UNITED THERAPEUTICS Corp
Form 10-K
February 28, 2012

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2011

OR

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

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

United Therapeutics Corporation

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**52-1984749**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
1040 Spring Street, Silver Spring, MD	**20910**
(Address of Principal Executive Offices)	(Zip Code)

(301) 608-9292
Registrant's Telephone Number, Including Area Code

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

Title of each class	**Name of each exchange on which registered**
Common Stock, par value $.01 per share and associated preferred stock purchase rights	NASDAQ Global Select Market

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

None
(Title of Class)

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

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

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

Indicate by check mark 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 ý No o

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

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

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

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

The aggregate market value of the Common Stock held by non-affiliates of the registrant, based on the closing price on June 30, 2011, as reported by the NASDAQ Global Select Market was approximately $2,783,978,000

The number of shares outstanding of the issuer's common stock, par value $0.01 per share, as of February 23, 2012, was 53,626,744.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for the registrant's 2012 annual meeting of shareholders scheduled to be held on June 26, 2012, 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 include:

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® (epoprostenol), the first FDA-approved prostacyclin therapy for PAH. In addition to the United States, Remodulin is approved in 36 other countries, most of which have approved both routes of administration. 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. In December 2011, we submitted a new drug application (NDA) to the FDA for treprostinil diethanolamine sustained release tablets (oral treprostinil) for the treatment of PAH. Our subsidiary, Lung LLC, 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 effect 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 (MAbs). MAbs 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.

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. In September 2011, we were awarded a contract from the U.S. National Institute of Allergy and Infectious Diseases for studies directed at the development of a broad spectrum antiviral drug based on our glycobiology antiviral platform.

Cell-Based Therapy. In June 2011, we entered into a license agreement with Pluristem Ltd. (Pluristem) to develop and commercialize its cell-based product known as PLacental eXpanded (PLX) cells for the treatment of pulmonary hypertension using Pluristem's proprietary cell technology. We are currently conducting preclinical toxicology and pharmacology studies to support a potential investigational new drug application for the treatment of PAH.

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

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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.

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:

Product	Mode of Delivery	Indication/Market	Current Status	Our Territory
Remodulin	Continuous subcutaneous	Pulmonary arterial hypertension	Approved in the U.S., most of Europe*, Argentina, Australia, Canada, Chile, Israel, Mexico, Peru, Saudi Arabia, South Korea, Taiwan and Venezuela; commercial sales in most of these countries	Worldwide
Remodulin	Continuous intravenous	Pulmonary arterial hypertension	Commercial in the U.S., Canada, Israel, Switzerland, Argentina and Saudi Arabia; also approved in most of Europe*, Mexico, Peru and South Korea	Worldwide
Tyvaso	Inhaled	Pulmonary arterial hypertension	Commercial in the U.S.; Phase III in Europe	Worldwide
Adcirca	Oral	Pulmonary arterial hypertension	Commercial in the U.S.	United States
Oral Treprostinil (UT-15C)	Oral	Pulmonary arterial hypertension	NDA filed with FDA	Worldwide
Oral Treprostinil (UT-15C) Combination Therapy	Oral	Pulmonary arterial hypertension	Phase III	Worldwide
Ch14.18 MAb	Intravenous	Neuroblastoma	Phase III	Worldwide
Remodulin	Continuous intravenous via implantable pump	Pulmonary arterial hypertension	Phase III	United States, United Kingdom, France, Germany, Italy and Japan
Beraprost-MR	Oral	Pulmonary arterial hypertension	Phase I	North America, Europe, Mexico, South America, Egypt, India, South Africa and Australia
8H9 MAb	Intravenous	Metastatic brain cancer	Phase I	Worldwide
IW001	Oral	Idiopathic pulmonary fibrosis and primary graft dysfunction	Phase I	Worldwide

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Product	Mode of Delivery	Indication/Market	Current Status	Our Territory
Glycobiology Antiviral Agents	Oral	Broad-spectrum agents against viral infectious diseases	Pre-Clinical	Worldwide
PLX Cells	Intravenous	Pulmonary hypertension	Pre-Clinical	Worldwide
Pulmonary Tissue Replacement and Remodeling	Various	End-stage lung disease	Pre-Clinical	Worldwide

* We have obtained approval for subcutaneous Remodulin in 23 member countries of the European Economic Area (EEA), as well as other non-EEA countries in Europe, and have received pricing approval in most of these countries. We have obtained approval for intravenous Remodulin in 23 EEA countries and Switzerland, and will submit pricing applications in select countries based on market factors.

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 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 (ETRAs).

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

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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, the active pharmaceutical 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. We recognized approximately $430.1 million, $403.6 million and $331.6 million in Remodulin revenues, representing 58%, 68% and 92% of our net revenues, for the years ended December 31, 2011, 2010 and 2009, 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 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. Remodulin is the only prostacyclin analogue approved for patients with NYHA class II-IV symptoms.

Outside of the United States, Remodulin is approved for treatment of PAH in 36 countries by continuous subcutaneous administration. Remodulin is also approved for treatment of PAH by continuous intravenous administration in 31 countries outside the U.S., including 23 countries in Europe that granted approval in December 2011. 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 China (application filed in September 2011) and Japan (filing anticipated in late 2012 or early 2013).

We believe Remodulin offers many competitive advantages over Flolan, which is delivered continuously through a surgically implanted intravenous catheter connected to an external pump and is not approved for subcutaneous use. 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 produce 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 Remodulin 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 (the active ingredient in Flolan) for the treatment of PAH, which has all of the attributes of Flolan discussed above. In June 2008, the FDA approved another intravenous version of epoprostenol, developed by GeneraMedix, Inc. (GeneraMedix), which is stable at room

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temperature but shares most of Flolan's other 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, daily pump refills and large pump size. In February 2009, GeneraMedix licensed the commercial rights for its epoprostenol therapy to Actelion Pharmaceuticals Ltd (Actelion), marketed as Veletri®. Actelion also markets Tracleer®, an ETRA, and Ventavis®, an inhaled prostacyclin, for the treatment of PAH.

In February 3, 2012, we received notice of an abbreviated new drug application by Sandoz Inc. requesting FDA approval to market a generic version of the 10 mg/mL strength of Remodulin. For further details, see the section below entitled *Governmental Regulation Hatch-Waxman Act*.

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 central venous catheter infection and a serious bloodstream infection known as sepsis, as do Flolan, Veletri and generic epoprostenol.

International Regulatory Review of Subcutaneous and Intravenous Remodulin

Remodulin is approved in 36 countries throughout the world. In 31 of these countries, it is approved for both subcutaneous and intravenous use. In the other approved countries, Remodulin is approved for subcutaneous use only.

We used the mutual recognition process, described more fully in *Governmental Regulation Marketing Pharmaceutical Products Outside the United States*, to obtain approval of subcutaneous Remodulin in most countries in the European Economic Area (EEA). The mutual recognition process for subcutaneous Remodulin was completed in August 2005, with positive decisions received from 23 EEA 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. A license variation for intravenous Remodulin was approved on December 23, 2011, thus permitting marketing of intravenous Remodulin in each of the 23 member countries where subcutaneous Remodulin had been previously approved. In Europe, a risk management plan (RMP) is routinely required as part of the regulatory approval process for new medicines and also for significant variations involving a change to the route of administration, formulation or indication. For intravenous Remodulin, we will implement a RMP focused on minimizing the known risks of central venous catheter-related blood stream infections associated with intravenous administration.

Remodulin is available under the named-patient system in the EEA member countries where Remodulin is not approved (including the UK, Ireland and Spain). Under the named-patient system, our distributors are permitted to import Remodulin into EEA member countries based on requests for Remodulin for use in treating specific patients, but neither we nor our distributors are permitted to market the product in those countries. We are evaluating the resubmission of our applications for Remodulin in Ireland and Spain.

Intravenous Remodulin Administered via Implantable Pump

We are also working with Medtronic, Inc. (Medtronic) on demonstrating the safety of its Synchromed® II implantable infusion pump for intravenous Remodulin. Medtronic commenced a clinical trial administering Remodulin using the Synchromed in April 2011. In certain countries in Europe, an implantable pump distributed by OMT GmbH & Co. KG is used to deliver intravenous Remodulin to certain patients.

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Tyvaso

We commenced commercial sales of Tyvaso in the United States in September 2009. We sell Tyvaso to the same specialty pharmaceutical distributors in the United States that distribute Remodulin. For the years ended December 31, 2011, 2010 and 2009, we recognized approximately $240.4 million, $151.8 million and $20.3 million in Tyvaso revenues, representing 32%, 26% and 6%, respectively, of our net revenues.

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 (body-wide) 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 required to be administered using our proprietary Tyvaso Inhalation System, which consists of 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 ampule emptied into the Tyvaso Inhalation System 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 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 an NDA to obtain FDA approval to market Tyvaso for the treatment of PAH in the United States. In July 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 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 are enrolling patients 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, 2014.

Under the PMCs, we committed 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. The modifications and usability

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analysis have been completed, and in September 2011, the FDA notified us that we had fulfilled the requirements of the PMCs.

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 through July 2016, during which the FDA may not approve any application to market the same drug for the same indication, except in limited circumstances.

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 drug 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 European Union (EU). 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 (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.

In mid-2011, we reached an agreement with the EMA on a new study design acceptable for the filing of an MAA in Europe. We expect the new trial will be conducted in patients who are either not on an approved background therapy (ETRA or PDE-5 inhibitor) or have been on an approved background therapy for up to one year. The trial's planned primary endpoint is the median change in six-minute walk distance after 24 weeks. The principal reinforcing secondary endpoint will be time to clinical worsening, generally defined as (1) death; (2) an unplanned hospitalization due to PAH; (3) initiation of prostacyclin for the treatment of PAH; (4) a lung transplant; (5) an atrial septostomy procedure, a surgical procedure in which a small hole is created between the upper two chambers of the heart; or (6) a decrease in six-minute walk distance of at least fifteen percent from baseline (or too ill to walk) as a result of the progression of PAH. In order to statistically assess the secondary endpoint of time to clinical worsening, the study will continue to enroll until a pre-specified number of events occur. We plan to begin enrollment during the second half of 2012 and anticipate target enrollment of approximately 800 subjects to obtain data on approximately 256 clinical worsening events.

Adcirca

We began selling 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 prices established by Lilly, which are at parity with Cialis pricing and typically set at a discount from an average wholesale price to pharmaceutical wholesalers. For the years ended December 31, 2011, 2010 and 2009, we recognized approximately $70.6 million, $36.3 million and $5.8 million in Adcirca revenues, representing 9%, 6% and 2%, respectively, of our net revenues.

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

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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. Adcirca is dosed 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 6.3 million 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.

UT-15C Sustained Release Tablets (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 was a 12-week study of patients who are not on any background therapy.

We commenced both trials using a 1.0 mg tablet, but during the open-label extension trial (and an associated pharmacokinetic substudy) we discovered that treprostinil concentrations were higher in PAH

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patients than in healthy individuals due to the difference in overall absorption, metabolism and excretion of the drug between these two populations. Consistent with these differences, a number of patients randomized to receive the drug discontinued the study 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 suggested 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 who completed the trial were unable to titrate their doses above 1.0 mg twice-daily.

In June 2009, we began enrollment of our FREEDOM-C^2 trial, which was a 16-week study of PAH patients on an approved background therapy. In this trial, patients were provided access to a 0.25 mg tablet and doses were titrated in 0.25 mg to 0.5 mg increments. In March 2011, we completed enrollment of FREEDOM-C^2 with 313 patients, compared to a target enrollment of 300 patients. In August 2011, we announced the completion of FREEDOM-C^2 and that the trial did not achieve statistical significance for the primary endpoint of improvement in six-minute walk distance at week 16. Specifically, the placebo-corrected median change in six-minute walk distance at week 16 was 10 meters (p=0.089, Hodges-Lehmann estimate and non-parametric analysis of covariance in accordance with the trial's pre-specified statistical plan).

Enrollment in FREEDOM-M was initially closed in October 2008, with 171 patients enrolled in the trial. In March 2009, the FDA approved a protocol amendment to add patients to the ongoing FREEDOM-M trial. These additional patients were provided access to a 0.25 mg tablet when beginning the trial. We completed enrollment of FREEDOM-M in January 2011 with 349 patients, with the population for the primary analysis consisting of the 228 patients who had access to the 0.25 mg tablet at randomization. In June 2011, we announced the completion of the FREEDOM-M trial and that the trial met its primary endpoint of improvement in six-minute walk distance at week 12. Analysis of the FREEDOM-M results demonstrated that patients in that study receiving oral treprostinil improved their median six-minute walk distance by approximately 23 meters (p=0.0125, Hodges-Lehmann estimate and non-parametric analysis of covariance in accordance with the trial's pre-specified statistical analysis plan) as compared to patients receiving placebo. The median change from baseline at week 12 was 25 meters for patients receiving oral treprostinil and -5 meters for patients receiving placebo. This clinical treatment effect is supported by other secondary efficacy endpoints including the change in six-minute walk distance observed at week 8 (Hodges-Lehmann estimate of +17 meters; p = 0.0307) and combined six-minute walk distance and Borg Dyspnea Score rating (shortness of breath test) at week 12 (p=0.0497). These findings were further supported by the highly statistically significant results obtained from the overall population (349 patients, including those who did not have access to the 0.25 mg tablet at the beginning of the trial), which had a placebo-corrected median change from baseline in six-minute walk distance of +25.5 meters at week 12 (p=0.0001, Hodges-Lehmann estimate).

