inventory obsolescence	2,398	4,675	586
Share-based compensation	113,942	101,015	28,703
Gains/losses on trading securities	7,688	4,494	1,595
Amortization of debt discount and issue costs	16,839	15,714	14,670
Deferred tax expense (benefit)	41,923	(1,038)	(34,394)
Amortization of discount or premium on investments	2,574	1,551	(999)
Equity loss in affiliate and other	967	(1,848)	(2,514)
Excess tax benefit from share-based compensation	(23,826)	(4,406)	(21,090)
<b>Changes in assets and liabilities:</b>			
Accounts receivable	(23,452)	(21,956)	(2,329)
Inventories	(9,196)	(9,061)	(2,630)
Prepaid expenses	(587)	3,422	(5,682)
Other assets	(4,776)	(196)	(16,123)
Accounts payable	(2,734)	(3,645)	18,509
Accrued expenses	25,612	9,203	3,641
Other liabilities	(59,676)	(29,057)	22,419
<b>Net cash provided by (used in) operating activities</b>	<b>211,532</b>	<b>99,723</b>	<b>(40,429)</b>
<b>Cash flows from investing activities:</b>			
Purchases of property, plant and equipment	(18,640)	(95,400)	(124,415)
Purchases of held-to-maturity investments	(662,225)	(310,634)	(321,363)
Purchases of available-for-sale investments			(24,600)
Maturities of held-to-maturity investments	421,528	249,083	266,051
Sales of available-for-sale investments			31,850
Sales of trading investments	36,200		
Acquisition of Tyvaso Inhalation System business		(3,568)	
Restrictions on cash	13,901	(2,099)	(8,766)
<b>Net cash used in investing activities</b>	<b>(209,236)</b>	<b>(162,618)</b>	<b>(181,243)</b>
<b>Cash flows from financing activities:</b>			
Proceeds received from mortgage financing	70,000		
Payments of transaction costs related to the mortgage financing	(1,055)		
Payment of lease obligation	(31,442)		
Proceeds from the sale of treasury stock			150,000
Proceeds from exercise of stock options	85,427	32,071	41,936
Excess tax benefits from share-based compensation	23,826	4,406	21,090
<b>Net cash provided by financing activities</b>	<b>146,756</b>	<b>36,477</b>	<b>213,026</b>
Effect of exchange rate changes on cash and cash equivalents	2,758	(2,682)	(1,225)
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>151,810</b>	<b>(29,100)</b>	<b>(9,871)</b>
Cash and cash equivalents, beginning of year	100,352	129,452	139,323

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Cash and cash equivalents, end of year	\$	252,162	\$	100,352	\$	129,452
<b>Supplemental cash flow information:</b>						
Cash paid for interest	\$	1,818	\$	1,250	\$	1,250
Cash paid for income taxes	\$	22,683	\$	23,931	\$	1,628
<b>Non-cash investing and financing activities:</b>						
Lease obligation incurred	\$		\$		\$	29,000
Acquisition of Tyvaso Inhalation System Business	\$		\$	4,776	\$	
Non-cash additions to property, plant and equipment	\$	2,445	\$	2,571	\$	6,391

See accompanying notes to consolidated financial statements.

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**UNITED THERAPEUTICS CORPORATION**

**Notes to Consolidated Financial Statements**

**1. Organization and Business Description**

United Therapeutics Corporation 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 conditions. As used in these notes to the consolidated financial statements, unless the context requires otherwise, the terms "we," "us," "our," and similar terms refer to United Therapeutics Corporation and its consolidated subsidiaries.

Our lead product is Remodulin® (treprostinil) Injection (Remodulin), which was initially approved in 2002 by the United States Food and Drug Administration (FDA) for subcutaneous (under the skin) administration. Subsequently, the FDA broadened its approval of Remodulin for intravenous (in the vein) use and for the treatment of patients who require transition from Flolan®, the first drug approved by the FDA for the treatment of PAH. Remodulin is also approved for use in countries outside of the United States, predominantly for subcutaneous administration. In 2009, we received FDA approval for Adcirca® (tadalafil) Tablets (Adcirca) and for Tyvaso® (treprostinil) Inhalation Solution (Tyvaso). We have generated pharmaceutical revenues and license fees in the United States, Canada, the European Union, South America, Central 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**

*Basis of Presentation and Principles of Consolidation*

The accompanying consolidated financial statements of United Therapeutics and its wholly owned subsidiaries have been prepared in accordance with accounting principles generally accepted in the United States (GAAP). All intercompany balances and transactions have been eliminated in consolidation.

*Use of Estimates*

The preparation of the consolidated financial statements in accordance with GAAP requires our 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. We base our estimates on assumptions regarding historical experience, currently available information and anticipated developments that we believe are reasonable and appropriate. Consequently, actual results could differ from those estimates. Our significant accounting policies that require use of subjective and/or complex judgment and estimates impact the following financial statement areas: revenue recognition, share-based compensation, marketable investments, fair value measurements, income taxes, goodwill and other intangible assets, and obligations related to our Supplemental Executive Retirement Plan.

*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 our 0.50% Convertible Senior Notes due October 2011 (Convertible Senior Notes) are reported in Notes 4 *Marketable Investments* and 5 *Fair Value Measurements*, respectively. The recorded value of our mortgage loan approximates its fair value as it bears a variable rate of interest that we believe approximates the market rate of interest for debt with similar credit risk profiles, terms and maturities. Refer to Note 9 *Debt Mortgage Financing*.

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**UNITED THERAPEUTICS CORPORATION**

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

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

***Fair Value Measurements***

The fair value of an asset or liability should represent 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 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.

Assets and liabilities subject to fair value measurement disclosures are required to be classified according to a three-level, fair value hierarchy with respect to the inputs (or assumptions) used in their 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, the use of unobservable inputs is permitted 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 in which an asset or liability is disclosed within the fair value hierarchy is based on the lowest level input that is significant to the related fair value measurement in its entirety. The guidance under the fair value measurement framework applies to other existing accounting guidance in the Financial Accounting Standard Board (FASB) codification that requires or permits fair value measurements. Refer to related disclosures at Note 5 *Fair Value Measurements* to 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.

***Trade Receivables***

Trade receivables consist of short-term amounts due from customers and are stated at the amount we expect to collect. We establish an allowance for doubtful accounts, if any, 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 the held-to-maturity securities, as an adjustment to yield, using the effective interest method.

Debt 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. During the year ended December 31, 2010, we sold all of our trading securities, which were comprised of auction-rate securities.

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

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

attributable to the estimated credit loss for held-to-maturity debt securities. 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, among others, general market conditions, the duration and extent to which fair value has been less than the carrying value, the investment issuer's financial condition and business outlook and our assessment as to whether it is more likely than not that we will be required to sell a security prior to recovery of its amortized cost basis.

***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):

	December 31,	
	2010	2009
<b>Pharmaceutical Products:</b>		
Raw materials	\$ 2,788	\$ 4,751
Work in progress	18,598	12,101
Finished goods	13,098	8,899
Delivery pumps and supplies and cardiac monitoring equipment	1,036	609
 Total inventories	 \$ 35,520	 \$ 26,360

***Goodwill and Other Intangible Assets***

The carrying amount of goodwill is not amortized but subject to annual impairment testing at the reporting unit level. We evaluate goodwill for impairment during the fourth quarter of each year, 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 (Step 1 of the goodwill impairment test). Frequently, we estimate the fair value of a reporting unit by calculating its expected future discounted cash flows based on historical operating results adjusted for anticipated future market and operating trends and forecasts. 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. If the carrying amount of a reporting unit exceeds its fair value, then the amount of an impairment loss, if any, is measured as the excess of the carrying amount of goodwill over its implied fair value (Step 2 of the goodwill impairment test).

On February 7, 2011, we entered into an agreement to sell our wholly-owned subsidiary, Medicomp, Inc. (Medicomp). Based on the estimated fair value of the purchase consideration, we wrote off the entire carrying amount of Medicomp's goodwill. We recognized the cumulative impairment loss of \$6.2 million under selling, general and administrative expenses on our consolidated statement of operations for the year ended December 31, 2010. Refer to Note 20 *Subsequent Event* for a description of the agreement to sell Medicomp and the impairment of goodwill.

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

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

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

	As of December 31, 2010			As of December 31, 2009		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Goodwill(1)	\$ 2,487	\$	\$ 2,487	\$ 8,763	\$	\$ 8,763
Other intangible assets(1):						
Technology, patents and tradenames	8,991	(5,368)	3,623	9,364	(4,586)	4,778
Customer relationships and non-compete agreements	4,762	(1,011)	3,751	5,150	(273)	4,877
<b>Total</b>	<b>\$ 16,240</b>	<b>\$ (6,379)</b>	<b>\$ 9,861</b>	<b>\$ 23,277</b>	<b>\$ (4,859)</b>	<b>\$ 18,418</b>

(1)

Includes foreign currency translation adjustments.

We are amortizing other intangible assets over an estimated weighted average life of 6.8 years. Related amortization expense for the years ended December 31, 2010, 2009 and 2008, was \$1.6 million, \$717,000 and \$588,000, respectively. As of December 31, 2010, aggregate amortization expense related to intangible assets for each of the five succeeding years and thereafter is estimated as follows (in thousands):

Years ending December 31,	
2011	\$ 1,477
2012	1,333
2013	1,310
2014	1,303
2015	1,049
Thereafter	902
	<b>\$ 7,374</b>

***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	10-39 Years
Furniture, equipment and vehicles	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

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## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

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

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

	As of December 31,	
	2010	2009
Land	\$ 20,236	\$ 20,024
Buildings, building improvements and leasehold improvements	239,473	236,198
Buildings under construction	7,241	
Holter and event cardiac monitoring systems	6,390	5,550
Furniture, equipment and vehicle	70,897	65,430
	344,237	327,202
Less accumulated depreciation	(38,193)	(23,343)
Property, plant and equipment, net	\$ 306,044	\$ 303,859

Depreciation expense for the years ended December 31, 2010, 2009 and 2008, was \$17.6 million, \$10.7 million and \$3.9 million, respectively.

"Buildings under construction" at December 31, 2010 consists of direct costs to construct our facilities, including capitalized interest. Our current construction plans include the expansion of our North Carolina facility and our corporate headquarters campus in Maryland. As of December 31, 2010, we estimate that future costs to complete these construction projects will be approximately \$127.0 million, and we expect to complete these projects by mid-2012. At December 31, 2010 and 2009, we capitalized interest of \$103,000 and \$5.2 million, respectively, relating to our various construction projects.

***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.

***Revenue Recognition******Remodulin and Tyvaso***

We sell both Remodulin and Tyvaso to our specialty pharmaceutical distributors under similar contractual arrangements. Sales of Remodulin and Tyvaso are recognized when title and risk of ownership pass to our distributors upon satisfactory delivery to our distributors' facilities i.e. all of our performance obligations under these distributor arrangements have been satisfied. We record sales of Remodulin and Tyvaso net of various product sales allowances in the period that associated revenues are recognized. These sales allowances include estimated rebates and other reimbursements, prompt payment discounts and service fees to our distributors. Calculating these sales allowances involves the use of significant estimates and judgments and information from external sources.

Estimates for accruals and related revenue reductions for rebates and reimbursements are derived from an analysis of historical levels of rebates/reimbursements to both state Medicaid agencies and third-party payers by product, relative to sales of each product. In formulating our estimates, we also consider the impact of anticipated changes in product sales trends and government rebate programs, particularly as they relate to eligibility requirements and/or rebate pricing. We analyze rebate data

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**UNITED THERAPEUTICS CORPORATION**

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

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

separately for Remodulin and Tyvaso, as these therapies have been developed to treat PAH patients at different stages in the disease continuum and therefore, rebate eligibility and pricing requirements can differ for each therapy.

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.

We pay our distributors for contractual services rendered. 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 specialty pharmaceutical distributors do not possess return rights; however, we provide exchange rights in the event that product was damaged during shipment, or has expired. The shelf life of Remodulin and Tyvaso is three years from the date of manufacture. The number of product exchanges has been minimal because we sell Remodulin and Tyvaso with a shelf life generally in excess of one year before expiration and our distributors generally hold a 30 to 60 day inventory of our products. In addition, we do not require, nor do we provide incentives for our distributors to assume, inventory levels of Remodulin or Tyvaso beyond what would be considered reasonable and customary in the ordinary course of business and we closely track inventory levels in the distribution channels. Accordingly, exchanges for expired product have been minimal. In addition, exchanges for damaged product have occurred infrequently. When a shipment of Remodulin or Tyvaso has been damaged in transit to the distributor and we have been promptly notified, we do not recognize revenue on that shipment until the damaged product has been replaced, generally within several days after we receive notification of the damage.

The financial effects of exchange rights for Remodulin have been immaterial and we expect the historic volume of exchanges to remain consistent in the future. Obsolescence due to dating expiration has also been minimal given the fast pace at which Remodulin moves through the distribution channel. Specifically, Remodulin exchanges have comprised substantially less than one percent of the volume of vials that we sell. Because historical and anticipated future exchanges of Remodulin have been, and are expected to be, immaterial, we do not record a reserve for estimated exchange rights in the period of sale. Furthermore, because Tyvaso is distributed in the same manner and under similar contractual arrangements as Remodulin, the level of product exchanges for Tyvaso has been, and is expected to remain, comparable to that for Remodulin. Accordingly, we have not recognized a reserve for anticipated future exchanges of Tyvaso. Lastly, we closely monitor exchange data for both of these therapies to ensure that our assumptions continue to be reasonable, appropriate and current.

*Adcirca*

Adcirca is manufactured for us by Eli Lilly and Company (Lilly) and distributed through Lilly's pharmaceutical wholesaler network. Specifically, Lilly handles all of the administrative functions associated with the sale of Adcirca on our behalf, including the receipt and processing of customer purchase orders, shipment of Adcirca to customers, and the invoicing and collection of customer payments. In addition, sales terms for Adcirca include return rights that extend throughout the distribution channel. We recognize sales of Adcirca on a gross basis (net of allowances) upon delivery to customers due to the following factors: (1) we are responsible for the acceptability of the product purchased by wholesalers; (2) we bear all inventory risk, as title and risk of loss pass to us at the shipping point from Lilly's manufacturing facility; (3) we assume credit risk if Lilly is unable to collect amounts due from customers; and (4) we assume the risk and cost of a product recall, if required.



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**UNITED THERAPEUTICS CORPORATION**

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

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

Adcirca revenues are recognized net of the following sales allowances: reserves for product returns, rebates for Medicaid and third-party payers, prompt pay discounts and wholesaler fees. Calculation of these allowances involves the use of significant judgment and estimates. Until we have sufficient historical data to base estimates for product returns, we have based initial estimates for returns on published industry data related to specialty pharmaceuticals, which is the segment most relevant to Adcirca. In addition, we compare patient prescription data to sales on a quarterly basis to ensure a reasonable relationship between prescription and sales patterns. Allowances for Medicaid and other third-party payer rebates are derived from an analysis of historical levels of rebates/reimbursements to both state Medicaid agencies and third-parties payers. Prompt pay discounts are based on contractual terms with distributors, and they typically have taken advantage of such discounts. Lastly, wholesaler fees are based on the contractual fee percentage for each wholesaler relative to sales to that wholesaler.

***Research and Development***

Research and development costs are expensed as incurred except for refundable 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; or for major unproven changes to our production processes;

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

Up-front payments made in connection with arrangements to obtain license and distribution rights to pharmaceutical product candidates prior to the regulatory approval of those product candidates, absent any alternative future uses.

***Share-Based Compensation***

Share-based awards that require cash settlement upon exercise, such as those granted under our Share Tracking Awards Plan, are classified as a liability. Accordingly, the fair value of related cash settled awards is re-measured at each reporting date until awards are exercised or are otherwise no longer outstanding. Related changes in the fair value of outstanding cash-settled awards at each reporting date are recognized as adjustments to share-based compensation expense.

The amount of share-based compensation to be recognized in connection with stock option awards is based on the grant date fair value of the award. 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.

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**UNITED THERAPEUTICS CORPORATION**

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

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

***Income Taxes***

Income taxes are accounted for in accordance with the asset and liability method. 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.

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.

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

Basic earnings per share is computed by dividing net 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, both basic and diluted loss per share is calculated by dividing the net loss by the weighted average shares outstanding. Potentially dilutive securities are excluded from the calculation 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 financial institutions that we believe are creditworthy and financially sound. Our investments in commercial paper and marketable debt investments have been issued by federally sponsored agencies and corporate entities with high credit ratings. 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 subject us to undue investment risk. At any given period, our trade receivables are concentrated among a small number of principal customers. If any of 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 rely on a single supplier, Catalent Pharma Solutions, Inc. to perform stability studies on Remodulin and Tyvaso, manufacture Tyvaso and analyze other products we are developing. Until early 2011, Baxter Pharmaceutical Solutions, LLC was the sole manufacturer of

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## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

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

Remodulin. Until late 2010, NEBU-TEC was the sole approved facility to produce the Tyvaso Inhalation System. Lilly provides exclusive manufacturing, distribution and collection services for us relating to Adcirca. Although our current suppliers could be replaced, we believe that a change in one of our suppliers could disrupt the distribution of our commercial products or services and impede the progress of our clinical trials and other research and development.

*Concentration of products, revenues and customers.* During the years ended December 31, 2010, 2009 and 2008, sales of Remodulin accounted for 67%, 90% and 96%, respectively, of our total net revenues. Net sales of Remodulin in the United States to our three distributors comprised 86%, 88% and 89%, respectively, of our total net Remodulin revenues. In addition, these three U.S.-based distributors are our sole customers for Tyvaso. Sales of Tyvaso during the years ended December 31, 2010 and 2009 (its first year of commercial sale) comprised 25% and 5% of our net revenues.

At December 31, 2010 and 2009, 77% and 80%, respectively, of our accounts receivable were due from our three U.S.-based distributors. While we rely on our distributors to market Remodulin and Tyvaso, there are several other qualified distributors that could replace any one of our current distributors should the need arise.

During the years ended December 31, 2010, 2009 and 2008, we derived 65%, 71% and 64% of our total net pharmaceutical revenues from one customer. Estimated net revenues from that customer were as follows (in thousands):

	For Years Ended December 31,		
	2010	2009	2008
Accredo Health Group, Inc.	\$ 387,251	\$ 253,314	\$ 175,252

**3. Recently Issued Accounting Standards**

In December 2010, the FASB issued Accounting Standards Update (ASU) No. 2010-28, *Intangibles - Goodwill and Other (Topic 350) When to Perform Step 2 of the Goodwill Impairment Test for Reporting Units with Zero or Negative Carrying Amounts* (ASU 2010-28). ASU 2010-28 modifies the first step of the goodwill impairment test for reporting units with zero or negative carrying amounts. If the carrying amount of a reporting unit is zero or negative, the second step of the impairment test must be performed to measure the amount of impairment loss, if any, when it is more likely than not that a goodwill impairment exists. In considering whether it is more likely than not that a goodwill impairment exists, an entity shall evaluate whether any adverse qualitative factors exist. ASU No. 2010-28 is effective for fiscal years and interim periods within those years beginning after December 15, 2010. We are currently assessing what, if any, impact the adoption of ASU 2010-28 will have on our consolidated financial statements.

In April 2010, the FASB issued ASU No. 2010-17, *Revenue Recognition - Milestone Method* (ASU No. 2010-17). ASU No. 2010-17 sets forth guidance on the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate for research and development arrangements. Specifically, consideration that is contingent upon the completion of a milestone may be recognized in its entirety as revenue in the period that milestone has been achieved if the milestone, in its entirety, meets all of the criteria to be considered substantive at the inception of an arrangement. ASU No. 2010-17 is effective prospectively for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010 and applies to research or development

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**UNITED THERAPEUTICS CORPORATION**

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

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

deliverables under which the performance obligation is satisfied over a period of time and a portion, or all, of the consideration is contingent upon uncertain future events or circumstances. A reporting entity's decision to use the milestone method of revenue recognition is a policy election. ASU No. 2010-17 will be effective for us January 1, 2011 and adoption of this standard will not have any impact on our consolidated financial statements.

In January 2010, the FASB issued ASU No. 2010-06, *Fair Value Measurements and Disclosures (Topic 820) Improving Disclosures about Fair Value Measurements* (ASU No. 2010-06). ASU No. 2010-06 requires: (1) fair value disclosures of assets and liabilities by class; (2) disclosures about significant transfers in and out of Levels 1 and 2 on the fair value hierarchy, in addition to Level 3; (3) purchases, sales, issuances and settlements be disclosed on a gross basis on the reconciliation of beginning and ending balances of Level 3 assets and liabilities; and (4) disclosures about valuation methods and inputs used to measure the fair value of Level 2 assets and liabilities. ASU No. 2010-06 became effective for the first financial reporting period beginning after December 15, 2009, except for disclosures about purchases, sales, issuances and settlements of Level 3 assets and liabilities, which will be effective for fiscal years beginning after December 15, 2010. Adoption of the currently effective provisions of ASU No. 2010-06 had no impact on our consolidated financial statements. Level 3 disclosure requirements regarding gross presentation of purchases, sales, issuances and settlements are not expected to impact our consolidated financial statements.

In December 2009, the FASB issued ASU No. 2009-17, *Consolidations (Topic 810) Improvements to Financial Reporting By Enterprises Involved with Variable Interest Entities* (ASU No. 2009-17). ASU 2009-17 requires a qualitative approach for determining the primary beneficiary of a variable interest entity and replaces the quantitative evaluation previously set forth under FASB Interpretation No. 46 (revised December 2003), *Consolidation of Variable Interest Entities*. This approach is focused on identifying the reporting entity that has the ability to direct the activities of a variable interest entity that most significantly affects the entity's economic performance and has the obligation to absorb the entity's losses or has the right to receive benefits from the entity. ASU No. 2009-17, among other things, will require enhanced disclosures about a reporting entity's involvement in variable interest entities. The guidance under ASU No. 2009-17 became effective for the first annual period beginning after November 15, 2009 and interim periods within that first annual period. Adoption of ASU 2009-17 did not have a material impact on our consolidated financial statements.

In October 2009, the FASB issued ASU No. 2009-13, *Revenue Recognition (Topic 605) Multiple-Deliverable Revenue Arrangements: a consensus of the FASB Emerging Issues Task Force* (ASU 2009-13). ASU 2009-13 establishes a selling-price hierarchy for determining the selling price of each element within a multiple-deliverable arrangement. Specifically, the selling price assigned to each deliverable is to be based on vendor-specific objective evidence (VSOE) if available, third-party evidence if VSOE is unavailable, and estimated selling prices if neither VSOE or third-party evidence is available. In addition, ASU 2009-13 eliminates the residual method of allocating arrangement consideration and instead requires allocation using the relative selling price method. ASU 2009-13 will be effective prospectively for multiple-deliverable revenue arrangements entered into, or materially modified, in fiscal years beginning on or after June 15, 2010. ASU 2009-13 will be effective for us on January 1, 2011 and adoption of this standard will not have any impact on our consolidated financial statements.