The durability of the clinical response was also assessed by evaluating exercise capacity at the time that treprostinil plasma concentration was expected to be the lowest, commonly referred to as trough, (11-13 hours after the previous evening's dose of oral treprostinil) measured during the week 11 visit. The results from this trough six-minute walk test demonstrated the durability of the clinical response throughout the entire dosing interval with a 13 meter (p=0.065, Hodges-Lehmann estimate) and 17 meter (p=0.0025, Hodges-Lehmann estimate) improvement in six-minute walk distance for the primary analysis population and overall patient population, respectively.

Based on the positive results achieved in this trial, we submitted an NDA on December 27, 2011. The NDA also contained the results of the FREEDOM-C and FREEDOM-C^2 studies, which did not

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demonstrate efficacy of oral treprostinil in combination with other therapies. The FDA has accepted the NDA for review and has indicated the filing will be subjected to the standard 10-month review period commencing from the submission date. We have also applied to the FDA for orphan drug designation for oral treprostinil. We currently have no plans to apply for the approval of oral treprostinil in Europe.

Although we believe oral treprostinil is approvable on the basis of the FREEDOM-M study, there can be no guarantee that our NDA will be approved, particularly in light of the FREEDOM-C and FREEDOM-C^2 studies. Furthermore, if our NDA is approved, the results of the FREEDOM-C and FREEDOM-C^2 studies may nonetheless limit our ability to market oral treprostinil in combination with other therapies, and reduce its commercial potential. Therefore, in an effort to provide clinical support for the efficacy of oral treprostinil in combination with other PAH therapies and to expand the labeling for oral treprostinil if it is approved, we are designing additional studies. In particular, we are finalizing the protocol of a new phase III clinical trial, FREEDOM-C^3. FREEDOM-C^3 is anticipated to be a placebo-controlled study in newly diagnosed patients who have recently initiated an approved background therapy (an ETRA or PDE-5 inhibitor), with one co-primary endpoint being the time to clinical worsening, generally defined as (1) death; (2) an unplanned hospitalization due to PAH; (3) initiation of prostacyclin for the treatment of PAH; (4) a decrease in six-minute walk distance of at least fifteen percent from baseline (or too ill to walk) as a result of the progression of PAH; or (5) unsatisfactory long-term clinical response. The other planned co-primary endpoint is median change in six-minute walk distance at six months, which provides a substantially longer exposure and potentially higher dose than patients received in the FREEDOM-C and FREEDOM-C^2 trials. We plan to begin enrollment of FREEDOM-C^3 during the first half of 2012 and anticipate target enrollment of approximately 800 subjects to obtain data on approximately 400 clinical worsening events. Because we believe that patients in both the FREEDOM-C and FREEDOM-C^2 trials were not provided sufficient amounts of oral treprostinil over an adequate period of time, FREEDOM-C^3 is intended to study the effects of oral treprostinil over a longer period of time than our previous studies and hopefully will enable patients to achieve a higher dose.

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

The DISTOL-1 study, "Digital Ischemic Lesions in Scleroderma Treated With Oral Treprostinil Diethanolamine" was a 20-week phase II study to assess the effect of oral treprostinil in reducing net ulcer burden compared to placebo in patients with systemic sclerosis. The study also included secondary assessments of the frequency of complete healing of the main ulcer, time to healing, formation of new ulcers, and patient and physician functional and quality of life scores. Preliminary analysis of the study results indicates that the use of oral treprostinil did not significantly reduce net ulcer burden. Based on these results, we have no further plans to develop oral treprostinil to reduce ulcer burden in patients with systemic sclerosis.

Beraprost-MR

We have the exclusive right to develop and market a modified-release formulation of beraprost (beraprost-MR) in the United States, Canada, Mexico, South America, Europe, Egypt, India, South Africa and Australia for the treatment of cardiovascular indications, pursuant to our license agreement with Toray Industries, Inc. (Toray), which is described below under *Strategic Licenses and Relationships Toray Amended License Agreement*.

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

In November 2011, we announced that a phase II trial of beraprost-MR failed to meet its primary and secondary endpoints. We and Toray continue to assess the results of the phase II trial, and are in the process of designing new trials and dosing regimens for beraprost-MR.

Idiopathic Pulmonary Fibrosis and Primary Graft Dysfunction Collagen Type V

In February 2010, Lung LLC 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 Dysfunction, 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 agreement, Lung LLC 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.

Cell-Based Therapy

In June 2011, we entered into a license agreement with Pluristem Ltd. (Pluristem) to develop and commercialize a cell-based product for the treatment of pulmonary hypertension using Pluristem's proprietary cell technology. The license agreement became effective in August 2011, at which time we made a one-time, non-refundable payment of $7.0 million to Pluristem, $5.0 million of which consisted of a license fee that was charged to research and development expenses during the quarter ended September 30, 2011. We are currently conducting preclinical toxicology and pharmacology studies to support a potential investigational new drug application for the treatment of PAH.

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 forms of cancers. 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. 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.

Results from NCI's phase III study were published in September 2010. The results described that immunotherapy with Ch14.18 significantly improved patient outcome compared with standard therapy in patients with high risk neuroblastoma. Specifically, the two-year estimate for event-free survival was 66%±5% in the Ch14.18 immunotherapy group and 46%±5% in the standard therapy group (p=0.01 without adjustment for interim analyses). The Ch14.18 immunotherapy group was also significantly better than the standard therapy group in the estimated rate of overall survival (86%±4% vs.

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75%±5% at two years, p=0.02 without adjustment for interim analyses). This study was coordinated by the Children's Oncology Group, a national consortium of researchers supported by the NCI.

Under the terms of the CRADA, NCI is conducting a clinical trial in approximately 100 patients to define more clearly the safety and toxicity profile of Ch14.18 immunotherapy in children, and we are developing 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 phase III clinical trial described above and all other necessary studies supported by NCI, will be used as the basis for a biologics license application we plan to file seeking FDA approval of Ch14.18 immunotherapy for the treatment of neuroblastoma. We have received orphan drug designation for Ch14.18 from the FDA and EMA.

8H9 Antibody

Pursuant to a December 2007 agreement with Memorial Sloan-Kettering Cancer Center, we obtained certain license rights to an investigational monoclonal antibody, 8H9, for the treatment of metastatic brain cancer. 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

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 that we may elect to test.

On September 30, 2011, we were awarded a contract with an aggregate value of up to $45.0 million under a Broad Agency Announcement from the U.S. National Institute of Allergy and Infectious Diseases for studies directed at the development of a broad spectrum antiviral drug based on our glycobiology antiviral platform. Under the contract's base period of 42 months we will receive $10.6 million in funding, and there are eight milestone-based options to expand the project and funding under the contract, up to an aggregate of $45.0 million.

Pulmonary Tissue Replacement and Remodeling

In July 2011, we acquired 100 percent of the outstanding stock of Revivicor, Inc. (Revivicor), a company focused on developing genetic biotechnology platforms to provide alternative tissue sources for treatment of human degenerative disease through tissue and organ transplantation. We acquired Revivicor to pursue early stage development of products for the treatment of end-stage lung disease. We are also engaged in preclinical development of regenerative medicine technologies for pulmonary tissue remodeling in end-stage lung disease. The acquisition date fair value of the consideration paid for Revivicor consisted of $4.2 million in cash and $3.4 million in contingent consideration. Pursuant to the terms of the acquisition, contingent consideration consists of up to $25.0 million upon the achievement of specific developmental and regulatory milestones. For further details, see *Note 17 Acquisitions* to our consolidated financial statements included in this Annual Report on Form 10-K.

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

Until March 2011, we provided telemedicine monitoring services to detect cardiac arrhythmias and ischemic heart disease through our wholly-owned subsidiary Medicomp, Inc. (Medicomp). In February 2011, we entered into an agreement and plan of merger to sell Medicomp to a group of private investors. As Medicomp did not represent a core component of our business, its sale allowed us to devote more resources to our principal operations. In March 2011, we closed the transaction and received aggregate consideration of $14.9 million, consisting of shares of our common stock held by the investors, with an aggregate value of $2.8 million, and a $12.1 million ten-year promissory note issued by Medicomp. Immediately after closing the sale, we purchased a 19.9 percent ownership interest in Medicomp in exchange for $1.0 million in cash and an approximately $2.0 million reduction in the face value of the promissory note.

Due to our agreement to sell Medicomp, we recognized an impairment charge of $6.2 million, representing the write-off of the carrying value of Medicomp's goodwill, in fourth quarter of 2010. We recognized a gain of $860,000 in 2011 on the sale of Medicomp. In addition, during the second quarter of 2011, we met all the criteria for reporting Medicomp as a discontinued operation. As a result, we have included the operating results of Medicomp, including the gain recognized on its disposal, within discontinued operations on our consolidated statements of operations for the years ended December 31, 2011, 2010 and 2009. For further details, see *Note 18 Sale of Medicomp, Inc.* to our consolidated financial statements included in this Annual Report on Form 10-K.

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 116 employees as of December 31, 2011. We have divided our domestic sales force into two teams. One team sells Remodulin and Tyvaso, while the other team sells Adcirca. The efforts 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 Accredo Health Group, Inc. (Accredo), CuraScript, Inc. (CuraScript) 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

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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 treprostinil 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 transfer price that we establish. 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 and Tyvaso 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 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. Lilly retains authority under the license agreement for all regulatory activities with respect to Adcirca, as well as retail pricing, which is expected to be at price parity with Cialis. Lilly has generally increased the price of Adcirca twice a year.

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. Lee's Pharma submitted an application for approval of intravenous and subcutaneous Remodulin in China in September 2011. Mochida is conducting an open-label phase III study to support a new drug application for subcutaneous and intravenous Remodulin in

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Japan, which we anticipate will be filed during late 2012 or early 2013. In addition, Grupo Ferrer Internacional, S.A. (Grupo Ferrer) has been actively working toward commencing commercial sales of subcutaneous Remodulin in Taiwan and recently launched subcutaneous and intravenous Remodulin in South Korea. In some countries, such as Japan, in order to commercialize Remodulin we are required to conduct new clinical trials, called bridging studies, to demonstrate the efficacy and safety of Remodulin in their local patient population prior to approval. Therefore it could take several years before we can commence commercial sales in new 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. Lilly retains authority for all regulatory activities with respect to Adcirca, as well as retail pricing, which is expected to be at price parity with Cialis. 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.

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, pursuant to which Lilly may raise the manufacturing cost of Adcirca.

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Stock Purchase Agreement

Under the terms of the stock purchase agreement, in December 2008, we issued 6.3 million 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. 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 our common stock held. According to the Schedule 13G/A filed by Lilly on February 16, 2012, Lilly currently beneficially owns approximately 3.2 million shares of our common stock.

Toray Amended License Agreement

In June 2000, we licensed from Toray the exclusive right to develop and market beraprost-SR, a chemically stable oral prostacyclin analogue in a sustained release formulation, for the treatment of cardiovascular indications. In March 2007, Lung LLC 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 granted us additional exclusive rights to commercialize beraprost-MR in Europe and broadened the indication to vascular disease (excluding renal disease), among other revisions. In September 2010, we entered into a supplement to our license agreement under which we agreed on the timing of two of the milestone payments under our existing agreement. In July 2011, we amended and replaced our existing March 2007 license agreement regarding beraprost-MR. The terms of the July 2011 license agreement did not materially change from the previous license agreement and license agreement supplements except for a reduction in royalty rates. Our exclusive rights to develop beraprost-MR extend to North America, Europe, Mexico, South America, Egypt, India, South Africa and Australia.

Significant Agreement Terms

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 June 2000 agreement to receive an option grant to purchase 1,000,000 shares of our common stock. 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.

The original agreement specified that we make certain milestone payments to Toray during the development period and upon U.S. or EU regulatory approval. In 2010, we agreed on timing of the last two developmental milestone payments, in the amounts of $4.0 million and $5.0 million. In the fourth quarter of 2010, all conditions relating to these milestone payments were satisfied; 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 was paid to Toray in July 2011. These milestone payments were expensed as research and development when incurred since beraprost-MR has not demonstrated commercial feasibility.