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## 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, 2010	\$ 282,005	\$ 52	\$ (152)	\$ 281,905
Corporate notes and bonds at December 31, 2010	225,394	144	(68)	225,470
<b>Total</b>	<b>\$ 507,399</b>	<b>\$ 196</b>	<b>\$ (220)</b>	<b>\$ 507,375</b>

As reported on the consolidated balance  
sheet at December 31, 2010:

Current marketable securities	\$ 374,921
Noncurrent marketable securities	132,478
	<b>\$ 507,399</b>

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Government sponsored enterprises at December 31, 2009	\$ 172,531	\$ 559	\$ (247)	\$ 172,843
Corporate notes and bonds at December 31, 2009	96,697	158	(49)	96,806
<b>Total</b>	<b>\$ 269,228</b>	<b>\$ 717</b>	<b>\$ (296)</b>	<b>\$ 269,649</b>

As reported on the consolidated balance  
sheet at December 31, 2009:

Current marketable securities	\$ 129,140
Noncurrent marketable securities	140,088
	<b>\$ 269,228</b>

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## 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,			
	2010		2009	
	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss
Government sponsored enterprises:				
Less than one year	\$ 152,844	\$ (152)	\$ 54,299	\$ (247)
Greater than one year				
	152,844	(152)	54,299	(247)
Corporate notes:				
Less than one year	107,883	(68)	64,499	(49)
Greater than one year				
	107,883	(68)	64,499	(49)
<b>Total</b>	<b>\$ 260,727</b>	<b>\$ (220)</b>	<b>\$ 118,798</b>	<b>\$ (296)</b>

We attribute the unrealized losses on held-to-maturity securities as of December 31, 2010 and 2009, to the variability in related market interest rates. We do not intend to sell these securities, nor is it more likely than not that we will be required to sell them prior to the end of their contractual term. Furthermore, we believe these securities do not subject us to undue market risk or counterparty credit risk. As such, we do not consider these securities to be other than temporarily impaired.

The following table summarizes the contractual maturities of held-to-maturity marketable investments at December 31, 2010 (in thousands):

	December 31, 2010	
	Amortized Cost	Fair Value
Due in less than one year	\$ 374,921	\$ 374,908
Due in one to two years	132,478	132,467
Due in three to five years		
Due after five years		
<b>Total</b>	<b>\$ 507,399</b>	<b>\$ 507,375</b>

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

	For Years Ended December 31,		
	2010	2009	2008
Gross proceeds	\$	\$	\$ 31,850
Realized gains	\$	\$	\$

Realized losses      \$      \$      \$

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**UNITED THERAPEUTICS CORPORATION**

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

**4. Marketable Investments (Continued)**

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.

*Trading Investments*

During the years ended December 31, 2010 and 2009, we recognized trading gains of \$6.9 million and \$1.9 million respectively. For the year ended December 31, 2008, we recognized \$2.5 million in trading losses. In July 2010, we sold all of our marketable investments that were classified as trading securities.

*Equity Investments*

As of December 31, 2010 and 2009, we owned less than 1% of the common stock of Twin Butte Energy Ltd. (Twin Butte). Our investment in Twin Butte is classified as available-for-sale and reported at fair value based on the quoted market price.

As of December 31, 2010, we maintain an investment totaling approximately \$4.9 million in the preferred stock of a privately held corporation within our telemedicine segment. We account for this investment at cost, as its fair value is not readily determinable. The fair value of our investment has not been estimated at December 31, 2010, as there have been no events or developments indicating that the investment may be impaired. This investment is included within non-current other assets on our consolidated balance sheets.

**5. Fair Value Measurements**

Assets and liabilities subject to fair value measurements are required to be disclosed within a specified fair value hierarchy. The fair value hierarchy ranks the quality and reliability of inputs or assumptions used in the determination of fair value and requires assets and liabilities carried at, or permitted to be carried at, fair value to be classified and disclosed in one of the following categories:

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 as 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.



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## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## 5. Fair Value Measurements (Continued)

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

	As of December 31, 2010			
	Level 1	Level 2	Level 3	Balance
<b>Assets</b>				
Money market funds(1)	\$ 91,206	\$	\$	\$ 91,206
Federally-sponsored and corporate debt securities(2)		507,375		507,375
Available-for-sale equity investment	373			373
<b>Total Assets</b>	<b>\$ 91,579</b>	<b>\$ 507,375</b>	<b>\$</b>	<b>\$ 598,954</b>
<b>Liabilities</b>				
Convertible Senior Notes	\$ 421,721	\$	\$	\$ 421,721
Contingent Consideration Tyvaso Inhalation System acquisition(3)			1,894	1,894
	\$ 421,721	\$	\$ 1,894	\$ 423,615

	As of December 31, 2009			
	Level 1	Level 2	Level 3	Balance
<b>Assets</b>				
Auction-rate securities(4)	\$	\$	\$ 29,332	\$ 29,332
Auction-rate securities put option(5)			6,741	6,741
Money market funds(1)	48,220			48,220
Federally-sponsored and corporate debt securities(2)		269,649		269,649
Available-for-sale equity investment	161			161
<b>Total Assets</b>	<b>\$ 48,381</b>	<b>\$ 269,649</b>	<b>\$ 36,073</b>	<b>\$ 354,103</b>
<b>Liabilities</b>				
Convertible Senior Notes	\$ 361,843	\$	\$	\$ 361,843
Contingent Consideration Tyvaso Inhalation System acquisition(3)			5,602	5,602
	\$ 361,843	\$	\$ 5,602	\$ 367,445

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

(2) Included in current and non-current marketable investments on the accompanying consolidated balance sheets. The fair value of these securities is derived using a market approach i.e., from pricing models that rely on relevant observable market data including interest rates, yield curves, recently reported trades of comparable securities, credit spreads and benchmark securities to determine the fair value of such securities. See also Note 4 *Investments Held-to-Maturity Investments* to these consolidated financial statements.

(3)

Included in non-current liabilities on the accompanying consolidated balance sheets. The liability has been recognized in connection with our acquisition of the assets, properties and rights used to manufacture the Tyvaso Inhalation System from NEBU-TEC International Med Products Eike Kern GmbH (NEBU-TEC) in September 2009. The terms of the acquisition require us to pay

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Table of Contents**UNITED THERAPEUTICS CORPORATION****Notes to Consolidated Financial Statements (Continued)****5. Fair Value Measurements (Continued)**

contingent consideration of up to €10.0 million in specified increments if the number of patients using the Tyvaso Inhalation System meets or exceeds certain thresholds measured at designated intervals. We also have the option to purchase NEBU-TEC's next generation nebulizer, the SIM-Neb. If we exercise this option, we could no longer be required to make future contingent payments. The fair value of the contingent consideration has been measured using a probability weighted discounted cash flow (DCF) model which incorporates a discount rate based on our estimated weighted average cost of capital and our projections regarding the timing and number of patients using the Tyvaso Inhalation System. The DCF model also incorporates the probability and impact of exercising our option to acquire the SIM-Neb and the potential introduction of new therapies.

(4)

Included in non-current marketable investments on the accompanying consolidated balance sheet at December 31, 2009. In November 2008, we agreed to the terms of an Auction-Rate Securities Rights Offer (Rights Offer) with the investment firm that maintained our auction-rate securities (ARS) account pursuant to which we obtained the right to sell back at par value our ARS to the investment firm at any time between June 30, 2010 and July 2, 2012 (Put Option). In June 2010, we exercised our right to sell our remaining ARS for their par value (\$19.0 million). In connection with the transaction, we recognized a gain of \$5.6 million, which has been included under the caption "Other, net" on the accompanying consolidated statement of operations for the year ended December 31, 2010. Proceeds from the sale were invested in other marketable investments in accordance with our investment policy.

(5)

Included within other non-current assets on the accompanying consolidated balance sheet at December 31, 2009. In June 2010, we exercised the Put Option to initiate the sale of our ARS. Consequently, we recognized a loss of \$5.5 million to write off the value of this financial instrument as of the date of exercise. The loss has been included under the caption "Other, net" on our consolidated statement of operations for the year ended December 31, 2010. Prior to its exercise in June 2010, we accounted for the Put Option under the fair value option and used a DCF model to measure its fair value.

The tables below provide a reconciliation of the beginning and ending balances of assets and liabilities measured at fair value using significant unobservable inputs (Level 3) for the years ended December 31, 2010 and 2009 (in thousands):

	Auction-rate Securities	Auction-rate Securities Put Option	Contingent Consideration Tyvaso Inhalation System Acquisition	Total
Balance January 1, 2010 Asset (Liability)	\$ 29,332	\$ 6,741	\$ (5,602)	\$ 30,471
Transfers to (from) Level 3				
Total gains/(losses) realized/unrealized included in earnings(1)	6,868	(6,741)	1,776	1,903
Total gains/(losses) included in other comprehensive income			586	586
Purchases/sales/issuances/settlements, net	(36,200)		1,346	(34,854)
Balance December 31, 2010 Asset (Liability)	\$	\$	\$ (1,894)	\$ (1,894)

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## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## 5. Fair Value Measurements (Continued)

	Auction-rate Securities	Auction-rate Securities Put Option	Contingent Consideration Tyvaso Inhalation System Acquisition	Total
Balance January 1, 2009 Asset (Liability)	\$ 27,976	\$ 7,685	\$	\$ 35,661
Transfers to (from) Level 3				
Total gains/(losses) realized/unrealized included in earnings(1)	1,906	(944)	(1,816)	(854)
Total gains/(losses) included in other comprehensive income			10	10
Purchases/sales/issuances/settlements, net	(550)		(3,796)	(4,346)
Balance December 31, 2009 Asset (Liability)	\$ 29,332	\$ 6,741	\$ (5,602)	\$ 30,471

(1)

For the year ended December 31, 2010, includes gains of \$1.8 million attributable to the change in unrealized gains relating to liabilities still held at December 31, 2010 (recognized within selling, general and administrative expenses on our consolidated statements of operations). For the year ended December 31, 2009, includes net losses of \$854,000 attributable to the change in unrealized gains and losses relating to assets and liabilities still held at December 31, 2009 (included within other income and selling, general and administrative expenses, respectively, on our consolidated statement of operations).

## 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 gene therapy for the treatment of PAH. Although we own a majority of Northern's outstanding common stock, we may appoint only two of 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. Consequently, the minority owners of Northern have substantive participating rights. These substantive participating rights prevent us from controlling the operations of 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 net losses. At December 31, 2010, the investment balance is approximately \$720,000 and has been included within other non-current assets on our consolidated balance sheet.

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## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

**7. Accrued Expenses**

Accrued expenses consisted of the following (in thousands):

	December 31,	
	2010	2009
Royalties and rebates	\$ 26,946	\$ 15,258
Payroll related	11,271	8,707
Research related	8,549	2,457
Other	3,514	3,342
<b>Total</b>	<b>\$ 50,280</b>	<b>\$ 29,764</b>

**8. Share Tracking Awards Plan**

We maintain the United Therapeutics Corporation Share Tracking Awards Plan (STAP) under which we grant long-term, equity-based compensation to eligible participants. Awards granted under the STAP are non-dilutive as they are not settled in shares of our common stock. Rather, awards convey the right to receive in cash an amount equal to the appreciation of our common stock, which is calculated as the positive difference between the closing price of our common stock on the date of exercise and the date of grant. Outstanding awards generally vest in equal increments on each anniversary of the date of grant over a three- or four-year period and expire on the tenth anniversary of the date of grant. The maximum number of awards available for grant is 9,000,000, of which approximately 481,000 remained available for issuance as of December 31, 2010. During the first quarter of 2011, we expect to increase the pool of available STAP awards by approximately 2.0 million primarily to accommodate anticipated grants under our long-term incentive bonus and compensation plans.