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In 2011, we agreed to a reduction in the royalty rates based on sales of beraprost-MR. In exchange for the reduction in royalty rates, we agreed to pay Toray $50.0 million in equal, non-refundable payments over the five-year period ending in 2015. Since these payments are non-refundable and have no contingencies attached to them, we recognized a liability of $46.3 million, which represented the present value of the related payments discounted by our estimated current cost of debt. With the establishment of the liability, we recognized a corresponding charge to research and development expenses during the quarter ended September 30, 2011. Toray has the right to terminate the license agreement in the event of a change of control of our company under certain circumstances.

NEBU-TEC Agreement of Sale and Transfer

In December 2008, we entered into an agreement with NEBU-TEC International Med Products Eike Kern GmbH (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 €2.0 million). The transaction closed in September 2009 after we received FDA approval for Tyvaso. Under the terms of our agreement, we manage all aspects of 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.

In December 2011, we closed on an agreement with NEBU-TEC to purchase all rights to its SIM-Neb device, which is currently under development. Under the terms of the agreement, we will assume all funding responsibilities for the development and production of the SIM-Neb and NEBU-TEC will receive milestone payments for FDA and EMA approvals and additional milestone payments based on the number of commercial patients using the SIM-Neb.

Pluristem License Agreement

In June 2011, we entered into a license agreement with Pluristem Ltd. (Pluristem) for exclusive worldwide rights to develop and commercialize a cell-based product for the treatment of pulmonary hypertension using Pluristem's proprietary PLX cell technology. The license agreement became effective in August 2011, at which time we made a one-time, non-refundable payment of $7.0 million to Pluristem, $5.0 million of which consisted of a license fee that was charged to research and development expenses during the quarter ended September 30, 2011. The agreement provides for additional milestone payments to Pluristem at various stages, as well as royalties on commercial sales.

ImmuneWorks Development Agreement

In February 2010, Lung LLC 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, 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 agreement, Lung LLC 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.

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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. Under the agreement, Glaxo is entitled to receive royalties on sales exceeding a specified threshold for a minimum period of ten years (or until expiration of the licensed patents) following the date of the first commercial sale of any product containing treprostinil. Glaxo retains an exclusive option and right of first refusal to negotiate an agreement with us if we decide to license any commercialization rights with respect to treprostinil-based products anywhere in the world.

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 our own patent application for a new synthesis and production method for treprostinil in October 1997 in the United States, Europe and various 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 treprostinil. In the second quarter of 2012, our obligation to pay royalties under this license agreement expires. However, this will not result in any immediate impact on our aggregate royalty rate for Remodulin because the royalty offset provisions under the Glaxo assignment agreement (which does not expire until the Glaxo patent expires) will cause a corresponding increase in our royalty rate to Glaxo. Our 1997 synthesis 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 continue to conduct research into new methods to synthesize treprostinil 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.

Patent Term Extension

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. Similar procedures exist in Europe and other countries for obtaining patent extensions on new products that are approved after a regulatory review period. See the section below *Governmental Regulation Hatch-Waxman Act* for further details.

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

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also agreed to pay Lilly royalties equal to 5 percent of our net sales of Adcirca 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 retained authority for all regulatory activities with respect to Adcirca, including retail pricing, which is expected to be at price parity with Cialis.

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. Lilly has the right to terminate in the event of a change of control of our company. 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 treprostinil tablet. Under the agreement, we will pay Supernus certain amounts upon the achievement of specified milestones based on the development of oral treprostinil and its commercial launch, including a $2.0 million milestone payment upon commercial launch for the first product using their technology. 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.

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 is conducting 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 are developing the commercial production capability for the antibody. As part of developing our commercial production 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 we plan to file seeking FDA approval of Ch14.18 immunotherapy for the treatment of neuroblastoma.

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Memorial Sloan Kettering License

Pursuant to a December 2007 agreement with Memorial Sloan-Kettering Cancer Center, we obtained certain license rights to an investigational monoclonal antibody, 8H9, for the treatment of metastatic brain cancer. 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.

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 for the years ended December 31, 2011, 2010 and 2009 totaled approximately $180.0 million, $165.3 million and $120.4 million, respectively. See *Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations Major Research and Development Projects* for additional information regarding expenditures related to major research and development projects.

Production and Supply

We synthesize treprostinil, the active ingredient in Remodulin and Tyvaso, and treprostinil diethanolamine, the active ingredient for oral treprostinil, at our facility in Silver Spring, Maryland. In June 2009 and November 2009, we received FDA and European regulatory approval, respectively, to synthesize treprostinil at our Silver Spring facility. In March 2011 and August 2011, we received FDA approval to produce Tyvaso and Remodulin, respectively, at our Silver Spring facility. European regulatory approval to produce Remodulin at our Silver Spring facility is pending.

Baxter Pharmaceutical Solutions, LLC (Baxter) currently produces Remodulin for commercial use 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 produced using a different set of equipment and in larger quantities than the currently approved process at Baxter. Since Baxter will produce Remodulin on different equipment and in a larger 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 regulatory approval of the new equipment and process during 2012. Baxter continues to produce Remodulin for us according to the currently-approved process. In 2011, the FDA and European regulatory authorities approved Jubilant Hollister-Stier Contract Manufacturing and Services as an additional Remodulin producer, in the larger quantities described above.

We rely on Catalent Pharma Solutions, Inc. (Catalent) to do the following: (1) conduct stability studies on Remodulin, (2) serve as an additional producer of Tyvaso and oral treprostinil tablets and (3) analyze other products we develop. We are also manufacturing oral treprostinil tablets, which are being used in our clinical trials, in our facility in Research Triangle Park, North Carolina (RTP Facility). Approval is pending for the manufacture of a commercial supply of oral treprostinil tablets at our RTP facility as part of the NDA we submitted to the FDA in December 2011.

We intend to use our own facilities to produce our primary supply of Remodulin, Tyvaso and oral treprostinil tablets, and we will continue to contract with third parties to supplement our production capacity. Also, although we maintain a two-year inventory of Remodulin and Tyvaso based on expected demand, we believe that having third parties approved to produce these products will mitigate some of our risks, including the risk that we might not be able to produce sufficient quantities to meet patient

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demand. 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.

We manufacture the nebulizer used in our Tyvaso Inhalation System. While we 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 third parties could provide similar products, services and materials, there are few companies that could replace our existing producers 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 (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 and Veletri. 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 and Ilomedin®. Approved in December 2004 in the United States and in September 2003 in Europe, Ventavis (iloprost) 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 (Bayer) in Europe as Iloprost. In January 2007, CoTherix was acquired by Actelion, the manufacturer and distributor of Tracleer and distributor of Veletri. Iloprost is also marketed by Bayer in certain countries outside the United States in an intravenous form known as Ilomedin;

Tracleer. The first oral drug to be approved for PAH, Tracleer (bosentan) is also the first drug in its class, which consists of drugs known as ETRAs. 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 (sildenafil) 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; and

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

There are also a variety of investigational PAH therapies in the later stages of development, including the following:

Macitentan, an oral ETRA being developed by Actelion, is currently undergoing a phase III trial;

Riociguat, an oral agent targeting a similar vasodilatory pathway as PDE-5 inhibitors, is currently undergoing a phase III trial sponsored by Bayer;

Selexipag, an oral prostacyclin receptor antagonist being developed jointly by Actelion and Nippon Shinyaku Co., Ltd. in Japan, and by Actelion outside Japan, is currently undergoing a phase III trial; and

Gleevec® (imatinib), a small molecule kinase inhibitor in oral tablet form approved for treating various cancers, is being studied in PAH. Novartis Pharmaceuticals Corporation completed a phase III trial for PAH in September 2011 and has announced it expects to file for approval in the U.S. and EU during the first quarter of 2012.

Oral therapies (Adcirca, Revatio, Tracleer and Letairis) are commonly prescribed as first-line treatments for the least severely ill patients (NYHA Class II patients). As patients progress in their disease severity (NYHA Class III and IV), inhaled therapies (Tyvaso and Ventavis) or infusion therapies (Remodulin and Flolan) are commonly added. 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 and the development of new 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 could also face competition from generic pharmaceutical companies in the future. In February 3, 2012, we received notice of an abbreviated new drug application by Sandoz Inc. requesting FDA approval to market a generic version of the 10 mg/mL strength of Remodulin. For further details, see the section below entitled *Governmental Regulation Hatch-Waxman Act.* In addition, certain Revatio patents are expected to expire in 2012, which could lead to the introduction of one or more generic PDE-5 inhibitors for the treatment of PAH.

We compete with the developers, manufacturers and distributors of 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, approval, labeling, record keeping, 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 (FDC Act), the Public Health Service Act, and other federal statutes and regulations, may subject a

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company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending 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, which must become effective before clinical testing may commence;
- 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;
- 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. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted. A 30-day review period after the filing of each IND is generally required prior to the commencement of clinical testing in humans. Absent FDA objection within 30 days after submission, the IND becomes effective. If the FDA has not indicated that it needs more time to review the IND or that it has substantial questions 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: (i) in compliance with federal regulations; (ii) in compliance with good clinical practices (GCP), an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; and (iii) under 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

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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 metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness. 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 obtain additional information about clinical efficacy and safety in a larger number of patients, typically at geographically diverse clinical study sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug.

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 fees, currently exceeding $86,000 per product and $497,000 per establishment. These fees are typically increased annually. However, the application 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 are reviewed in six months. We expect the FDA to amend each of these goals to extend them by two months for applications received after September 2012. Priority review can be applied to drugs that the FDA determines offer major advances in treatment, or provide a treatment where no adequate therapy exists. For biologics, priority review is further limited to drugs intended to treat a serious or life-threatening disease. The review process may be extended by the FDA for three additional months to consider certain late-submitted information, including information intended to clarify information already provided in the submission. The FDA may also refer applications for novel pharmaceutical products or pharmaceutical products that 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.

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In the United States, after the FDA evaluates the NDA and the manufacturing facilities, the FDA may issue either an approval letter or a complete response letter. A complete response letter generally outlines 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 conditions 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. As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy (REMS) to help ensure that the benefits of the drug outweigh the potential risks. A REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use (ETASU). ETASU can include, but are not limited to, special training, certification, prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. 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. 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. Orphan drug designation must be requested before submitting an NDA. 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 convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA applicant to receive orphan drug designation and FDA approval for a particular active ingredient to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the U.S. for that product, for that indication. During the seven-year 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.

The FDA granted orphan drug 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 drug designation. The FDA has granted orphan drug designation for Tyvaso, and we have applied for orphan drug designation for oral treprostinil.

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Pediatric Information

Under the Pediatric Research Equity Act of 2007 (PREA), NDAs, BLAs and supplements to NDAs and 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 for which the drug is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, the PREA does not apply to any drug for an indication for which orphan drug designation has been granted. The Best Pharmaceuticals For Children Act (BPCA) provides NDA holders a six-month extension of any exclusivity, patent or non-patent, for a drug if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Hatch-Waxman Act

The Hatch-Waxman Act (also known as the Drug Price Competition and Patent Term Restoration Act) was enacted in 1984 to encourage research and development of new drugs and 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 to compensate for patent time lost during the FDA review and approval process and periods of market exclusivity to encourage continuing research on, for example, new uses, strengths or dosage forms for existing drugs. In seeking 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. Upon approval of a drug, each of the patents listed in the application is 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 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

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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. 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, federal law provides for an exclusivity period of three years, during which the FDA cannot grant effective approval of an ANDA for such new condition of use, dosage form or strength that meets certain statutory requirements. 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.

On February 3, 2012, we received a Paragraph IV Certification Notice Letter from Sandoz Inc. (Sandoz) advising us that Sandoz has submitted an ANDA to the FDA requesting approval to market a generic version of the 10 mg/mL strength of Remodulin. In the Notice Letter, Sandoz states that it intends to market a generic version of Remodulin before the expiration of U.S. Patent No. 5,153,222, which expires in October 2014; U.S. Patent No. 6,765,117, which expires in October 2017; and U.S. Patent No. 7,999,007, which expires in March 2029. Sandoz's Notice Letter states that the ANDA contains a Paragraph IV Certification alleging that these patents are not valid, not enforceable and/or will not be infringed by the commercial manufacture, use or sale of the proposed product described in Sandoz's ANDA submission.

We intend to vigorously enforce our intellectual property rights relating to Remodulin, including the three patents noted above which are listed in the FDA's Approved Drug Products List (the Orange Book). We are currently reviewing the Notice Letter, which was directed to all three Orange Book-listed patents. We have 45 days from receipt of the Notice Letter to commence a patent infringement lawsuit against Sandoz. Such a lawsuit would automatically preclude the FDA from approving Sandoz's ANDA for up to 30 months or until the issuance of a district court decision that is adverse to us, whichever occurs first.

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

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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.

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 continue to be required following FDA approval of an NDA or a BLA. The FDA also may require post-marketing testing, known as phase IV 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.

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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.

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 may be available at the applicant's option for other products. The centralized procedure provides for the grant of a single marketing authorization that is valid in all EU member countries. The decentralized/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 is required to 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 typically only commence in a country once pricing approval has been obtained.

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 EEA under the mutual recognition process described above. We withdrew applications in Spain, the United Kingdom and Ireland and are currently evaluating resubmitting applications in Spain and Ireland. In December 2011, we received approval for intravenous Remodulin in all of the 23 member nations where subcutaneous Remodulin is approved.

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.

Biologics

Biological products used for the prevention, treatment, or cure of a disease, or condition, of a human being are subject to regulation under the FDC Act, except the section of the FDC Act which governs NDA applications. Instead, biological products are approved for marketing under provisions of the Public Health Service Act (PHSA) via a BLA. However, the application process and requirements

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for approval of BLAs are very similar to those for NDAs. To help reduce the increased risk of the introduction of adventitious agents, the PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction, or spread, of communicable diseases in the United States and between states.

After a BLA is approved, the product may also be subject to official lot release. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official lot release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products. As with drugs, after approval of biologics, manufacturers must address any safety issues that arise, are subject to recalls or a halt in manufacturing, and are subject to periodic inspection after approval.

The PPACA included a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCI Act, which created an abbreviated approval pathway for biological products shown to be similar to, or interchangeable with, an FDA-licensed reference biological product. This is conceptually similar to the Hatch-Waxman Act in that it attempts to minimize duplicative testing. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study. Interchangeability requires that a product must demonstrate that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. However, complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation which are still being addressed by the FDA.

A reference biologic is granted twelve years of exclusivity from the time of first licensure of the reference product. The first biologic product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against other biologics submitted under the abbreviated approval pathway for the lesser of (i) one year after first commercial marketing; (ii) eighteen months after the initial application if there is no legal challenge; (iii) eighteen months after the resolution in the applicant's favor of a lawsuit challenging the biologics' patents if an application has been submitted; or (iv) 42 months after the application has been approved if a lawsuit is ongoing within the 42-month period.

Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

Cell and Tissue Based Biologics

Manufacturers of cell and tissue based products must comply with the FDA's current good tissue practices (cGTP), which are FDA regulations that govern the methods used in, and the facilities and controls used for, the manufacture of such products. The primary intent of the cGTP requirements is to ensure that cell and tissue based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable diseases.

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U.S. Regulation of Medical Devices

New medical devices are also subject to FDA approval and extensive regulation under the FDCA. Under the FDCA, medical devices are classified into one of three classes: Class I, Class II, or Class III. The classification of a device into one of these three classes generally depends on the degree of risk associated with the medical device and the extent of control needed to ensure safety and effectiveness.

Class I devices are those for which safety and effectiveness can be assured by adherence to a set of general controls. These general controls include compliance with the applicable portions of the FDA's Quality System Regulation (QSR), which sets forth good manufacturing practice requirements; facility registration and product reporting of adverse medical events listing; truthful and non-misleading labeling; and promotion of the device only for its cleared or approved intended uses. Class II devices are also subject to these general controls, and to any other special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. Review and clearance by the FDA for these devices is typically accomplished through the so-called 510(k) pre-market notification procedure. A Class III device requires approval of a premarket application (PMA), an expensive, lengthy and uncertain process requiring many years to complete.

When 510(k) clearance is sought, a sponsor must submit a pre-market notification demonstrating that the proposed device is substantially equivalent to a previously approved device. If the FDA agrees that the proposed device is substantially equivalent to the predicate device, then 510(k) clearance to market will be granted. After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require pre-market approval.

Clinical trials are almost always required to support a PMA and are sometimes required for a 510(k) pre-market notification. These trials generally require submission of an application for an investigational device exemption, or IDE. An IDE must be supported by pre-clinical data, such as animal and laboratory testing results, which show that the device is safe to test in humans and that the study protocols are scientifically sound. The IDE must be approved in advance by the FDA for a specified number of patients, unless the product is deemed a non-significant risk device and is eligible for more abbreviated investigational device exemption requirements.

Both before and after a medical device is commercially distributed, manufacturers and marketers of the device have ongoing responsibilities under FDA regulations. The FDA reviews design and manufacturing practices, labeling and record keeping, and manufacturers' required reports of adverse experiences and other information to identify potential problems with marketed medical devices. Device manufacturers are subject to periodic and unannounced inspection by the FDA for compliance with the QSR, current good manufacturing practice requirements that govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, servicing, labeling, storage, installation, and distribution of all finished medical devices intended for human use.

If the FDA finds that a manufacturer has failed to comply or that a medical device is ineffective or poses an unreasonable health risk, it can institute or seek a wide variety of enforcement actions and remedies, ranging from a public warning letter to more severe actions such as:

fines, injunctions, and civil penalties;

recall or seizure of products;

operating restrictions, partial suspension or total shutdown of production;

refusing requests for 510(k) clearance or PMA approval of new products;

withdrawing 510(k) clearance or PMA approvals already granted; and

criminal prosecution.

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The FDA also has the authority to require repair, replacement or refund of the cost of any medical device.

The FDA also administers certain controls over the export of medical devices from the United States, as international sales of medical devices that have not received FDA approval are subject to FDA export requirements. Additionally, each foreign country subjects such medical devices to its own regulatory requirements. In the EU, a single regulatory approval process has been created, and approval is represented by the CE Mark.

The nebulizer used with our Tyvaso Inhalation System was included in our NDA for Tyvaso, and was cleared by the FDA as a Class II medical device subject to compliance with the QSR.

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 Remodulin at a rate equal to 95% of the published average wholesale price as of October 1, 2003 (the Medicare Part B payment formula, under the Durable Medical Equipment Regional Carrier Guidelines, for drugs infused through durable medical equipment) and for Tyvaso at a rate of 106% of the average sales price (the Medicare Part B payment formula for drugs inhaled through durable medical equipment and also under the Durable Medical Equipment Regional Carrier Guidelines). Adcirca, an oral drug, is reimbursed under the Medicare Part D program. 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 Part B 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

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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. Many pharmaceutical and other 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 minimum Medicaid rebate rate from 15.1 percent to 23.1 percent of average manufacturer price became 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, 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

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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, with the first report due on March 31, 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 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 statute. 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 jurisdictions, including the District of Columbia, Maine, Massachusetts, Minnesota, Vermont and West Virginia, require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to healthcare practitioners in those jurisdictions. Some of these jurisdictions also prohibit various 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, Connecticut, 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 543 employees as of February 5, 2012. We believe our employee relations are excellent.

Industry Segments and Geographic Areas

Prior to the sale of Medicomp in March 2011, we operated in two business segments: pharmaceuticals and telemedicine. Our core business is pharmaceuticals in which we closely monitor the revenues and gross margins generated by our commercial products. 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*.

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EXECUTIVE OFFICERS OF THE REGISTRANT

The following is a list, as of February 28, 2012, 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.

Name	Age	Position
Martine A. Rothblatt, Ph.D., J.D., M.B.A.	57	Chairman, Chief Executive Officer and Director
Roger Jeffs, Ph.D.	50	President, Chief Operating Officer and Director
John M. Ferrari	57	Chief Financial Officer and Treasurer
Paul A. Mahon, J.D.	48	Executive Vice President, General Counsel and Corporate Secretary

Martine A. Rothblatt, Ph.D., J.D., M.B.A., founded 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 Chief Executive Officer of Sirius Satellite Radio. She also represented the radio astronomy interests of the National Academy of Sciences' Committee on Radio Frequencies before the Federal Communications Commission and led the International Bar Association's efforts to present the United Nations with a draft Human Genome Treaty. Her book, *YOUR LIFE OR MINE: HOW GEOETHICS CAN RESOLVE THE CONFLICT BETWEEN PUBLIC AND PRIVATE INTERESTS IN XENOTRANSPLANTATION*, was published by Ashgate in 2004. She is a co-inventor on three of our patents pertaining to treprostinil.

Roger Jeffs, Ph.D., received his undergraduate degree in chemistry from Duke University and his Ph.D. in pharmacology from the University of North Carolina. Dr. Jeffs joined United Therapeutics in September 1998 as Director of Research, Development and Medical. He was promoted to Vice President of Research, Development and Medical in 2000 and to President and Chief Operating Officer in 2001. From 1993 to 1995, Dr. Jeffs worked at Burroughs Wellcome & Company where he was a member of the clinical research team that developed Flolan, the first FDA-approved therapy for patients with pulmonary arterial hypertension. From 1995 to 1998, Dr. Jeffs worked at Amgen, Inc. where he served as the worldwide clinical leader of the Infectious Disease Program. Dr. Jeffs currently leads our global clinical, commercial, manufacturing and business development efforts.

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;

Our ability to obtain future financing;

The value of our common stock and our ability to complete future common stock repurchases;

The maintenance of domestic and international regulatory approvals;

The timing and outcome of clinical studies, including our future anticipated studies of oral treprostinil and Tyvaso, and regulatory filings;

The expected volume and timing of sales of Remodulin® (treprostinil) Injection (Remodulin), Adcirca® (tadalafil) tablets (Adcirca) and Tyvaso® (treprostinil) Inhalation Solution (Tyvaso);

The expected likelihood and timing of regulatory submissions and approvals for drug candidates under development and the timing of related sales, including the expected United States Food and Drug Administration (FDA) review period for our new drug application (NDA) for oral treprostinil and the approvability of our NDA, our anticipated application for approval of Remodulin in Japan, our pending application for approval of Remodulin in China, and our expected filing of a biologics license application with the FDA for Ch14.18;

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

The impact of competing therapies, including generic products and newly-developed therapies, on sales of our commercial products;

The expectation that we will be able to produce sufficient quantities and maintain adequate inventories of our commercial products, through both our in-house production capabilities and third-party production sites and our ability to obtain and maintain related approvals by the FDA and other regulatory agencies;

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

Our expectations regarding our ability to defend our intellectual property relating to Remodulin against generic challenges, including the recent abbreviated new drug application filed by Sandoz Inc. (Sandoz);

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

The potential impact of the pending business combination between Express Scripts, Inc. (the parent company of CuraScript, Inc.) and Medco Health Solutions, Inc. (the parent company of Accredo Therapeutics, Inc.) on our business;

Any statements that include 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.

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

Risks Related to Our Business

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

Sales of Remodulin and Tyvaso comprise a substantial majority of our total revenues. 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 our production process, and any failure to manage our internal production processes could result in 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 European Medicines Agency (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 addition, approval of an NDA may be subject to delays if the FDA determines that it cannot review or approve the NDA as submitted. In such case, the FDA would issue a refuse-to-file letter or a complete response letter outlining the deficiencies in the submission, and the FDA may require substantial additional studies, testing or information in order to complete its review of the application. We may fail to address any such deficiencies adequately, in which case we would be unable to obtain FDA approval to market the product candidate.

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;

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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, contracted clinical trial administrators or clinical studies conducted entirely by third parties do not adhere to trial protocols and required quality controls under good clinical practice (GCP) under FDA regulations and similar regulations outside the United States;

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;

The results of preclinical testing raise concerns regarding product safety or efficacy; and

The results of our clinical trials conducted in countries outside of the United States are not acceptable to the United States or other countries, and the results of our clinical trials conducted in the United States are not acceptable to regulators in other countries.

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.

Our future growth depends, in part, on our plans to commercialize and further develop oral treprostinil. If the FDA delays or denies approval of our NDA for oral treprostinil, and/or we are unsuccessful in further clinical studies of oral treprostinil, our business, financial condition and results of operations could be materially adversely affected.

In November 2008, we reported that our FREEDOM-C phase III clinical trial of oral treprostinil in patients with pulmonary arterial hypertension (PAH) did not achieve statistical significance for its primary endpoint (p=0.072). These results prompted us to amend the protocol for our FREEDOM-M phase III clinical trial of oral treprostinil and initiate an additional phase III clinical trial of oral treprostinil, FREEDOM-C^2. In June 2011, we announced the completion of the FREEDOM-M trial, which achieved statistical significance for its primary endpoint (p=0.0125). However, our FREEDOM-C^2 trial did not achieve statistical significance for its primary endpoint (p=0.089), as we announced in August 2011. Although we have filed an NDA for oral treprostinil and believe the NDA should be approvable on the basis of the FREEDOM-M results alone in accordance with published FDA guidance we believe to be applicable, we may face delays in obtaining FDA approval of our NDA for oral treprostinil, or we may not be able to obtain FDA approval at all, for the reasons described above under "*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",* among others. Furthermore, even if the FDA approves our NDA, the FREEDOM-M results may support only a monotherapy label indication, and not an indicated use in conjunction with a PAH background therapy, which would impose limits on the permitted marketing of oral treprostinil. In addition, if oral treprostinil is approved by the FDA, the results of both the FREEDOM-C and FREEDOM-C^2 would likely be listed in the oral treprostinil labeling and may negatively impact the timing and magnitude of oral treprostinil's commercial opportunity by impacting patient demand, physician prescribing patterns or reimbursement rates.

We are currently planning additional trials intended to demonstrate oral treprostinil's efficacy in combination with other therapies. If we are unsuccessful in these efforts, this may further dampen our prospects for revenue growth from oral treprostinil.