The STAP liability balance was \$125.6 million and \$64.2 million at December 31, 2010, and December 31, 2009, respectively, and has been included in other current liabilities on our consolidated balance sheets.

In estimating the fair value of awards, we are required to use inputs that materially impact the determination of fair value and the amount of compensation expense recognized. These inputs include the expected volatility of the price of our common stock, the risk-free interest rate, the expected term of awards, the expected forfeiture rate and the expected dividend yield.

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 use of the simplified method in developing an estimate

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## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## 8. Share Tracking Awards Plan (Continued)

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 cash 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 table below presents the assumptions used to measure the fair value of awards at December 31, 2010, 2009 and 2008:

	December 31,		
	2010	2009	2008
Expected volatility	46.8%	47.3%	48.0%
Risk-free interest rate	1.7%	2.8%	1.6%
Expected term of awards (in years)	4.5	5.0	5.6
Forfeiture rate	6.7%	5.4%	6.3%
Expected dividend yield	0.0%	0.0%	0.0%

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## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

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

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 January 1, 2010	6,363,720	\$ 32.19		
Granted	2,426,319	54.46		
Exercised	(1,138,648)	28.04		
Forfeited	(270,911)	38.63		
Outstanding at December 31, 2010	7,380,480	\$ 39.91	8.5	\$ 172,053
Awards exercisable at December 31, 2010	1,975,851	\$ 31.65	7.9	\$ 62,385
Awards expected to vest at December 31, 2010	5,043,553	\$ 42.93	8.7	\$ 102,338

The weighted average fair value of awards granted, as of their date of grant, during the years ended December 31, 2010, 2009 and 2008, was \$26.23, \$29.12 and \$16.13, respectively.

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

	Year Ended December 31,		
	2010	2009	2008
Cost of service sales	\$ 552	\$ 331	\$ 17
Research and development	42,791	27,106	3,463
Selling, general and administrative	47,926	34,209	4,965
Share-based compensation expense before taxes	91,269	61,646	8,445
Related income tax benefits	(33,770)	(22,809)	(3,378)
Share-based compensation expense, net of taxes	\$ 57,499	\$ 38,837	\$ 5,067
Total share-based compensation expense capitalized in inventory	\$ 3,002	\$ 2,336	\$ 72

Cash paid to settle STAP exercises during the years ended December 31, 2010, 2009 and 2008 was \$32.9 million, \$8.2 million and none, respectively.

**9. Debt***Convertible 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 semi-annually on April 15 and October 15 of each year. The Convertible Senior Notes are unsecured, unsubordinated debt obligations that rank equally with all of our other unsecured and unsubordinated indebtedness. The conversion price is \$37.61 per share and the number of shares on which the aggregate consideration is to be determined upon conversion is approximately 6,646,000.





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**UNITED THERAPEUTICS CORPORATION**

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

**9. Debt (Continued)**

Conversion can occur: (1) any time after July 15, 2011; (2) during any calendar quarter that follows a calendar quarter in which the price of our common stock exceeded 120% of the conversion price for at least 20 days during the 30 consecutive trading-day period ending on the last trading day of the quarter; (3) 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 number of shares underlying the Convertible Senior Notes; (4) upon specified distributions to our shareholders; (5) in connection with corporate transactions; or (6) in the event that our common stock ceases to be listed on the NASDAQ Global Select Market and is not listed for trading on another U.S. national or regional securities exchange.

Upon conversion, a holder of our Convertible Senior Notes will receive: (1) 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 (2) to the extent the conversion value exceeds the principal amount of the Convertible Senior Notes, 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, holders can require us to purchase from them all or a portion of their Convertible Senior Notes for 100% of the principal value plus any accrued and unpaid interest. At December 31, 2010, the aggregate conversion value of the Convertible Senior Notes exceeded their principal value by approximately \$170.2 million using a conversion price of \$63.22, the closing price of our common stock on that date. We have reserved sufficient shares of our common stock to satisfy the conversion requirements related to the Convertible Senior Notes.

The closing price of our common stock exceeded 120% of the conversion price of the Convertible Senior Notes for more than 20 trading days during the 30 consecutive trading day period ending on December 31, 2010. Consequently, the Convertible Senior Notes were convertible at the election of their holders. This contingent conversion measurement is calculated at the end of each quarterly reporting period.

Because the terms of the Convertible Senior Notes provide for settlement wholly or partially in cash, we are required to account for the liability and equity components of these debt instruments separately in a manner that reflects our non-convertible borrowing rate. Accordingly, we estimated the fair value of the Convertible Senior Notes without the conversion feature as of the date of issuance (Liability Component). The estimated fair value of the Liability Component was \$177.6 million. The excess of the proceeds received over the estimated fair value of the Liability Component totaling \$72.4 million was allocated to the conversion feature (Equity Component) and a corresponding offset was recognized as a discount to reduce the net carrying value of the Convertible Senior Notes. The discount is being amortized to interest expense over a five-year period ending October 2011 (the expected life of the Liability Component) using the interest method and an effective rate of interest of 7.5%, which corresponds to our estimated non-convertible borrowing rate at the date of issuance.

Table of Contents**UNITED THERAPEUTICS CORPORATION****Notes to Consolidated Financial Statements (Continued)****9. Debt (Continued)**

Interest expense associated with the Convertible Senior Notes consists of the following (in thousands):

	<b>For Years Ended December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
Contractual coupon rate of interest	\$ 1,250	\$ 1,250	\$ 1,250
Discount amortization	15,705	14,581	13,537
<b>Interest expense Convertible Senior Notes</b>	<b>\$ 16,955</b>	<b>\$ 15,831</b>	<b>\$ 14,787</b>

Amounts comprising the carrying amount of the Convertible Senior Notes are as follows (in thousands):

	<b>December 31,</b>	
	<b>2010</b>	<b>2009</b>
Principal balance	\$ 249,968	\$ 249,978
Discount, net of accumulated amortization of \$58,402 and \$42,697	(14,000)	(29,706)
<b>Carrying amount</b>	<b>\$ 235,968</b>	<b>\$ 220,272</b>

***Call Spread Option***

Concurrent with the issuance of the Convertible Senior Notes, we purchased call options on our common stock in a private transaction with Deutsche Bank AG London (Call Option). The Call Option allows us to purchase up to approximately 6.6 million shares of our common stock at a price of \$37.61 per share, which is equal to the amount of our common stock related to the conversion value that we could deliver to holders of the Convertible Senior Notes upon conversion. We will be required to issue shares of our common stock upon conversion if the price of our common stock exceeds \$37.61 per share upon conversion. The Call Option will terminate upon the earlier of the maturity date of the Convertible Senior Notes or the first day all of the Convertible Senior Notes are no longer outstanding due to conversion or otherwise. We paid approximately \$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 simultaneously with the issuance of the Convertible Senior Notes, we sold a warrant to Deutsche Bank AG London under which Deutsche Bank AG London has the right to purchase approximately 6.6 million shares of our common stock at an exercise price of \$52.85 per share (Warrant). Proceeds received from the Warrant totaled approximately \$45.4 million and were recorded as additional paid-in-capital.

The shares deliverable to us under the Call Option must be obtained from existing shareholders. Any shares that we may be required to deliver under the Warrant can consist of registered or unregistered shares, subject to potential adjustments to the settlement amount. The maximum number of shares of our common stock that we may be required to deliver in connection with the Warrant is approximately 6.6 million. We have reserved approximately 6.6 million shares for the settlement of the Warrant and had sufficient shares available as of December 31, 2010, to effect such settlement.

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 conversion price of

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**UNITED THERAPEUTICS CORPORATION**

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

**9. Debt (Continued)**

the Convertible Senior Notes and the Warrant has a higher strike price per share that caps the amount of protection these instruments could provide against dilution. The Call Option and Warrant can be settled on a net share basis.

These instruments are considered both indexed to our common stock and classified as equity; therefore, the Call Option and Warrant are not accounted for as derivative instruments.

***Mortgage Financing***

On December 27, 2010, we entered into a Credit Agreement with Wells Fargo Bank, National Association (Wells Fargo) and Bank of America, N.A., pursuant to which we obtained \$70.0 million in debt financing. Proceeds from the loan were used to pay off the synthetic lease arrangement with Wachovia (discussed in Note 10 *Commitments and Contingencies Lease Obligation*) and will also be used to help fund working capital requirements. The Credit Agreement has a forty-eight month term maturing in December 2014 and is secured by a first mortgage lien on our Facilities in Research Triangle Park, North Carolina and Silver Spring, Maryland. Annual principal payments will be based on a twenty-five year amortization schedule using a fixed rate of interest of 7.0 percent and the outstanding debt will bear a floating rate of interest per annum based on the one month London Interbank Offer Rate (LIBOR), plus a credit spread of 3.75 percent, or approximately 4.0 percent as of December 31, 2010. Alternatively, we have the option to change the rate of interest charged on the loan to 2.75 percent plus the greater of: (1) Wells Fargo's prime rate, or, (2) the federal funds effective rate plus 0.05 percent, or, (3) LIBOR plus 1.0 percent. The Credit Agreement also permits prepayment of the outstanding loan balance in its entirety, with varying declining prepayment premiums at specified intervals. The prepayment premium is initially 1.5 percent if the debt is prepaid within the first six-months of the term and declines in 0.5 percent increments at each successive six-month interval such that there is no premium if the loan is prepaid after December 2012. At December 31, 2010, we capitalized \$1.1 million in related transaction costs which will be amortized as interest expense over the term of the Credit Agreement using the effective interest method.

The Credit Agreement subjects us to the following financial covenants: (1) a maximum consolidated leverage ratio of 2.5:1.0, calculated as the ratio of our consolidated indebtedness to "Consolidated EBITDA" which is defined as consolidated net income, adjusted for the following as applicable: (i) interest expense; (ii) income taxes; (iii) non-cash license fees; (iv) depreciation and amortization; (v) impairment charges; and (vi) share-based compensation (stock option and share tracking award expense), to be measured as of the last day of each fiscal quarter on a rolling four quarter basis; and (2) minimum liquidity of no less than \$150.0 million. Under the Credit Agreement, minimum liquidity is defined as the sum of our cash and cash equivalents, plus the fair value of our marketable investments as of the last day of a fiscal quarter less the sum of indebtedness that matures within the next twelve months and the liability related to vested STAP awards in excess of \$50.0 million. In addition, the Credit Agreement subjects us to various customary negative covenants. As of December 31, 2010, we were in compliance with the preceding covenants.

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## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

**9. Debt (Continued)**

As of December 31, 2010, future maturities relating to the Credit Agreement are as follows (in thousands):

Years ending December 31,	
2011	\$ 1,071
2012	1,148
2013	1,231
2014	66,550
<b>Total</b>	<b>\$ 70,000</b>

*Interest Expense*

Details of interest expense include the following components (in thousands):

	For Years Ended December 31,		
	2010	2009	2008
Interest expense	\$ 19,817	\$ 18,029	\$ 16,196
Capitalized interest	(103)	(5,154)	(4,757)
<b>Total</b>	<b>\$ 19,714</b>	<b>\$ 12,875</b>	<b>\$ 11,439</b>

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

Until December 2010, we leased our Phase I Laboratory, the first completed building in our Silver Spring facility, pursuant to a synthetic lease arrangement entered into in June 2004 with Wachovia Development Corporation and its affiliates (Wachovia), now an affiliate of Wells Fargo. Under the lease, Wachovia funded \$32.0 million toward the construction of the Phase I Laboratory on land that we own. After completing construction in May 2006, Wachovia leased the Phase I Laboratory to us. The base term of the lease was scheduled to end in May 2011, at which time we had planned to exercise our option to purchase the Phase I Laboratory for approximately \$32.0 million. However, in order to secure the Credit Agreement, we terminated the Lease and acquired title to the Phase I Laboratory for \$32.0 million in December 2010. Upon termination of the lease, \$35.1 million of cash and marketable investments held as collateral under the lease was released.