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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, as well as several other therapies under development, including various late-stage investigational products that have recently completed or are undergoing phase III pivotal trials. For the treatment of PAH, we compete with a number of approved products in the United States and worldwide, including the following: Flolan®, Ventavis®, Ilomedin®, Tracleer®, Revatio®, Letairis®, Veletri® and generic epoprostenol. Patients and doctors may perceive these competing products, or products developed in the future, 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.

Actelion Ltd, Gilead Sciences, Inc. and Pfizer Inc. presently control the majority of the approved therapies for PAH in the United States. Each of these companies has achieved considerable market penetration 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.

We have had periods in which we incurred 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 those outside of our control, could affect our profitability and cause uneven quarterly and/or annual operating results.

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, including several investigational PAH therapies for which phase III pivotal trials are underway or have been recently completed. In addition, alternative approaches to treating chronic diseases, such as gene therapy or cell therapy, may make our products obsolete or noncompetitive. If introduced into the market, 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 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 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

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attempting to limit or regulate the price of medicinal products and are frequently challenging the pricing of new and expensive drugs. Our prostacyclin analogue products, Remodulin and Tyvaso, are expensive therapies. Consequently, it may be difficult for our specialty pharmaceutical distributors or wholesalers to obtain sufficient reimbursement of our products from third-party payers to make selling our products economically feasible for them. 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 or provides a lower out-of-pocket cost to them. Presently, most third-party payers, including Medicare and Medicaid, provide reimbursement for our commercial products. Future reimbursements under Medicare and Medicaid 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 the United States, there is an increased focus from the federal government and others on analyzing the impact of various regulatory programs on the federal deficit, which could result in increased pressure on federal programs to reduce costs. For example, on August 2011, President Obama signed a bill that raises the U.S. federal debt ceiling and mandates significant additional deficit reduction over the next decade. While many proposals have been put forth, specific reductions in federal spending have not yet been determined. In addition, financial pressures may cause government or other third-party payers to more aggressively seek cost containment through mandatory discounts or rebates on our products, policies requiring the automatic substitution of generic products, higher hurdles for initial reimbursement approvals for new products or other similar measures. For example, there have been recent proposals to reduce reimbursement rates and/or adopt mandatory rebates under Medicare Part B, which covers Remodulin and Tyvaso.

A reduction in the availability or extent of reimbursement from government healthcare programs could have a material adverse effect on the sales of our products, our business and results of operations.

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 through the implementation of reference pricing, price cuts, rebates, revenue-related taxes and profit control, and expect prices of prescription pharmaceuticals to decline over the life of the product or as prescription volumes increase.

Finally, the ultimate pricing and reimbursement of our investigational products, upon their approval, is inherently uncertain and subject to the risks discussed above. In particular, the pricing for oral treprostinil, if approved, is subject to a number of uncertainties, including those described above, and our ability to achieve optimal pricing may be negatively impacted by the results of our FREEDOM-C and FREEDOM-C^2 trials, which failed to achieve statistical significance for their primary endpoints.

Our production strategy exposes us to significant risks.

We must be able to produce sufficient quantities of our commercial products to satisfy demand. The process of producing our products is difficult and complex, and currently involves a number of third parties. We synthesize treprostinil, the active ingredient in Remodulin, Tyvaso and treprostinil

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diethanolamine, the active ingredient in our oral treprostinil tablet, in our Silver Spring, Maryland facility using raw materials and advanced intermediate compounds supplied by vendors. Although we have received FDA approval to produce Remodulin and Tyvaso at our own facilities, we continue to outsource some of the production of Remodulin to Baxter Pharmaceutical Solutions, LLC (Baxter) and Jubilant Hollister-Stier Contract Manufacturing and Services (Jubilant Hollister-Stier), and some of the production of Tyvaso to Catalent Pharma Solutions, Inc. We manufacture the Tyvaso Inhalation System nebulizer at our facility in Germany, where NEBU-TEC International Med Products Eike Kern GmbH (NEBU-TEC) supplies personnel. We also manufacture the Tyvaso Inhalation System nebulizer through a third-party, Minnetronix, Inc.

We produce oral treprostinil diethanolamine tablets for use in our clinical trials, but neither we nor our third-party vendors would be able to produce oral treprostinil diethanolamine tablets for commercial use in the U.S. or internationally without FDA approval or the corresponding international approvals of the facility.

As long as we utilize third-party vendors for significant portions of our production process, we will remain exposed to the risks described below under "*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 are in the process of internalizing additional processes to increase our control of production, this approach will also subject us to risks as we engage in increasingly complex production processes. For example, Remodulin and Tyvaso must be produced in a sterile environment and we have limited 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, we are developing Ch14.18 MAb, a monoclonal antibody. As with all biologic products, monoclonal antibodies are inherently more difficult to manufacture than our current products and involve increased risk of viral and other contaminations.

The FDA recently issued an advisory to manufacturers regarding the potential formation of glass fragments in injectable drugs filled in small-volume glass vials. We recently conducted a thorough review of our manufacturing processes and those of our third-party suppliers and have no conclusive evidence at this time to suggest that the glass vials we use for Remodulin form glass fragments. We continue to assess our products, but cannot guarantee that our manufacturing process will not result in hazards such as these.

Additional risks presented by our production strategy include:

- We and our third-party producers 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 production processes, we do not exercise the same level of control over regulatory compliance by our third-party producers;

- As we expand our production operations to include new elements of the production process or new products, we may experience difficulty designing and implementing processes and procedures to ensure compliance with applicable regulations;

- Even if we and our third-party producers comply with domestic and international drug production regulations, the sterility and quality of the products being produced could be substandard and, therefore, such products would be unavailable for sale or use;

- If we have to replace a third-party producer or our own production operations with another producer, the FDA and its international counterparts would require new testing and compliance inspections. Furthermore, a new producer would have to be familiarized with the processes necessary to produce and commercially validate our products, as producing our treprostinil-based

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products is complex. Any new third-party producers and any new production 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;

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

The supply of materials and components necessary to produce and package our products may become scarce or interrupted. Disruptions to the supply of these materials could delay the production, shipping and subsequent sale of such products. Any products produced 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.

We actively involve third parties to assist us in conducting clinical trials, obtaining regulatory approvals, conducting pharmacovigilance-related activities including drug safety and reporting of adverse events, and marketing and distributing our products, as we do not possess the internal capacity, and in some cases the expertise, to fully perform all of these functions. Accordingly, the success of these third parties in performing their contractual obligations is critical to our operations.

We synthesize treprostinil using 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 production of treprostinil for commercial use and for use in our clinical trials.

We rely on Baxter and Jubilant Hollister-Stier to produce Remodulin for us. 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. We also have received FDA approval to produce Remodulin using our Silver Spring, Maryland facility, and are awaiting international approvals; however, we remain reliant on third parties such as Baxter and Jubilant Hollister-Stier for additional capacity, manufacturing for international sales and as backup manufacturers.

We have received FDA approval to produce Tyvaso in our Silver Spring, Maryland facility; however, we remain reliant on Catalent for additional production capacity and as a backup manufacturer. We also rely substantially on third parties, currently Minnetronix, Inc. and NEBU-TEC, to produce the Tyvaso Inhalation System nebulizer.

We rely heavily on these third parties to adhere to and maintain manufacturing processes in accordance with all applicable regulatory requirements. If any of these critical third-party production and supply arrangements are interrupted for compliance or other reasons, we may not have sufficient inventory to meet future demand.

We rely on Accredo Health Group, Inc., CuraScript, Inc. and CVS 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. From time-to-time, we increase the price of products sold to our U.S.-based and international distributors. Our price increases may not be fully reimbursed by third-party payers. If our distributors do not

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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.

In July 2011, Express Scripts, Inc. (the parent company of CuraScript, Inc.) announced its agreement to acquire Medco Health Solutions, Inc. (the parent company of Accredo Health Group, Inc.). The parties announced that they expect to complete the transaction in the first half of 2012, pending regulatory and shareholder approvals. If the transaction is completed as announced, we will only have two specialty pharmaceutical distributors selling Remodulin and Tyvaso in the United States. In addition, our products may be less significant to the operations of the combined companies and receive fewer resources for the sale and support of our products, which could adversely impact our revenues.

Finally, the combined company's pharmacy benefit management business will also have increased leverage in negotiating the terms of rebates and discounts on behalf of third-party payers, which could impact reimbursement levels for our products.

We rely on Eli Lilly and Company (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 the growth of our business. In addition, Lilly has the right to determine the price of Adcirca, which generally moves in parity with its price for Cialis® (which has the same active ingredient). Since FDA approval of Adcirca, Lilly has announced a price increase on both Cialis and Adcirca twice each year. Changes in Lilly's prices could adversely impact demand or reimbursement for Adcirca, particularly if a generic PDE-5 enters the market following the expiration of certain Revatio patents that is anticipated in 2012.

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. Manufacturing interruptions could be significant given the length of time and complexity involved in obtaining necessary regulatory approvals for alternative arrangements, through either third parties or internal manufacturing processes.

We rely heavily on third-party contract research organizations to conduct our clinical trials. In addition, the success of certain of our development stage products will depend on clinical trials sponsored by third parties. Examples of such clinical trials include the phase III study of Ch14.18 conducted by the National Cancer Institute, ongoing studies conducted by Medtronic, Inc. using its implantable pump to deliver intravenous Remodulin and ongoing studies conducted by ImmuneWorks, Inc. of its IW001 product. Failure by any of these parties to conduct or assist us in conducting clinical trials in accordance with study protocols, quality controls and GCP could limit our ability to rely on results of those trials in seeking regulatory approvals.

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. Our research and development efforts must comply with extensive regulations, including those promulgated by the FDA and the United States Department of Agriculture. 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, including strict pharmacovigilance and adverse event reporting requirements. Any future product approvals we receive could be accompanied by significant restrictions on the use or marketing of the product. Our product candidates, including, in particular, oral treprostinil,

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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 post-marketing requirements and post-marketing commitments, 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, research and development, pharmacovigilance and adverse event reporting, marketing or sales activities could result in regulatory restrictions on our products, including withdrawal of our products from the market. 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 the issues that led to such regulatory action.

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

After our products receive regulatory approval, they remain subject to ongoing regulation, which can impact, among other things, product labeling, manufacturing practices, pharmacovigilance and 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 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 the occurrence of 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, regulatory 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.

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 have been deemed 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, failure to follow FDA rules and guidelines relating to promotion and advertising can result in the FDA's refusal to approve a product, the suspension or withdrawal of an approved product from the market, product recalls, fines, disgorgement of money, operating restrictions, injunctions or criminal prosecution.

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We must comply with various laws in jurisdictions 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 in jurisdictions around the world, including anti-kickback and false claims statutes, the Foreign Corrupt Practices Act and the UK Bribery Act, restrict particular marketing practices in the pharmaceutical and medical device industries. Although we have compliance programs and procedures 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 increase the risks of noncompliance with these laws.

In the United States, the federal health care 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 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.

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 product from reimbursement under government programs, criminal fines, and imprisonment.

The Patient Protection and Affordable Care Act (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 31, 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

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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. Depending on the state, legislation may prohibit various other marketing related activities, or 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.

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.

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 decision to prescribe 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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Negative attention from special interest groups may impair our business.

As is common with pharmaceutical and biotechnology companies, our early-stage research and development involves animal testing, which we conduct both directly and through contracts with third parties. Notwithstanding the vital role of animal research in the drug discovery and development process, certain special interest groups categorically object to the use of animals for research purposes. Historically, our research and development activities have not been the subject of significant animal rights media attention. However, research activities with animals have been the subject of adverse attention, including demonstrations near facilities operated by other companies in our industry. Any negative attention, threats or acts of vandalism directed against our animal research activities in the future could impair our ability to operate our business efficiently.

If any of the license or other agreements under which intellectual property rights are licensed to, or were acquired by, us are breached or terminated, our right to continue to develop, make and sell the products covered by such agreement could be impaired or lost.

Our business depends upon our continuing ability to exploit our intellectual property rights in the drugs and other products that have been discovered and initially developed by others and that we are developing further and commercializing. These intellectual property rights have either been licensed by us pursuant to a product license agreement or have been acquired by us pursuant to a purchase agreement. Under each of our product license agreements, we are granted a license to exploit certain intellectual property owned by others that covers a drug or other product. Under each of our purchase agreements, we have purchased certain intellectual property that covers a drug or other product. We may be required to obtain a license of other intellectual property owned by third parties to continue to develop and commercialize our products.

This dependence on intellectual property developed by others involves the following risks:

We may be unable to obtain rights to intellectual property that we determine we need for our business at a reasonable cost or at all;

If any of our product license or purchase agreements are terminated, we may lose our rights to develop, make and sell the products to which such agreement relates;

Our license and purchase agreements generally provide the licensor or seller with the right to terminate the agreement in the event we breach such agreement *e.g.*, if we fail to pay royalties and other fees timely and do not cure the failure within a stated time period; and

If a licensor of intellectual property that is exclusively licensed to us breaches its obligation or otherwise fails to maintain the intellectual property licensed to us, we may lose any ability to prevent others from developing or marketing similar products that are covered by such intellectual property. In addition, we may be forced to incur substantial costs to maintain the intellectual property ourselves or take legal action seeking to force the licensor to do so.