*Operating Leases*

We lease primarily facilities space and office equipment under operating lease arrangements that have terms expiring at various dates through 2018. Certain lease arrangements include renewal options and escalation clauses. In addition, various lease agreements to which we are a party require that we comply with certain customary 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.

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## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

**10. Commitments and Contingencies (Continued)**

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

Years ending December 31,	
2011	\$ 4,364
2012	2,626
2013	2,419
2014	1,700
2015	1,868
Thereafter	4,819
	\$ 17,796

Total rent expense was \$2.7 million, \$2.7 million and \$2.5 million for the years ended December 31, 2010, 2009 and 2008, respectively.

***Milestone and Royalty Payments***

We are party to certain license agreements as described in Note 15 *License Agreements* 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):

Years ending December 31,		(1)
2011	\$ 2,500	
2012	2,000	
2013	2,000	
2014	300	
2015 and thereafter	8,000	
Total	\$ 14,800	

(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 to which we are a party require us to pay royalties refer to Note 15 *Assignment and License Agreements* to these consolidated financial statements. Related royalties are generally based on a percentage of net sales of related products or other products and range from 1.0 percent to 30.0 percent of net product revenues.

***Research agreement***

We maintain a research agreement with the University of Oxford (Oxford) to develop antiviral compounds. Research under this agreement is performed by Oxford Glycobiological Institute, which is headed by a member of our board of directors and our scientific advisory board. 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



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**UNITED THERAPEUTICS CORPORATION**

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

**10. Commitments and Contingencies (Continued)**

and royalties are subject to reduction depending upon third-party contributions to discoveries and/or third-party licenses necessary to develop products. The current five-year term of the research agreement runs through September 30, 2011 and we are obligated to make 60 equal monthly payments totaling approximately \$3.7 million. As of December 31, 2010, approximately \$475,000 remained outstanding.

In August 2010, we extended the term of our research agreement with Oxford for an additional five-year period beginning on October 1, 2011. In connection with the extension of this agreement, we agreed to pay Oxford approximately \$2.9 million in sixty equal monthly installments beginning on October 1, 2011.

During the twelve months ended December 31, 2010, 2009 and 2008, we incurred \$610,000, \$588,000 and \$734,000, respectively, in expenses under the terms of the agreement.

From time to time, we may enter into other arrangements with Oxford relating to specific development activities that are outside the scope of our research agreement described above. In August 2010, we entered into a service arrangement with Oxford to conduct specific tests of our lead antiviral candidate against specific viruses for a fee of approximately \$174,000. In December 2010, we entered into a service agreement with Oxford to assist in the development of an antiviral compound for the treatment of the hepatitis-C virus. Pursuant to the terms of this arrangement, we agreed to pay Oxford approximately \$227,000 for these services.

**11. Stockholders' Equity**

*Authorized Shares of Common Stock*

Effective June 28, 2010, we amended our Amended and Restated Certificate of Incorporation to increase the number of authorized shares of our common stock from 100,000,000 shares to 245,000,000 shares.

*Stock Split*

In September 2009, we completed a stock split in the form of a stock dividend pursuant to which one share of our common stock was distributed for each share issued and outstanding (or held in treasury) at the close of business on the date of record, September 14, 2009. All references in the consolidated financial statements to the price and number of shares of our common stock and per share data, including data pertaining to share based awards, have been restated to reflect the effects of the stock split for all periods presented.

*Equity Incentive Plan*

We may grant stock options under our equity incentive plan (EIP). The EIP provides for the issuance of up to 29,879,034 shares of our common stock, of which 15,879,034 have been reserved for issuance to our CEO in accordance with her employment agreement. As of December 31, 2010, there were 10,954,737 shares available for issuance under the EIP. Options granted under the EIP are nontransferable, contain a maximum contractual term of ten years and typically vest in equal annual increments over a maximum period of three years, except for awards to our CEO, which vest immediately upon grant in accordance with the terms of her employment agreement. The exercise price of related stock-option awards can be no less than the fair market value of our common stock on the

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**UNITED THERAPEUTICS CORPORATION**

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

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

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 \$32.50 (Original Options) were canceled and replaced with options having an exercise price of \$30.75 (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 retained 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, were subject to a one-year vesting term i.e., related Replacement Options became exercisable on December 26, 2009; and

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

The Offer was accounted for as a modification of existing option award terms. As such, total compensation associated with the Replacement Options consisted of the grant date fair value of the Original Options for which the requisite service period was expected to be rendered (or had already been rendered) at the Exchange Date, plus the incremental cost associated with the modification of terms. A total of 3,145,232 Original Options with a weighted average exercise price of \$40.53 were exchanged for Replacement Options. Incremental compensation expense associated with the Offer was approximately \$7.8 million.

***Employee Stock 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. These assumptions include the expected volatility of our common stock, risk-free interest rate, the expected term of stock option 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.



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## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

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

*Expected term* The expected term reflects an estimation of the time period we expect an option grant to remain outstanding. We use 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 canceled 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,		
	2010	2009	2008
Expected volatility	45.4%	47.6%	47.6%
Risk-free interest rate	2.1%	2.6%	1.6%
Expected term of options (in years)	5.1	5.1	4.8
Forfeiture rate	0.0%	0.0%	3.0%
Expected dividend yield	0.0%	0.0%	0.0%

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

	Options	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in 000s)
Outstanding at January 1, 2010	8,578,788	\$ 29.92		
Granted	598,361	62.16		
Exercised	(3,216,652)	25.47		
Forfeited	(34,529)	25.00		
Outstanding at December 31, 2010	5,925,968	\$ 35.64	6.7	\$ 163,446
Options exercisable at end of period	5,799,972	\$ 35.68	6.7	\$ 159,741
Expected to vest at December 31, 2010	117,913	\$ 34.20	6.7	\$ 3,421

The weighted average fair value of employee stock options granted during the years ended December 31, 2010, 2009 and 2008, was \$26.14, \$22.21 and \$26.80, respectively. The total fair value of vested employee options was \$29.0 million, \$42.7 million and \$68.8 million, during the years ended December 31, 2010, 2009 and 2008, respectively.

Table of Contents**UNITED THERAPEUTICS CORPORATION****Notes to Consolidated Financial Statements (Continued)****11. Stockholders' Equity (Continued)**

Total share-based compensation relating to employee stock options for the years ended December 31, 2010, 2009 and 2008, is as follows (in thousands):

	Year Ended December 31,		
	2010	2009	2008
Cost of service sales	\$ 15	\$ 46	\$ 52
Research and development	3,087	9,188	10,344
Selling, general and administrative	19,265	29,930	15,158
Stock option expense before taxes	22,367	39,164	25,554
Related income tax benefits	(8,231)	(14,491)	(10,222)
Total stock option expense, net of taxes	\$ 14,136	\$ 24,673	\$ 15,332
Total stock option expense capitalized in inventory	\$ 290	\$ 972	\$ 520

As of December 31, 2010, there was \$477,000 in unrecognized compensation cost related to unvested employee stock options which is expected to be recognized during 2011.

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

	Year Ended December 31,		
	2010	2009	2008
Number of options exercised	3,335,114	1,358,067	2,045,944
Cash received from options exercised	\$ 85,427	\$ 32,611	\$ 41,936
Total intrinsic value of options exercised	\$ 102,905	\$ 29,060	\$ 58,657
Tax benefits realized from options exercised	\$ 23,826	\$ 4,406	\$ 21,090

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## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## 11. Stockholders' Equity (Continued)

*Earnings (loss) per Share*

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

	For Years Ended December 31,		
	2010	2009	2008
Net income (loss) (numerator)	\$ 105,916	\$ 19,462	\$ (49,327)
Shares (denominator):			
Basic weighted-average shares outstanding	56,142	53,314	45,802
Effect of dilutive securities:			
Convertible Senior Notes	2,131	399	
Stock options(1)	1,243	2,420	
Diluted weighted-average shares	59,516	56,133	45,802
Earnings (loss) per share			
Basic	\$ 1.89	\$ 0.37	\$ (1.08)
Diluted	\$ 1.78	\$ 0.35	\$ (1.08)
Stock options and warrants excluded from calculation(2)	6,885	6,786	16,240

(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*

In June 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, extended the expiration date of the Preferred Share Purchase Rights (Rights) from December 29, 2010 to June 26, 2018, and increased the purchase price of each Right from \$64.75 and \$400.00, respectively. 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. As of December 31, 2010, we have not issued any shares of our Series A Preferred Stock.

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## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

**12. Comprehensive Income (Loss)**

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

	Year Ended December 31,		
	2010	2009	2008
Net income (loss)	\$ 105,916	\$ 19,462	\$ (49,327)
Other comprehensive income:			
Foreign currency translation (loss) gain	(642)	2,802	(5,489)
Marketable investments available-for-sale			
Unrealized holding gains (losses), net of tax	134	44	(4,702)
Reclassification adjustment for other-than-temporary impairment realized in income, net of tax			4,511
Unrealized gain (loss) on available-for-sale securities, net	134	44	(191)
Unrecognized prior period service cost, net of tax	(3,224)	92	(414)
Unrecognized actuarial pension loss, net of tax	(1,129)	(1,339)	(136)
Comprehensive income (loss)	\$ 101,055	\$ 21,061	\$ (55,557)

**13. Income Taxes**

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

	Year Ended December 31,		
	2010	2009	2008
Current:			
Federal	\$ 26,302	\$ 14,304	\$
State	1,879	1,999	1,275
Foreign	846	158	391
Total current	29,027	16,461	1,666
Deferred			
Federal	(5,301)	(24,397)	(68,695)
State	1,480	(2,508)	(5,311)
Foreign	(1,289)	168	(206)
Total deferred	(5,110)	(26,737)	(74,212)
Other non-current(1)			
Federal	15,855	7,965	36,408
State	1,608	1,616	1,744
Foreign	543		
Total other	18,006	9,581	38,152
Total income tax (expense) benefit	\$ 41,923	\$ (695)	\$ (34,394)

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

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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 expense (benefit) as reported (in thousands):

	Year Ended December 31,		
	2010	2009	2008
Federal tax provision computed at 35%	\$ 51,743	\$ 7,738	\$ (29,302)
State tax provision, net of federal tax provision	1,233	748	(2,024)
Change in valuation allowance allocated to tax expense		(833)	
General business credits	(14,759)	(10,899)	(7,101)
Incentive stock option expense	(1,201)	(1,354)	1,288
Section 199 deduction	(3,627)	(2,207)	
Nondeductible compensation expense	7,342	4,821	
Nondeductible expenses	1,192	1,291	2,745
<b>Total income tax (benefit) expense</b>	<b>\$ 41,923</b>	<b>\$ (695)</b>	<b>\$ (34,394)</b>

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

	December 31,	
	2010	2009
Deferred tax assets:		
General business credits	\$ 89,211	\$ 80,882
Impairment losses on investments	2,875	2,895
Realized losses on marketable investments	2,732	2,752
License fees capitalized for tax purposes	58,942	60,200
Nonqualified stock options	30,379	36,064
SERP	7,188	4,498
STAP awards	31,801	18,696
Other	22,611	14,194
<b>Total deferred tax assets</b>	<b>245,739</b>	<b>220,181</b>
Deferred tax liabilities:		
Plant and equipment principally due to differences in depreciation	(23,341)	(5,834)
Other	(1,657)	
<b>Net deferred tax asset before valuation allowance</b>	<b>220,741</b>	<b>214,347</b>
Valuation allowance	(6,021)	(6,186)
<b>Net deferred tax assets</b>	<b>\$ 214,720</b>	<b>\$ 208,161</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

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corresponding charge to earnings in the period such a determination is made. Conversely, future reductions to the valuation allowance would result in the recognition of a tax benefit in the period we conclude a reduction is warranted. In September 2009, we completed a corporate restructuring related to certain of our wholly-owned subsidiaries. Consequently,

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## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

**13. Income Taxes (Continued)**

we reduced our valuation allowance maintained against certain state net operating losses in the amount of \$5.6 million.