Certain agreements under which we acquired or licensed intellectual property rights may restrict our ability to develop related products in certain countries or for particular diseases and may impose other restrictions that affect our ability to develop and market related products in the most effective manner.

When we acquire or are licensed intellectual property rights to drugs and other products that have been discovered and initially developed by others, these rights are frequently limited. For instance, our rights to market Adcirca are geographically limited to the United States and Puerto Rico. 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

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Lilly sells Adcirca to us. Provisions in our license and purchase agreements may impose other restrictions that affect our ability to develop and market products to which the intellectual property that is the subject of such agreements relates. For example, GlaxoSmithKline PLC retained an exclusive option and right of first refusal to negotiate an agreement with us if we decide to license any commercialization rights with respect to Remodulin and Tyvaso anywhere in the world. Similarly, our amended license agreement with Toray Industries, Inc. (Toray) 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.

Our intellectual property rights may not effectively deter competitors from developing competing products that, if successful, could materially adversely affect our revenues and profits.

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. Three of our 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 been granted one patent in the European Union and one patent in Japan, each of which covers our treprostinil synthesis and production methods and will expire in October 2018. Our U.S. patent covering an improved diluent for Remodulin will expire in March 2029. 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 European Union in 2018 and 2020, respectively.

We continue to conduct research into new methods to synthesize treprostinil and have two issued 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 any of our patents, competitors may develop generic versions of our products that were covered by the expired patent and market those generic versions to compete with our products. Competitors may also seek to design around our patents prior to their expiration in an effort to develop competing products that do not infringe our patents.

The scope of any patent we hold may not deter competitors from developing a product that competes with the product we sell that is covered by the patent. Patent laws of foreign jurisdictions may not protect our patent rights to the same extent as the patent laws of the United States. Furthermore, our suppliers who have granted us exclusive rights may have inadequate intellectual property protections. Competitors also may attempt to invalidate our existing patents before they expire.

In addition to patent protection, we also rely on trade secrets to protect our proprietary know-how and other technological advances that we do not disclose to the public. We enter into confidentiality agreements with our employees and others to whom we disclose trade secrets and other confidential information. These agreements do not necessarily prevent our trade secrets from being used or disclosed without our authorization and confidentiality agreements may be difficult to enforce or may not provide an adequate remedy in the event of unauthorized disclosure.

The validity, enforceability and scope of certain of our patents covering Remodulin are currently being challenged as a result of a recent abbreviated new drug application (ANDA) filing from a generic drug company. The outcome of the current or any future challenges to the validity, enforceability or scope of our patent portfolio could significantly reduce revenues from Remodulin.

On February 3, 2013, we received a Paragraph IV Certification Notice Letter from Sandoz advising that Sandoz has submitted an ANDA to the FDA requesting approval to market a generic version of the 10 mg/mL strength of Remodulin. In the Notice Letter, Sandoz states that it intends to market a generic version of Remodulin before the expiration of U.S. Patent No. 5,153,222, which expires in

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October 2014; U.S. Patent No. 6,765,117, which expires in October 2017; and U.S. Patent No. 7,999,007, which expires in March 2029. Sandoz's Notice Letter states that the ANDA contains a Paragraph IV Certification alleging that these patents are not valid, not enforceable and/or will not be infringed by the commercial manufacture, use or sale of the proposed product described in Sandoz's ANDA submission.

We are currently reviewing the Notice Letter, which was directed to all three patents listed above, each of which is listed in the FDA's Approved Drug Products List (the Orange Book). We have 45 days from receipt of the Notice Letter to commence a patent infringement lawsuit against Sandoz. Such a lawsuit would automatically preclude the FDA from approving Sandoz's ANDA for up to 30 months or until the issuance of a district court decision that is adverse to us, whichever occurs first.

Although we intend to vigorously enforce our intellectual property rights relating to Remodulin, there can be no assurance that we will prevail in our defense of our patent rights. Our existing patents could be invalidated, found unenforceable or found not to cover a generic form of Remodulin. If Sandoz or another ANDA filer were to receive approval to sell a generic version of Remodulin and/or prevail in any patent litigation, Remodulin would become subject to increased competition and our revenue would be adversely affected. In addition, regardless of the outcome, any patent litigation could be costly and time-consuming.

Third parties may allege that our products or services infringe their patents and other intellectual property rights, which could result in the payment of royalties that would affect our profits, subject us to costly and time-consuming litigation or result in our losing the ability to continue to sell the related products.

Third parties may seek to invalidate or otherwise challenge our patents. We may initiate litigation to enforce or defend our patents or intellectual property rights; however, litigation can be time consuming and costly and may not conclude favorably, and the outcome of patent infringement litigation often is difficult to predict. If we are unsuccessful with respect to any future legal action in the defense of our patents and our patents are invalidated or determined to be unenforceable, our business could be negatively impacted. Even if our patents are not determined to be invalid or unenforceable, it is possible that a competitor could circumvent our patents by effectively designing around the claims of our patents. Accordingly, our patents may not provide us with any competitive advantage.

To the extent third-party patents for which we currently do not hold licenses cover our products or services, a license to these patents would be necessary to manufacture, use, sell or provide these products and services without infringing these patents. In the case of products or services that utilize intellectual property of strategic collaborators or other suppliers, such suppliers may have an obligation to secure the needed license to these patents at their cost, but otherwise we would be responsible for the cost of these licenses. Payments of royalties and other amounts 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 the product alleged to be infringed to avoid infringing a third-party patent, we would be unable to continue to manufacture or sell the related products.

If a third party commences a legal action against us for infringement, we could be compelled to incur significant costs to defend the action and our management's attention could be diverted, whether or not the action were to have any merit. We cannot be certain that we could prevail in the action, and an adverse judgment or settlement resulting from the action could require us to pay substantial amounts in damages for infringement or substantial amounts to obtain a license to continue to use the intellectual property that is the subject of the infringement claim.

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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 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 material 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 our manufacturing facilities. However, our facilities may be insufficient to meet future demand for our products. Alternatively, we may have excess capacity at our 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 our facilities. Constructing our facilities is expensive and our ability to satisfactorily recover our investment 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.

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 maturity or conversion of our 1.0% Convertible Senior Notes due September 15, 2016 (2016 Convertible Notes), we must repay our investors in cash up to the principal balance of $250.0 million. In addition, in certain circumstances constituting a fundamental change under the 2016 Convertible

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Notes, we may be required to repurchase the notes for cash. In addition, awards granted under our Share Tracking Awards Plans (which we collectively refer to as the 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, our STAP will likely require significant future cash payments to participants to the extent the price of our common stock appreciates 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, which could have a material adverse effect on our business or financial condition.

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:

		High	Low
January 1, 2011	December 31, 2011	$ 70.70	$ 37.21
January 1, 2010	December 31, 2010	$ 64.24	$ 46.22
January 1, 2009	December 31, 2009	$ 52.88	$ 27.86

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

Quarterly and annual financial results;

Failure to meet estimates or expectations of securities analysts;

Timing of enrollment and results of our clinical trials;

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, Medicaid or other government payers, 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 our 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 obtain or maintain, our regulatory approvals from the FDA or international regulatory agencies, including, in particular, approval for oral treprostinil for the treatment of PAH;

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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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; and

General market conditions.

We may fail to meet our own projected revenues, as well as third-party projections for our revenues or profits.

Many securities analysts publish quarterly and annual projections of our revenues and profits. In addition, we have recently begun providing forward-looking guidance for revenues associated with our commercial products. 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 or our own projected revenues could have a significant impact on the price of our common stock.

Sales or issuances 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; (3) our investors become concerned that substantial sales of our common stock may occur; or (4) we issue shares upon the maturity of warrants issued as part of the hedging transactions from our 0.5% Convertible Senior Notes that matured in October 2011. For example, Lilly has begun to sell a significant portion of our common stock it currently holds. 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.

In addition, the conversion of some or all of the 2016 Convertible Notes, when the price of our common stock exceeds $67.56 per share, would dilute the ownership interests of our existing shareholders.

Any sales of common stock issued to holders of our convertible senior notes could adversely affect the prevailing market price of our common stock or result in short selling by market participants in expectation of a decline in the price of our common stock.

Our share repurchases may affect the value of the notes and our common stock.

Our Board of Directors has authorized a share repurchase program for up to $300 million of our common stock through October 3, 2013. As part of this broader repurchase program, we entered into an accelerated share repurchase agreement (ASR) with Deutsche Bank AG, London Branch, an affiliate of the initial purchaser, Deutsche Bank Securities, Inc., on October 17, 2011, which is described in more detail in Note 10 *Stockholders' Equity Share Repurchases* to our consolidated financial statements included in this Annual Report on Form 10-K. We have been advised that Deutsche Bank AG, London Branch expects to purchase and may sell our common stock or other of our securities in secondary market transactions during the term of the ASR transaction. The effect, if any, of any of these transactions and activities on the market price of our common stock will depend in part on market conditions, but any of these activities could affect the value of our common stock.

We are subject to counterparty risk with respect to the convertible note hedge transaction and the ASR transaction.

The counterparty to the convertible note hedge we entered into in connection with the issuance of our 2016 Convertible Notes (call options) and the ASR is the affiliate of a financial institution, and we will be subject to the risk that such counterparty may default under the call options or the ASR. Our exposure to the credit risk of such counterparty will not be secured by any collateral. Recent global

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economic conditions have resulted in the actual or perceived failure or financial difficulties of many financial institutions. If such counterparty becomes subject to insolvency proceedings, we will become an unsecured creditor in those proceedings with a claim based on our exposure at that time under the call options or the ASR. Our exposure will depend on many factors but, generally, the increase in our exposure will be correlated to the increase in the market price and in the volatility of our common stock. In addition, upon a default by the counterparty, we may suffer adverse tax consequences and dilution with respect to our common stock due to our obligation to deliver shares upon conversion of the notes. We cannot provide any assurance as to the financial stability or viability of such counterparty.

Provisions of Delaware law and our amended and restated certificate of incorporation, second amended and restated by-laws, shareholder rights plan, 2016 Convertible Notes, call spread hedge transactions, ASR 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 amended and restated certificate of incorporation, second amended and restated 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 amended and restated 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 may be required to repurchase the 2016 Convertible Notes from their holders in the event of a fundamental change and increase the conversion rate in connection with a make whole adjustment event in certain circumstances, including a change of control of our company. This may delay or prevent a change in control of our company that would otherwise be beneficial to our shareholders.

Terminating or unwinding the call spread hedge transactions or the ASR could require us to make substantial payments to the counterparty under those agreements or may increase our stock price. The costs or any increase in stock price that may arise from terminating or unwinding such agreements could make an acquisition of our company significantly more expensive to the purchaser.

Similarly, a change of control, under certain circumstances, could also result in an acceleration of the vesting of outstanding STAP awards. This, together with any increase in our stock price resulting from the announcement of a change of control, could make an acquisition of our company significantly more expensive to the purchaser. We also have a broad-based change of control severance program, under which employees may be entitled to severance benefits in the event they are terminated without cause (or they terminate their employment for good reason) following a change of control. This program could also increase the cost of acquiring our company.

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 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,

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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.

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 treprostinil-based compounds and monoclonal antibodies. We plan to use this facility to produce Remodulin, Tyvaso and monoclonal antibodies for commercial use. We have substantially completed the construction of an 85,000 square foot office building adjacent to our corporate headquarters. We also own several other buildings in Silver Spring used principally for office space, and we lease and own warehouse space near Silver Spring.

Florida We own an office building in Satellite Beach, Florida. We 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 personnel. We warehouse and distribute Tyvaso and manufacture oral treprostinil at this location. During the second quarter of 2011, we began 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.

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

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may be involved in 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.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

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PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

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:

	2011		2010	
	High	Low	High	Low
January 1 March 31	$ 69.54	$ 64.28	$ 61.46	$ 53.27
April 1 June 30	$ 70.70	$ 53.49	$ 58.52	$ 48.81
July 1 September 30	$ 57.38	$ 37.47	$ 56.07	$ 46.22
October 1 December 31	$ 47.54	$ 37.21	$ 64.24	$ 54.26

Number of Holders

As of February 21, 2012, there were 40 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.

Issuer Purchases of Equity Securities

Period	Total Number of Shares (or Units) Purchased	Average Price Paid Per Share (or Unit)	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares (or Units) That May Yet Be Purchased Under the Plans or Programs(1)
October 1, 2011 October 31, 2011	4,741,934	$ 44.71	4,741,934	$ 88,000,000
November 1, 2011 November 30, 2011				$ 88,000,000
December 1, 2011 December 31, 2011				$ 88,000,000
Total	4,741,934	$ 44.71	4,741,934	$ 88,000,000

(1) As previously disclosed in our Form 10-Q for the quarter ended September 30, 2011, on October 3, 2011, our Board of Directors approved a share repurchase program authorizing up to $300.0 million in aggregate repurchases of our common stock over a two-year period ending on October 3, 2013. In connection with the repurchase program, we acquired shares of our common stock during October 2011 pursuant to an accelerated share repurchase transaction. Refer to *Note 10 Stockholders' Equity Share Repurchases* to our consolidated financial statements included in this Annual Report on Form 10-K for details.

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Comparison of Five-Year Total Cumulative Shareholder Return

The following chart shows the performance from December 31, 2006 through December 31, 2011 of United Therapeutics common stock, compared with an investment in the stocks represented in each of the NASDAQ U.S. Stock Market Index and the NASDAQ Pharmaceutical Stock Index, assuming $100 is invested in each at the beginning of the period.

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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,				
	2011	**2010**	**2009**	**2008**	**2007**
Consolidated Statements of Operations Data:					
Revenues	$ 743,183	$ 592,899	$ 358,880	$ 272,012	$ 203,217
Operating expenses:					
Research and development	180,015	165,306	120,368	237,810	82,126
Selling, general and administrative	156,482	188,606	171,894	90,218	95,476
Cost of product sales	88,904	67,674	40,861	26,931	19,856
Total operating expenses	425,401	421,586	333,123	354,959	197,458
Operating income (loss)	317,782	171,313	25,757	(82,947)	5,759
Total other income (expense), net	(18,665)	(16,162)	(7,134)	(1,665)	(1,818)
Income (loss) from continuing operations before income tax	299,117	155,151	18,623	(84,612)	3,941
Income tax (expense) benefit	(81,874)	(43,945)	695	34,394	7,876
Income (loss) from continuing operations	217,243	111,206	19,318	(50,218)	11,817
Income (loss) from discontinued operations, net of tax(1)	625	(5,290)	144	891	536
Net income (loss)	$ 217,868	$ 105,916	$ 19,462	$ (49,327)	$ 12,353
Net income (loss) per common share:					
Basic(2)	$ 3.81	$ 1.89	$ 0.37	$ (1.08)	$ 0.29
Diluted(2)	$ 3.67	$ 1.78	$ 0.35	$ (1.08)	$ 0.28
Weighted average number of common shares outstanding:					
Basic(2)	57,163	56,142	53,314	45,802	42,448
Diluted(2)	59,395	59,516	56,133	45,802	44,902

	Year Ended December 31,				
	2011	**2010**	**2009**	**2008**	**2007**
Consolidated Balance Sheet Data:					
Cash, cash equivalents and marketable investments(3)	$ 747,378	$ 759,932	$ 378,120	$ 336,318	$ 299,792
Total assets	1,518,079	1,431,635	1,051,544	874,534	585,247
Debt	266,835	305,968	250,599	234,952	192,172
Retained earnings (deficit)	249,038	31,170	(74,746)	(93,927)	(30,375)
Total stockholders' equity	948,488	883,886	653,009	555,334	352,131

(1) In March 2011, we sold Medicomp, Inc., our former telemedicine subsidiary and subsequently discontinued all of our continuing telemedicine-related activities. Accordingly, the results of Medicomp, Inc., have been included within discontinued operations for each

of the years presented. Refer to *Note 18 Sale of Medicomp, Inc.* to our consolidated financial statements included in this Annual Report on Form 10-K for details.

(2)

Refer to *Note 10 Stockholders' Equity Earnings per Share* 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 for both continuing and discontinued operations.

(3)

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* included 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

Our key therapeutic products and product candidates include:

Prostacyclin analogues (Remodulin®, Tyvaso®, oral treprostinil and beraprost-MR): 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 for oncologic applications (Ch14.18 MAb and 8H9 MAb): antibodies that treat cancer by activating the immune system;

Glycobiology antiviral agents: a novel class of small, sugar-like molecules that have shown antiviral activity in a range of pre-clinical settings; and

Cell-Based Therapy: a cell-based product known as PLacental eXpanded (PLX) cells being studied for the treatment of pulmonary hypertension.

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. The FDA subsequently broadened its approval of Remodulin in 2004 for intravenous (in the vein) use and for the treatment of patients requiring transition from Flolan®, the first drug approved by the FDA for the treatment of PAH. Remodulin has also been approved in various countries outside of the United States. In most of these countries, Remodulin has been approved for both routes of administration. We announced in December 2011 that we received regulatory approval by the French regulatory agency, *Agence Française de Sécurité Sanitaire des Produits de Santé* (AFSSAPS) for the intravenous use of Remodulin to treat PAH. The AFSSAPS approval follows a review period during which 22 European Economic Area member nations, each of which had previously approved subcutaneous Remodulin through the mutual recognition process, reviewed and endorsed the final variation assessment report issued by AFSSAPS, which will allow the marketing of intravenous Remodulin in those nations. Our other commercial products include Adcirca (tadalafil) tablets (Adcirca) and Tyvaso (treprostinil) Inhalation Solution (Tyvaso). In May 2009, the FDA approved 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, we received FDA

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approval of Tyvaso, an inhaled therapy for the treatment of PAH. We launched both of these products for commercial sale during the third quarter of 2009. These two products enable us to 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-MR, both for the treatment of PAH.

We sold Medicomp, Inc., our former telemedicine subsidiary, to a group of private investors on March 31, 2011. In addition, in June 2011, we discontinued all of our continuing telemedicine-related activities. Accordingly, the results of Medicomp, Inc., including the gain recognized on its disposal, have been included in discontinued operations for each of the three years in the three-year period ended December 31, 2011 on our consolidated statements of operations. Refer to *Note 18 Sale of Medicomp, Inc.* to our consolidated financial statements included in this Annual Report on Form 10-K for details.

Revenues

Sales of Remodulin comprise the largest share of our revenues. Other significant sources of revenues include sales of Tyvaso and Adcirca. Sales of Tyvaso and Adcirca have continued to grow since their commercial introduction in 2009, 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. On July 21, 2011, Express Scripts, Inc., the parent company of CuraScript, announced the signing of a merger agreement with Medco Health Solutions, Inc., the parent company of Accredo. The parties announced that the merger, which is subject to regulatory and shareholder approvals, is expected to close in the first half of 2012. Presently, we do not expect the merger, if approved, to materially affect our business.

We require our distributors to maintain reasonable levels of contingent inventory 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 monthly orders based on estimates of future demand and considerations of contractual minimum inventory requirements. As a result, sales volume of Remodulin and Tyvaso can vary, depending on the timing and magnitude of these orders.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the Acts) contains broad provisions that will be implemented over the next several years. We are continually 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.

On January 1, 2011, certain provisions of the Acts that address the coverage gap in the Medicare Part D prescription drug program (commonly known as the "donut hole") became effective. Under these provisions, drug manufacturers are required to provide a 50 percent discount on branded prescription drugs to patients receiving reimbursement under Medicare Part D while they remain in this coverage gap. These provisions of the Acts apply to Adcirca, which is our only commercial pharmaceutical product covered by Medicare Part D. Approximately 35 percent of our Adcirca patients are covered under Medicare Part D. The vast majority of our Remodulin and Tyvaso Medicare patients are covered under Medicare Part B, which does not contain a similar coverage gap.

We were not materially impacted by the Acts during 2010 and our revenues were reduced by less than one percent in 2011 as a result of the Acts. However, the potential long-term impact of the Acts on our business is inherently difficult to predict as many details regarding the implementation of this legislation have not yet been determined. Presently, we have not identified any provisions that could

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materially impact our business, but will continue to monitor future developments related to this legislation.

Total revenues are reported net of: (1) estimated rebates; (2) prompt pay discounts; (3) allowances for product returns or exchanges; and (4) distributor fees. We estimate our liability for rebates based on an analysis of historical levels of rebates by product to both state Medicaid agencies and commercial third-party payers relative to sales of each product. In addition, we determine our obligation for prescription drug discounts required for Medicare Part D patients within the coverage gap based on estimations of the number of Medicare Part D patients and the period such patients will remain within the coverage gap. We provide prompt pay discounts to customers that pay amounts due within a specific time period and base our estimates for prompt pay discounts on observed customer payment behavior. We derive estimates relating to the allowance for returns of Adcirca from published industry data specific to specialty pharmaceuticals and will continue to do so until we have sufficient historical data on which to base our allowance. In addition, we compare patient prescription data for Adcirca to sales of Adcirca on a quarterly basis to ensure a reasonable relationship between prescription and sales trends. To date, we have not identified any unusual patterns in the volume of prescriptions relative to sales that would warrant reconsideration of, or adjustment to, the methodology we currently employ to estimate our allowance for returns. 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 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. Lastly, we estimate distributor fees based on contractual rates for specific services applied to the estimated units of service provided for the period.

Cost of Product Sales

Cost of product sales is comprised of (1) costs to produce and acquire products sold to customers; (2) royalty payments under license agreements granting us rights to sell related products; and (3) direct and indirect distribution costs incurred in the sale of products. We acquired the rights to sell our commercial products through license and assignment agreements with the developers of these products, as described in *Item 1 Business Patents and Proprietary Rights*. These agreements obligate us to pay royalties based on our net revenues from related 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.

We synthesize 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. Our production 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. We maintain inventories of these products equivalent to approximately two years of expected demand to ensure sufficient availability of Remodulin and Tyvaso at all times. We have reduced our target inventory levels from three years to two years in light of the recent approval of additional production sites for Remodulin and Tyvaso, including our own facilities which we expect will become our primary sources of supply, as these developments have helped mitigate the risk of shortages of commercial drug supply.

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 produce Remodulin in greater quantities using larger capacity equipment. This new process and related equipment will require FDA and international regulatory approval. We are currently conducting validation testing for the new equipment and process. Until FDA approval of the new process and equipment, Baxter will continue to produce Remodulin using the approved process and equipment. In January 2011, we received FDA approval of Jubilant Hollister-Stier Contract Manufacturing and Services as an additional producer for Remodulin in the larger

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quantities discussed above. In addition, in July 2011, we received FDA approval of our NDA supplement to use our Silver Spring, Maryland facility for the production of Remodulin.

European approval to produce Remodulin at our Silver Spring facility is pending. We intend to use our own facilities to produce our primary supply of Remodulin, Tyvaso and oral treprostinil tablets, and we will contract with third parties to supplement our production capacity.

We acquired the rights to the Tyvaso Inhalation System from NEBU-TEC International Med Products Eike Kern GmbH (NEBU-TEC) in September 2009. 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 Tech Services, Inc. to package daily supplies. Catalent Pharma Solutions, Inc. continues to manufacture Tyvaso for us and in March 2011, we received FDA approval to produce Tyvaso in our Silver Spring, Maryland facility.

Operating 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, which are conducted both internally and through 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 expense (benefit) in connection with any stock option grants and our share tracking award plans (STAP). STAP awards are required to be measured at fair value at the end of each reporting period until the awards are no longer outstanding. The fair value of both STAP awards and stock option grants are measured 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 in connection with the STAP from 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 period awards have accrued toward vesting. Generally, our stock option grants are measured at fair value at the date of grant and related compensation is recognized over the requisite service period, which typically coincides with the vesting period. However, in the case of options granted to our Chief Executive Officer, which vest upon issuance in accordance with her employment agreement, we recognize all compensation expense immediately at the date of grant. We accrue compensation expense for performance-related stock option grants when we determine that it is probable that the performance criteria will be met.

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

The FDA approved Tyvaso for the treatment of PAH in July 2009, and 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 about a product's safety, efficacy, or optimal use. PMRs are required studies, whereas PMCs are

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voluntary commitments. We are required to provide the FDA with 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 are enrolling patients 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, 2014.

Under the PMCs, we committed 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. The modifications and usability analysis have been completed, and in September 2011, the FDA notified us that we had fulfilled the requirements of the PMCs.

We are in the process of finalizing the design of a new clinical trial aimed at securing European Medicines Agency approval of Tyvaso for the treatment of PAH. We expect the new trial will be conducted in patients who are either not on an approved background therapy (ETRA or PDE-5 inhibitor) or are on an approved background therapy, but cannot be on dual background therapy for more than one year. The trial's planned primary endpoint is the median change in six-minute walk distance after 24 weeks. The principal reinforcing secondary endpoint will be time to clinical worsening, generally defined as (1) death; (2) an unplanned hospitalization due to PAH; (3) initiation of prostacyclin for the treatment of PAH; (4) a lung transplant; (5) an atrial septostomy procedure, a surgical procedure in which a small hole is created between the upper two chambers of the heart; or (6) a decrease in six-minute walk distance of at least fifteen percent from baseline (or too ill to walk) as a result of the progression of PAH. In order to statistically assess the secondary endpoint of time to clinical worsening, the study will continue to enroll until a pre-specified number of events occur. We plan to begin enrollment during the second half of 2012 and anticipate target enrollment of approximately 800 subjects to obtain data on approximately 256 clinical worsening events.