As of December 31, 2010, we had business tax credit carryforwards of approximately \$89.2 million. These carryforwards expire on various dates through 2025. Certain business tax credit carryforwards that were generated at various dates prior to December 2008 are 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 these business tax credits to expire unused. We are currently reviewing our stock trading history for the year ended December 31, 2010 to ascertain whether any further ownership changes have occurred pursuant to Section 382.

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, 2010	\$ 6,736
Gross increases tax positions in prior period	670
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, 2010	\$ 7,406
Unrecognized tax benefit at January 1, 2009	\$ 5,882
Gross increases tax positions in prior period	854
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, 2009	\$ 6,736
Unrecognized tax benefit at January 1, 2008	\$ 2,989
Gross increases tax positions in prior period	2,893
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, 2008	\$ 5,882

Included in unrecognized tax benefits at December 31, 2010, 2009 and 2008, is \$453,000, \$538,000 and \$1.8 million, respectively, of tax benefits that, if recognized, would impact the effective tax rate. For the years ended December 31, 2010, 2009 and 2008, we did not accrue, or recognize, any interest and penalties related to uncertain tax positions.

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.





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**UNITED THERAPEUTICS CORPORATION**

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

**13. Income Taxes (Continued)**

We are subject to federal and state taxation in the United States and various foreign jurisdictions. Our tax years from 2007 to 2009 are subject to examination by federal and state tax authorities. In addition, general business tax credits generated between 1998 and 2006 are subject to review as those credits were first utilized in 2008. 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*

We maintain the United Therapeutics Corporation Supplemental Executive Retirement Plan (SERP) to provide retirement benefits to certain senior members of our management team.

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 for any reason other than death, disability, or change in control prior to age 60 will not be entitled to any benefits under the SERP.

To help fund our obligations under the SERP, we maintain the United Therapeutics Corporation Supplemental Executive Retirement Plan Rabbi Trust Document (Rabbi Trust). 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 as of December 31, 2010 and 2009. Investments held in the rabbi trust have been included under the caption, "Marketable investments and cash restricted" on our consolidated balance sheets.

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.

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## 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,	
	2010	2009
Projected benefit obligation at beginning of year	\$ 14,502	\$ 9,173
Service cost	3,688	2,645
Interest cost	883	558
Plan amendments	5,452	
Actuarial loss (gain)	1,902	2,126
Projected benefit obligation at end of year	\$ 26,427	\$ 14,502
Fair value of plan assets at end of year		
Unfunded at end of year(1)	\$ 26,427	\$ 14,502

(1)

Included within other non-current liabilities on our consolidated balance sheets. The increase in the projected benefit obligation as of December 31, 2010 compared to December 31, 2009 reflects the addition of two new participants to the SERP during the current year and a reduction in the discount rate used to project our obligation under the SERP.

The accumulated benefit obligation for the SERP, a measure that does not encompass future increases in participant salaries, was \$17.1 million and \$9.5 million at December 31, 2010 and 2009, respectively.

Future estimated benefit payments, based on current assumptions, including election of lump-sum distributions and expected future service, are as follows (in thousands):

Years ending December 31,	
2011	\$
2012	
2013	
2014	
2015	24,213
2016-2020	
	\$ 24,213

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## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## 14. Employee Benefit Plans (Continued)

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

Years Ended December 31,	2010	2009
Discount Rate	4.80%	5.25%
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,	2010	2009	2008
Service cost	\$ 3,688	\$ 2,645	\$ 2,664
Interest cost	883	558	386
Prior period service cost amortization	370	146	145
Amortization of net actuarial loss	118		
<b>Total</b>	<b>\$ 5,059</b>	<b>\$ 3,349</b>	<b>\$ 3,195</b>

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

Years Ended December 31,	2010	2009	2008
Net unrecognized actuarial loss	\$ 1,784	\$ 2,126	\$ 200
Net unrecognized prior service cost	5,082	(146)	879
<b>Total</b>	<b>6,866</b>	<b>1,980</b>	<b>1,079</b>
Tax	(2,513)	(733)	(529)
<b>Total, net of tax</b>	<b>\$ 4,353</b>	<b>\$ 1,247</b>	<b>\$ 550</b>

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

December 31,	2010	2009	2008
Net unrecognized actuarial loss (gain)	\$ 4,068	\$ 2,284	\$ 158
Net unrecognized prior service cost	6,528	1,445	1,591
<b>Total</b>	<b>10,596</b>	<b>3,729</b>	<b>1,749</b>
Tax	(3,894)	(1,379)	(647)
<b>Total, net of tax</b>	<b>\$ 6,702</b>	<b>\$ 2,350</b>	<b>\$ 1,102</b>

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## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

**14. Employee Benefit Plans (Continued)**

Estimated amounts included in accumulated other comprehensive income as of December 31, 2010 that are expected to be recognized as components of net periodic pension cost on our statement of operations for the year ended December 31, 2011 comprise the following (in thousands):

Net prior service cost amortization	\$ 664
Amortization of net actuarial loss	137
<b>Total</b>	<b>\$ 801</b>

*Employee Retirement Plan*

We maintain a Section 401(k) Salary Reduction Plan (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 40 percent of a participant's salary deferral. Matching contributions vest immediately for participants who have been employed for three years; otherwise, matching contributions vest annually, in one-third increments over a three-year period until the three-year employment requirement has been met. Expenses related to the 401(k) Plan were \$1.4 million, \$847,000 and \$407,000 for the years ended December 31, 2010, 2009 and 2008, respectively.

**15. Assignment and License Agreements***GlaxoSmithKline 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 treprostinil) 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 treprostinil, currently Remodulin and Tyvaso. The terms of the agreement provide Glaxo 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 or Tyvaso, 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 percent of annual net sales of Remodulin and Tyvaso in excess of \$25.0 million. Related royalties are reduced by up to 50 percent 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 three 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.

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**UNITED THERAPEUTICS CORPORATION**

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

**15. Assignment and License Agreements (Continued)**

*License Agreement.* Lilly granted us an exclusive right to develop, market, promote and commercialize Adcirca 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 Adcirca 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 Adcirca, or (2) expiration of any government conferred exclusivity rights to Adcirca. In addition, at Lilly's discretion the license agreement may be terminated in the event that we undergo a change in control.

*Manufacturing and Supply Agreement.* Terms of the manufacturing and supply agreement provide that Lilly will manufacture Adcirca and distribute it via its wholesaler network in the same manner that it distributes its own pharmaceutical products. We agreed to purchase Adcirca from Lilly at a fixed manufacturing 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, non-refundable, non-creditable payment to Lilly of \$125.0 million. 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 6,301,674 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 ending on 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.

We expensed to research and development all up-front payments paid to Lilly totaling \$150.0 million during the fourth quarter of 2008, as Adcirca had not received regulatory approval and we had no alternative uses for the license rights.

***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, we amended the agreement to expand our rights to commercialize a modified release formulation of beraprost (beraprost-MR). In accordance with the terms of the amended agreement, we issued 400,000 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 \$27.21 per share. Accordingly, the repurchase value of the stock issued has been included within temporary equity on our consolidated balance sheets. If Toray requests that we repurchase these shares, we will reclassify an amount equal to the repurchase price 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 regulatory approval in the United States or the European Union. In September 2010, we entered into a supplement to our license agreement with Toray under which we agreed on the timing of two milestone payments under our existing agreement, in the amounts of \$4.0 million and \$5.0 million. All conditions relating to these milestone payments were satisfied in the fourth quarter of 2010; accordingly, during the quarter we paid Toray \$4.0 million and recognized a \$5.0 million liability and associated expense relating to the second milestone, which will be

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**UNITED THERAPEUTICS CORPORATION**

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

**15. Assignment and License Agreements (Continued)**

paid to Toray during the first quarter of 2011. Milestone payments are expensed as research and development when incurred since beraprost-MR has not demonstrated commercial feasibility.

***Supernus Pharmaceuticals, Inc.***

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 tadalafil product. The agreement requires us to make milestone payments to Supernus in connection with the development of oral tadalafil 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 using the technology granted under this license.

***ImmuneWorks, Inc.***

In February 2010, we entered into a Development Agreement with ImmuneWorks, Inc. to develop IW001, a purified bovine (derived from cows) Type V Collagen oral solution for the treatment of Idiopathic Pulmonary Fibrosis, a progressive lung disease characterized by abnormal and excessive deposition of fibrotic tissue in the lung, and Primary Graft Dysfunction, a type of organ rejection in patients receiving lung transplant. In addition to funding the development program, we were granted an option to acquire all of the issued and outstanding capital stock of ImmuneWorks, Inc.

***Other***

We are party to various other license agreements relating to our key therapeutic platforms and to other therapeutic platforms. These license agreements require us to make royalty payments based on a percentage of sales of related products ranging from 1.0 percent to 30.0 percent and may require other payments upon the achievement of certain milestones.

**16. Related Party Transaction**

In September 2002, we entered into a technical services agreement for certain telemedicine technology development services for Medicomp with Kurzweil Technologies, Inc. (KTI), a company controlled by Raymond Kurzweil, a non-independent member of our Board of Directors. Pursuant to this agreement, we paid KTI a monthly consulting fee. In addition, we agreed to pay KTI a five percent royalty on certain sales of products reasonably attributed to and dependent upon the technology developed by KTI under the technical services agreement which are covered by claims of an issued and unexpired U.S. patent(s). We terminated the services performed under this agreement in December 2006; however, we maintained the royalty obligation subsequent to termination. KTI has been awarded patents based on certain work performed under the technical services agreement. For the year ended December 31, 2010, royalties incurred to KTI were \$355,000. In connection with our agreement to sell Medicomp (see Note 20 *Subsequent Event*), KTI has tentatively agreed to terminate further royalty obligations under this agreement in exchange for a \$250,000 payment upon closing of the Medicomp sale. If we are not able to negotiate termination of the agreement, the agreement will be assigned to Medicomp upon closing of the Medicomp sale.

In May 2007, we entered into a new technical services agreement with KTI. Pursuant to this agreement, we agreed to pay KTI consulting fees of up to \$12,000 monthly. We also agreed to

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**UNITED THERAPEUTICS CORPORATION**

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

**16. Related Party Transaction (Continued)**

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 percent royalty on sales of certain products reasonably attributed to and dependent upon certain technology developed by KTI. We incurred \$144,000, \$172,000, and \$145,000 in expenses during the years ended December 31, 2010, 2009 and 2008, respectively under this agreement.

As of December 31, 2010 and 2009, we owed KTI \$97,000, and none, respectively.

**17. Distribution Agreements**

We entered into our distribution agreements for Tyvaso with our U.S.-based specialty pharmaceutical distributors in August 2009. The Tyvaso distribution agreements have one-year terms that renew automatically for additional one-year periods, unless terminated earlier. The Tyvaso distribution agreements are similar to the distribution agreements we have for Remodulin. Both distribution agreements contain similar contractual responsibilities including those relating to ordering specifications, inventory requirements and exchange rights. Distribution agreements for Tyvaso require of our distributors certain services on a fee-for-service basis. If any of our distribution agreements expire or terminate, we may under certain circumstances be required to repurchase any unsold Tyvaso inventory held by our distributors. None of our current distribution agreements grants our distributors the distribution rights for oral treprostinil.

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 2012. 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 in Japan and \$2.0 million upon the receipt of marketing approval in Japan. We recognize revenue ratably on fees received in connection with this arrangement from the period related fees are realizable through the expected date of regulatory approval.

In June 2010, we entered into an exclusive agreement with Lee's Pharmaceutical (HK) Limited (Lee's Pharma) to distribute subcutaneous and intravenous Remodulin in China. Lee's Pharma is also responsible, with our assistance, for obtaining marketing authorization for Remodulin in China, including conducting necessary studies. We will supply the drug used in these studies at no charge to Lee's Pharma. Commercial activities in China are not expected to begin until late 2012. Upon receipt of marketing authorization and pricing approval, Lee's Pharma will purchase Remodulin from us at an agreed-upon transfer price. Under our agreement, Lee's Pharma is required to make distributor rights payments to us on specified dates and upon the receipt of marketing approval. As of December 31, 2010, we have received \$200,000 in distributor rights payments and are expecting an additional \$1.4 million in 2011. Upon the receipt of marketing approval in China, a final payment of \$1.4 million will become due. We recognize revenue ratably on fees realizable in connection with this arrangement through the expected date of regulatory approval.



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**UNITED THERAPEUTICS CORPORATION**

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

**18. Acquisition of Tyvaso Inhalation System Business**

In September 2009 we acquired all of the assets, properties and rights used in the Tyvaso Inhalation System from NEBU-TEC pursuant to the terms of a December 2008 agreement. We acquired the Tyvaso Inhalation System business to obtain control over production of the device and related accessories. The assets and rights acquired included the necessary inputs, processes and outputs to be accounted for as a business combination. The acquisition date fair value of the consideration transferred included \$6.8 million in cash and \$4.8 million in contingent consideration, of which, \$9.8 million was allocated to identifiable intangible assets and \$1.3 million to goodwill.

Pursuant to the terms of the acquisition, we agreed to pay NEBU-TEC up to €10.0 million in contingent consideration in specified increments if the number of patients using the Tyvaso Inhalation System meets or exceeds certain thresholds measured at designated intervals. We also have the option to purchase NEBU-TEC's next generation nebulizer, the SIM-Neb.

**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 services. The telemedicine segment is managed separately because diagnostic services require different technology and marketing strategies than therapeutic products.

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, 2010, is presented below (in thousands):

	<b>Pharmaceutical</b>	<b>Telemedicine</b>	<b>Consolidated Totals</b>
Revenues from external customers	\$ 592,899	\$ 10,932	\$ 603,831
Net income (loss)	113,334	(7,418)	105,916
Interest income	2,939		2,939
Interest expense	(19,710)	(4)	(19,714)
Income tax expense	(41,872)	(51)	(41,923)
Depreciation and amortization	(16,908)	(1,012)	(17,920)
Equity loss in affiliate	(160)		(160)
Investments in equity method investees	720		720
Expenditures for long-lived assets	(17,197)	(1,443)	(18,640)
Goodwill	2,487		2,487
Total assets	1,408,722	22,913	1,431,635

Segment information as of and for the year ended December 31, 2009, is presented below (in thousands):

	<b>Pharmaceutical</b>	<b>Telemedicine</b>	<b>Consolidated Totals</b>
Revenues from external customers	\$ 358,880	\$ 10,968	\$ 369,848
Net income	19,398	64	19,462
Interest income	5,146		5,146
Interest expense	(12,875)		(12,875)
Income tax benefit	695		695
Depreciation and amortization	(10,685)	(709)	(11,394)
Equity loss in affiliate	(141)		(141)
Investments in equity method investees	880		880
Expenditures for long-lived assets	(92,790)	(2,610)	(95,400)
Goodwill	2,585	6,178	8,763
Total assets	1,031,087	20,457	1,051,544

Segment information as of and for the year ended December 31, 2008, is presented below (in thousands):

	<b>Pharmaceutical</b>	<b>Telemedicine</b>	<b>Consolidated Totals</b>
Revenues from external customers	\$ 272,012	\$ 9,485	\$ 281,497
Net (loss) income	(49,997)	670	(49,327)
Interest income	11,025		11,025
Interest expense	(11,439)		(11,439)
Income tax benefit	34,394		34,394
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	1,287	6,178	7,465
Total assets	856,950	17,584	874,534

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Table of Contents**UNITED THERAPEUTICS CORPORATION****Notes to Consolidated Financial Statements (Continued)****19. Segment Information (Continued)**

The preceding segment disclosures agree to consolidated totals when combined. There were no inter-segment transactions during any of the years presented.

Pharmaceutical segment revenues by product are as follows (in thousands):

Year Ended December 31,	2010	2009	2008
Remodulin	\$ 403,598	\$ 331,579	\$ 269,718
Tyvaso	151,797	20,268	
Adcirca	36,307	5,789	
Total	\$ 591,702	\$ 357,636	\$ 269,718

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 (in thousands):

Year Ended December 31,	2010	2009	2008
United States	\$ 546,745	\$ 328,939	\$ 249,209
Rest-of-World(1)	57,086	40,909	32,288
Total	\$ 603,831	\$ 369,848	\$ 281,497

(1) Sales primarily to countries located in Europe.

For the years ended December 31, 2010, 2009 and 2008, sales to one customer within our pharmaceutical segment comprised 64%, 68% and 62%, respectively, of total consolidated net revenues.

Long-lived assets (principally property, plant and equipment) located by geographic area are as follows (in thousands):

Year Ended December 31,	2010	2009	2008
United States	\$ 284,591	\$ 281,330	\$ 209,578
Rest-of-World(1)	21,453	22,529	13,139
Total	\$ 306,044	\$ 303,859	\$ 222,717

(1) Long-lived assets consisted of facilities acquired that are primarily located in the United Kingdom.

**20. Subsequent Event**

On February 7, 2011, we entered into an agreement and plan of merger pursuant to which we will sell our wholly owned telemedicine subsidiary, Medicomp, Inc. (Medicomp), to a group of private investors including Medicomp's current president. As Medicomp does not represent a core component of our business, its sale will allow us to devote more resources to our principal operations. Upon closing of the merger, we will sell 100 percent of the outstanding stock of Medicomp in exchange for aggregate consideration of \$14.9 million, consisting of

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approximately \$3.0 million in cash and/or shares of United Therapeutics common stock held by the investors, and an \$11.9 million, ten-year promissory note to be issued by Medicomp at closing. The promissory note will bear interest at 5.0 percent per annum. Closing of the sale is subject to customary closing conditions and regulatory approvals.

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## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

**20. Subsequent Event (Continued)**

Assuming timely receipt of regulatory approvals, we expect closing to occur in March or April 2011. Upon closing of the sale, we will acquire a 19.9 percent ownership interest in Medicomp in exchange for \$1.0 million in cash and a reduction in the face value of the promissory note by approximately \$2.0 million.

Additionally, we obtained royalty-free license rights to use Medicomp's proprietary detection technology to develop and commercialize a smart-phone based arrhythmia detection application for patients in the individual consumer market.

Due to the regulatory conditions to closing that are not within our control, the pending sale of Medicomp did not meet all of the criteria for held-for-sale classification as of December 31, 2010. In addition, we have not presented the results of Medicomp as a discontinued operation on our consolidated statements of operations because we continue to hold an investment in another telemedicine-related company (a 4% investment with a book value of \$4.9 million) and because of our plan to develop and commercialize a smart-phone based arrhythmia detection application using Medicomp's detection technology. As such, we expect to generate continuing cash flows from this component of our business subsequent to the disposition of Medicomp.

Major classes of assets and liabilities of Medicomp subject to this sale are presented below (in thousands):

	<b>December 31, 2010</b>	
<b>Assets</b>		
Cash	\$	1,329
Accounts receivable and inventory		1,692
Deferred tax assets		8,882
Other assets		4,308
Total assets	\$	16,211
Other current liabilities	\$	1,341

Based on the pending disposition of Medicomp, we evaluated the related goodwill for impairment as of December 31, 2010. We concluded that the selling price for Medicomp was reasonable relative to the selling prices of comparable entities within the telemedicine industry. Therefore, we used the selling price as an initial indicator that goodwill may be impaired. We then determined the fair value of Medicomp by adjusting the selling price based on the estimated fair value of the long-term promissory note. The fair value of the promissory note was determined using a discounted cash flow (DCF) model. Significant inputs used in the DCF model included the expected timing and amounts of cash flows and a discount factor representative of companies with a size and credit risk profile similar to Medicomp. The fair value of Medicomp and the implied fair value of goodwill were lower than their respective carrying values at December 31, 2010. As a result, we recognized an impairment charge of \$6.2 million to write-off the carrying value of Medicomp's goodwill. The impairment charge has been included in selling, general and administrative expenses for the year ended December 31, 2010. See also *Note 2 Summary of Significant Accounting Policies-Goodwill and Other Intangible Assets*.

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## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

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

The following presents summarized quarterly financial information for each of the years ended December 31, 2010 and 2009 (in thousands, except per share amounts):

	Quarter Ended			
	December 31, 2010	September 30, 2010	June 30, 2010	March 31, 2010
Net sales	\$ 166,477	\$ 170,983	\$ 137,491	\$ 128,880
Gross profit	146,010	148,922	120,525	113,712
Net income	9,544	39,736	37,707	18,929
Net income per share basic	\$ 0.17	\$ 0.70	\$ 0.67	\$ 0.35
Net income per share diluted	\$ 0.15	\$ 0.66	\$ 0.62	\$ 0.32

	Quarter Ended			
	December 31, 2009	September 30, 2009	June 30, 2009	March 31, 2009
Net sales	\$ 108,923	\$ 97,215	\$ 83,980	\$ 79,730
Gross profit	95,146	84,179	73,573	70,402
Net (loss) income	(3,330)	11,937	(2,344)	13,197
Net (loss) income per share basic	\$ (0.06)	\$ 0.22	\$ (0.04)	\$ 0.25
Net (loss) income per share diluted	\$ (0.06)	\$ 0.21	\$ (0.04)	\$ 0.24

**22. Legal Proceedings**

As previously disclosed in each of our Quarterly Reports on Form 10-Q beginning with the quarter ended September 30, 2009, as well as in our Annual Report on Form 10-K for the year ended December 31, 2009, purported shareholders filed derivative lawsuits against certain of our directors and named executive officers and us as a nominal defendant. On October 25, 2010, the parties entered into a stipulation to settle these derivative lawsuits. On January 21, 2011, the Court entered an order approving the stipulation and settlement, and the period for appealing that order expired on February 22, 2011. Although the order required the payment of certain fees and expenses to the attorneys for the plaintiffs, that amount has been paid in full by our insurance carrier at no expense to us. The derivative lawsuits are, therefore, resolved and have had no material impact on our statements of financial position or operations.

From time to time, we may be involved in other lawsuits and proceedings incidental to the conduct of our business. We are not a party to any lawsuit or proceeding that, in the opinion of our management, is likely to have a material adverse effect on our financial position or results of operations.

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**United Therapeutics Corporation**  
**Schedule II Valuation and Qualifying Accounts**  
**Years Ended December 31, 2010, 2009, and 2008**  
**(In thousands)**

**Valuation Allowance on Deferred Tax Assets**

	<b>Balance at Beginning of Year</b>	<b>Additions Charged to Expense</b>	<b>Deductions</b>	<b>Balance at End of Year</b>
Year ended December 31, 2010	\$ 6,186	\$	\$ (165)	\$ 6,021
Year ended December 31, 2009	\$ 11,822	\$ 100	\$ (5,736)	\$ 6,186
Year ended December 31, 2008	\$ 7,548	\$ 6,414	\$ (2,140)	\$ 11,822

**Reserve for Inventory Obsolescence**

	<b>Balance at Beginning of Year</b>	<b>Additions Charged to Expense</b>	<b>Deductions</b>	<b>Balance at End of Year</b>
Year ended December 31, 2010	\$ 1,271	\$ 1,676	\$ (85)	\$ 2,862
Year ended December 31, 2009	\$ 411	\$ 1,222	\$ (362)	\$ 1,271
Year ended December 31, 2008	\$ 508	\$ 183	\$ (280)	\$ 411

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**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, 2010. 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, 2010.

*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, 2010, 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, 2010, 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, 2010 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

**ITEM 9B. OTHER INFORMATION**

None.



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**PART III**

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

Information required by Item 10 regarding nominees and directors appearing under Proposal No. 1: *Election of Directors* in our definitive proxy statement for our 2011 annual meeting of shareholders scheduled for June 29, 2011 (the 2011 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 *Committees of our Board of Directors Audit Committee* in our 2011 Proxy Statement is hereby incorporated herein by this reference.

Information appearing under the heading *Section 16(a) Beneficial Ownership Reporting Compliance* in our 2011 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 the Investor Relations Department. If any amendment to, or a waiver from, a provision of the Code of Conduct and Ethics that applies to the principal executive officer, principal financial officer and principal accounting officer is made, such information will be posted on 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 headings *Corporate Governance, Board of Directors, Committees Non-Employee Director Compensation Compensation Discussion and Analysis, Summary Compensation Table and Grants of Plan-Based Awards Table, and Narratives to Summary Compensation Table and Grants of Plan-Based Awards Table* in our 2011 Proxy Statement and is hereby incorporated herein by this reference.

Information concerning the Compensation Committee required by Item 11 appears under the heading *Compensation Committee Report* in our 2011 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 *Beneficial Ownership of Common Stock* in our 2011 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, 2010, 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</b> (a)	<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))</b> (c)
Equity compensation plan approved by security holders	5,964,987	\$ 36.26	10,954,737
Equity compensation plans not approved by security holders	174,043	8.24	N/A
<b>Total</b>	<b>6,139,030</b>	<b>\$ 35.47</b>	<b>10,954,737</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 is contained in Note 11 *Shareholders' Equity* to the consolidated financial statements included 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 a standard agreement generally consistent with the form contained in Exhibit 10.10 to this Annual Report on Form 10-K.

**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 *Corporate Governance, Board of Directors, Committees Certain Relationships and Related Party Transactions, Corporate Governance, Board of Directors, Committees Related Party Transaction Policy, Corporate Governance, Board of Directors, Committees Director Independence and Committees of our Board of Directors* in our 2011 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 *Report of the Audit Committee and Information on our Independent Auditors* in our 2011 Proxy Statement and is hereby incorporated herein by this reference.

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**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 are listed on the Exhibit Index, which is incorporated by reference herein.

**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 shareholders upon written request to United Therapeutics and payment of a reasonable fee (covering the expense of furnishing copies). Shareholders may request exhibit copies by contacting: United Therapeutics Corporation, Attn: Investor Relations, 1040 Spring Street, Silver Spring, Maryland 20910.**



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<b>Signatures</b>	<b>Title</b>	<b>Date</b>
<u>/s/ CHRISTOPHER PATUSKY</u> Christopher Patusky	Director	February 24, 2011
<u>/s/ LOUIS W. SULLIVAN</u> Louis W. Sullivan	Director	February 24, 2011
<u>/s/ TOMMY G. THOMPSON</u> Tommy Thompson	Director	February 24, 2011

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#### EXHIBIT INDEX

<b>Exhibit No.</b>	<b>Description</b>
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	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K, filed on June 28, 2010.
3.3	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.
3.4	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, 3.2 and 3.3.
4.2	First Amended and Restated Rights Agreement, incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K filed on July 3, 2008.
4.3	Indenture, dated October 30, 2006, between the 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.
4.4	Resale Registration Rights Agreement, dated October 30, 2006, between the Registrant and Deutsche Bank Securities Inc., as the initial purchaser, incorporated by reference to Exhibit 4.2 of the Registrant's Current Report on Form 8-K filed October 30, 2006.
10.1**	United Therapeutics Corporation Amended and Restated Equity Incentive Plan, as amended effective as of September 24, 2004, incorporated by reference to Exhibit 10.1 of the Registrant's Form 10-Q for the quarter ended September 30, 2004.
10.2**	Amended and Restated Executive Employment Agreement dated as of January 1, 2009, between the Registrant and Martine A. Rothblatt, incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2009.
10.3**	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 quarter ended March 31, 2002.
10.4*	Exclusive License Agreement dated as of December 3, 1996, between the Registrant Pharmacia & Upjohn Company, incorporated by reference to Exhibit 10.8 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
10.5*	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).
10.6**	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 quarter ended March 31, 2002.
10.7	Form of Indemnification Agreement between the Registrant and each of its Directors and Executive Officers, incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2009.
10.8	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 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.

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<b>Exhibit No.</b>	<b>Description</b>
10.9	Technical Services Agreement dated August 27, 2002 between the Registrant and Kurzweil Technologies, Inc., incorporated by reference to Exhibit 10.26 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.
10.10**	Standard Non-plan Option Award Agreement used by the Registrant, incorporated by reference to Exhibit 10.39 of the Registrant's Form 10-K for the fiscal year ended December 31, 2002.
10.11**	Amendment to Employment Agreement dated December 11, 2002 between the Registrant and Roger Jeffs, incorporated by reference to Exhibit 10.40 of the Registrant's Form 10-K for the fiscal year ended December 31, 2002.
10.12**	Amendment to Employment Agreement dated December 11, 2002 between the Registrant and Paul Mahon, incorporated by reference to Exhibit 10.43 of the Registrant's Form 10-K for the fiscal year ended December 31, 2002.
10.13**	Amendment to Employment Agreement between Roger Jeffs, Ph.D. and the Registrant 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.
10.14**	Amendment to Employment Agreement between Paul A. Mahon and the Registrant 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.
10.15**	Form of terms and conditions for awards granted to Employees by the Registrant under the Amended and Restated Equity Incentive Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K filed on December 17, 2004.
10.16**	Form of terms and conditions for awards granted to Non-Employees by the Registrant under the Amended and Restated Equity Incentive Plan, incorporated by reference to Exhibit 10.2 of the Registrant's Form 8-K filed on December 17, 2004.
10.17**	United Therapeutics Corporation Supplemental Executive Retirement Plan, effective as of July 1, 2006, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on May 4, 2006.
10.18**	Employment Agreement, dated August 2, 2006, between John Ferrari and the Registrant, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on August 4, 2006.
10.19**	Amendment, dated July 31, 2006, to amended Employment Agreement, dated November 29, 2000, between Roger Jeffs, Ph.D. and the Registrant, incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on August 4, 2006.
10.20**	Amendment, dated July 31, 2006, to amended Employment Agreement, dated June 16, 2001, between Paul A. Mahon and the Registrant, incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed on August 4, 2006.
10.21	Confirmation, dated October 24, 2006, between Deutsche Bank AG London and the Registrant, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on October 30, 2006.
10.22	Confirmation, dated October 24, 2006, between Deutsche Bank AG London and the Registrant, incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on October 30, 2006.
10.23**	Amendment, dated December 28, 2006, to Employment Agreement, dated August 2, 2006, between John Ferrari and the Registrant, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on December 29, 2006.
10.24	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 the Registrant's Current Report on Form 8-K filed on December 28, 2007.

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<b>Exhibit No.</b>	<b>Description</b>
10.25**	United Therapeutics Corporation Share Tracking Awards Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008.
10.26**	First Amendment to the United Therapeutics Corporation Share Tracking Awards Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on September 18, 2009.
10.27**	Form of terms and conditions for awards granted to Non-Employees by the Registrant under the United Therapeutics Corporation Share Tracking Awards Plan, incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008.
10.28**	Form of terms and conditions for awards granted to Employees by the Registrant prior to January 1, 2010, under the United Therapeutics Corporation Share Tracking Awards Plan, incorporated by reference to Exhibit 10.3 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008.
10.29**	Form of Grant Letter used by Registrant under the United Therapeutics Corporation Share Tracking Awards Plan, incorporated by reference to Exhibit 10.4 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008.
10.30*	License Agreement, dated as of November 14, 2008, by and between Eli Lilly and Company and the Registrant, incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on December 24, 2008.
10.31*	Manufacturing and Supply Agreement, dated as of November 14, 2008, by and between Eli Lilly and Company, Lilly del Caribe, Inc. and the Registrant incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed on December 24, 2008.
10.32**	Form of Amendment to Employment Agreement between the Registrant and each of Roger Jeffs, Paul Mahon and John Ferrari, each dated as of January 1, 2009, incorporated by reference to Exhibit 10.3 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2009.
10.33**	Form of Amendment to Employment Agreement between the Registrant and each of Roger Jeffs, Paul Mahon and John Ferrari, each dated as of February 22, 2010, incorporated by reference to Exhibit 10.46 of the Registrant's Annual Report on Form 10-K for the year ended December 31, 2009.
10.34	Distribution Agreement dated August 17, 2009 between the Registrant and Accredo Health Group, Inc., incorporated by reference to Exhibit 10.47 of the Registrant's Annual Report on Form 10-K for the year ended December 31, 2009.
10.35**	Form of terms and conditions for awards granted to Employees by the Registrant on or after January 1, 2010, under the United Therapeutics Corporation Share Tracking Awards Plan, incorporated by reference to Exhibit 10.48 of the Registrant's Annual Report on Form 10-K for the year ended December 31, 2009.
10.36	Stipulation of Settlement, dated October 25, 2010, among the parties to a derivative lawsuit against the directors and officers of the Registrant identified therein, incorporated by reference to Exhibit 10.1 to the Registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2010.
10.37***	Credit Agreement, dated December 27, 2010, among the Registrant, the lenders party thereto from time to time, Wells Fargo Bank, National Association, as the Administrative Agent, and certain subsidiaries of the Registrant, as guarantors.
10.38***	Amended and Restated Distribution Agreement, dated as of February 21, 2011, between the Registrant and Accredo Therapeutics, Inc.
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



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<b>Exhibit No.</b>	<b>Description</b>
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.
101	The following financial information from our Annual Report on Form 10-K for the year ended December 31, 2010, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Stockholders' Equity, (iv) Consolidated Statements of Cash Flows, and (v) Notes to Consolidated Financial Statements (tagged as blocks of text)(1)

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(1) The XBRL related information in Exhibit 101 to this Annual Report on Form 10-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to liability of that section and shall not be incorporated by reference into any filing or other document pursuant to the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing or document.

\*

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 or Rule 246-2 of the Securities Act of 1934 as amended. The omitted portions of this document have been filed with the Securities and Exchange Commission.

\*\*

Designates management contracts and compensation plans.

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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.