Oral treprostinil

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 was a 12-week study of patients who are not on any background therapy.

We commenced both trials using a 1.0 mg tablet, but during the open-label extension trial (and an 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 suggested 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 who completed the trial were unable to titrate their doses above 1.0 mg twice-daily.

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In June 2009, we began enrollment of our FREEDOM-C^2 trial, which was a 16-week study of PAH patients on an approved background therapy. In this trial, patients were provided access to a 0.25 mg tablet and doses were titrated in 0.25 mg to 0.5 mg increments. In March 2011, we completed enrollment of FREEDOM-C^2 with 313 patients, compared to a target enrollment of 300 patients. In August 2011, we announced the completion of FREEDOM-C^2 and that the trial did not achieve statistical significance for the primary endpoint of improvement in six-minute walk distance at week 16. Specifically, the placebo-corrected median change in six-minute walk distance at week 16 was 10 meters (p=0.089, Hodges-Lehmann estimate and non-parametric analysis of covariance in accordance with the trial's pre-specified statistical plan).

Enrollment in FREEDOM-M was initially closed in October 2008, with 171 patients enrolled in the trial. In March 2009, the FDA approved a protocol amendment to add patients to the ongoing FREEDOM-M trial. These additional patients were provided access to a 0.25 mg tablet when beginning the trial. We completed enrollment of FREEDOM-M in January 2011 with 349 patients, with the population for the primary analysis consisting of the 228 patients who had access to the 0.25 mg tablet at randomization. In June 2011, we announced the completion of the FREEDOM-M trial and that the trial met its primary endpoint of improvement in six-minute walk distance at week 12. Analysis of the FREEDOM-M results demonstrated that patients receiving oral treprostinil improved their median six-minute walk distance by approximately 23 meters (p=0.0125, Hodges-Lehmann estimate and non-parametric analysis of covariance in accordance with the trial's pre-specified statistical analysis plan) as compared to patients receiving placebo. The median change from baseline at week 12 was 25 meters for patients receiving oral treprostinil and -5 meters for patients receiving placebo. This clinical treatment effect is supported by other secondary efficacy endpoints including the change in six-minute walk distance observed at week 8 (Hodges-Lehmann estimate of +17 meters; p = 0.0307) and combined six-minute walk distance and Borg Dyspnea Score rating (shortness of breath test) at week 12 (p=0.0497).

Based on the positive results achieved in this trial, we submitted an NDA on December 27, 2011. The FDA has accepted the NDA for review and has indicated the filing will be subjected to the standard 10-month review period commencing from the submission date. We have also applied to the FDA for orphan drug designation for oral treprostinil.

Although we believe oral treprostinil is approvable on the basis of the FREEDOM-M study, there can be no guarantee that our NDA will be approved, particularly in light of the FREEDOM-C and FREEDOM-C^2 studies. Furthermore, if our NDA is approved, the results of the FREEDOM-C and FREEDOM-C^2 studies may nonetheless limit our ability to market oral treprostinil in combination with other therapies, and reduce its commercial potential. Therefore, in an effort to provide clinical support for the efficacy of oral treprostinil in combination with other PAH therapies and improve the labeling for oral treprostinil if it is approved, we are designing additional studies. Because we believe that patients in both the FREEDOM-C and FREEDOM-C^2 trials were not provided sufficient amounts of oral treprostinil over an adequate period of time, FREEDOM-C^3 is intended to study the effects of oral treprostinil over a longer period of time than our previous studies and is intended to enable patients to achieve a higher dose. We are finalizing the protocol of a new phase III clinical trial, FREEDOM-C^3, which is described above at *Item 1 Business Products to Treat Cardiopulmonary Diseases UT-15C Sustained Release Tablets (Oral Treprostinil).* We currently have no plans to apply for the approval of oral treprostinil in Europe.

Beraprost-MR

In July 2011, we entered into an exclusive license agreement with Toray Industries, Inc. (Toray) to amend and replace our existing March 2007 license agreement regarding the development of an orally-administered, modified release formulation of the prostacyclin analogue beraprost (beraprost-MR), for the treatment of PAH. Terms of the July 2011 license agreement did not materially change from the

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previous license agreement and license agreement supplements except for a reduction in royalty rates. In exchange for the reduction in royalty rates, we agreed to pay Toray $50.0 million in equal, non-refundable payments over the five-year period ending in 2015. Since these payments are non-refundable and have no contingencies attached to them, we recognized a liability and a corresponding charge to research and development expenses of $46.3 million during the year ended December 31, 2011, which represented the present value of the related payments discounted by our estimated current cost of financing. In November 2011, we announced that a phase II trial of beraprost-SR failed to meet its primary and secondary endpoints. We and Toray continue to assess the results of the phase II trial and are in the process of designing new trials and dosing regimens for beraprost-MR.

Collagen Type V

Pursuant to our February 2010 development agreement with ImmuneWorks, Inc., we are 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.

Cell-Based Therapy

In June 2011, we entered into a license agreement with Pluristem Ltd. (Pluristem) to develop and commercialize a cell-based product for the treatment of pulmonary hypertension using Pluristem's proprietary cell technology. The license agreement became effective in August 2011, at which time we made a one-time, non-refundable payment of $7.0 million to Pluristem, $5.0 million of which consisted of a license fee that was charged to research and development expenses during the quarter ended September 30, 2011.

From inception to December 31, 2011, we have spent $752.1 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 submissions of Chimeric Monoclonal Antibody 14.18 (Ch14.18) for children with high-risk 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 is conducting a clinical trial in approximately 100 patients to define more clearly the safety and toxicity profile of Ch14.18 immunotherapy in children, and we are developing 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 phase III clinical trial and all other necessary studies supported by NCI, will be used as the basis for a Biologics License Application we expect to file seeking FDA approval of Ch14.18 immunotherapy for the treatment of neuroblastoma. We have received orphan drug designation for Ch14.18 from the FDA and European Medicines Agency.

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8H9 Antibody

Pursuant to a December 2007 agreement with Memorial Sloan-Kettering Cancer Center, we obtained certain license rights to an investigational monoclonal antibody, 8H9, for the treatment of metastatic brain cancer. 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.

We have spent $75.0 million from inception to December 31, 2011, 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 that we may elect to test.

On September 30, 2011, we were awarded a cost plus fixed fee contract with an aggregate value of up to $45.0 million under a Broad Agency Announcement from the U.S. National Institute of Allergy and Infectious Diseases for studies directed at the development of a broad spectrum antiviral drug based on our glycobiology antiviral platform. Under the contract's base period of forty-two months, we will receive $10.6 million in funding and there are eight milestone-based options to expand the project and funding under the contract, up to an aggregate of $45.0 million. We recognize revenue on this contract to the extent of costs incurred, plus a proportionate amount of fees earned.

We have spent $52.6 million from inception to December 31, 2011, on our infectious disease programs.

Future Prospects

Because PAH remains a progressive disease without a cure, we expect continued growth in the demand for our commercial products as alternatives or complements to other existing approved therapies. Furthermore, the commercial introduction of Tyvaso and Adcirca has enabled us to offer products to more patients along the full continuum of the disease. The continued achievement of our growth objectives will depend in large part upon the successful commercial development of products within our pipeline. To this end, we submitted to the FDA an NDA for oral treprostinil in December 2011, plan to initiate enrollment in the FREEDOM-C^3 study of oral treprostinil and a new event-driven phase III Tyvaso study during 2012 and continue to develop beraprost-MR. In addition, we seek to expand the use of our therapies to treat patients at earlier stages in the PAH disease progression.

Our future growth and profitability will depend on many factors including, but not limited to: (1) the timing and outcome of clinical trials and regulatory approvals, including the filing and approval of our NDA for oral treprostinil, and the PMR for Tyvaso; (2) the timing of the commercial launch of new products; (3) the pricing of and demand for our products and services; (4) the reimbursement of our products by public and private insurance organizations; (5) the competition we face within our industry; (6) our ability to effectively manage our growth in an increasingly complex regulatory environment; and (7) our ability to defend against generic competition, including the recent challenge to our Remodulin patents by a generic drug company.

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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 late-stage 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 and cash equivalents and marketable investments (excluding restricted amounts) at December 31, 2011 were $747.4 million, compared to approximately $759.9 million as of December 31, 2010. The decrease of $12.6 million resulted from the principal repayment of approximately $250.0 million upon the maturity of our 0.50 percent Convertible Senior Notes due October 15, 2011 (2011 Convertible Notes). This decrease was substantially offset by collections of accounts receivable and customary variances in the volume and timing of disbursements.

Accounts receivable at December 31, 2011, was $88.7 million, compared to $73.7 million at December 31, 2010. The $15.0 million increase corresponded to the increase in sales of our commercial products of nearly twenty percent during the quarter ended December 31, 2011, as compared to the quarter ended December 31, 2010.

The $10.5 million increase in inventory from $35.5 million at December 31, 2010 to $46.0 million at December 31, 2011, reflects our projections regarding future sales.

Goodwill and other intangible assets increased by approximately $12.2 million, from $9.9 million at December 31, 2010, to $22.1 million at December 31, 2011. The increase reflects the recognition of intangible assets and goodwill in connection with our acquisitions of Revivicor, Inc. in July 2011 and certain assets of NEBU-TEC in December 2011. For additional details, refer to *Note 17 Acquisitions*, to our consolidated financial statements included in this Annual Report on Form 10-K.

The increase in property, plant and equipment of $60.0 million, from $306.0 million at December 31, 2010 to $366.0 million at December 31, 2011, was largely driven by our ongoing construction projects in Maryland and North Carolina.

The decrease in deferred tax assets of $15.8 million from $214.7 million at December 31, 2010 to $198.9 million at December 31, 2011 reflects largely the decrease in deductible share-based compensation expense. Refer to *Note 12 Income Taxes* to the consolidated financial statements included in this Annual Report on Form 10-K for details.

The increase in other non-current assets of $16.6 million from $11.1 million at December 31, 2010 to $27.7 million at December 31, 2011 resulted primarily from the sale of Medicomp, Inc. in March 2011. Refer to *Note 18 Sale of Medicomp, Inc.* to the consolidated financial statements included in this Annual Report on Form 10-K for details. In addition, with the issuance of our 1.0 percent Convertible Senior Notes due September 15, 2016 (2016 Convertible Notes) in October 2011, capitalized offering expenses increased by $4.5 million.

Accounts payable at December 31, 2011 was $47.3 million, compared to $16.1 million at December 31, 2010. The increase in accounts payable of $31.1 million was attributable to customary variances in the magnitude, volume and timing of vendor invoices, particularly with respect to construction-related invoices.

Other current liabilities decreased by $18.2 million from $126.3 million at December 31, 2010, to $108.1 million at December 31, 2011. The liability for the STAP decreased by $45.6 million as a direct result of the decline in the price of our common stock. This decrease was offset, in part, by the following elements: (1) an increase in accruals of $6.9 million relating to estimated construction costs incurred for December 2011, for which vendor invoices have not yet been received; (2) $8.8 million

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increase associated with our royalty buy-down obligation to Toray which will be due within one year from December 31, 2011, net of related discount; and (3) an increase of $12.5 million in taxes payable.

Convertible notes (current and non-current) decreased by $41.8 million, from $236.0 million at December 31, 2010 to $194.2 million at December 31, 2011. The decrease in convertible notes reflects the settlement of our 2011 Convertible Notes, partially offset by the $194.2 million net carrying value recognized upon the issuance of the 2016 Convertible Notes. Refer to *Note 8 Debt* to the consolidated financial statements included in this Annual Report on Form 10-K for details.

Other noncurrent liabilities at December 31, 2011 were $80.5 million, compared to $39.3 million at December 31, 2010. The $41.2 million increase was largely due to the recognition of the net, non-current portion of our royalty buy-down obligation to Toray in the amount of $28.3 million and a $6.5 million increase in our supplemental executive retirement plan (SERP) obligation which reflects an increased number of SERP participants.

Additional paid-in capital increased by $64.0 million from $928.7 million at December 31, 2010 to $992.7 million at December 31, 2011. The increase consisted principally of the following elements: (1) increases of $24.0 million and $11.3 million, respectively, relating to proceeds received from stock-option exercises and related tax benefits; (2) an increase of $27.3 million recognized in connection with the value of the shares we received from the exercise of a note hedge upon the conversion of the 2011 Convertible Notes; and (3) an increase of $27.1 million representing the net effects of the issuance of the 2016 Convertible Notes and related note hedge and warrant transactions. These increases were partially offset by a reduction in additional paid-in capital of $26.2 million recognized in connection with an accelerated share repurchase transaction entered into in October 2011, as described more fully in *Note 10 Stockholders' Equity Share Repurchase* to our consolidated financial statements included in this Annual Report on Form 10-K.

Treasury stock was $283.0 million at December 31, 2011, compared to $67.4 million at December 31, 2010. The increase of $215.6 million resulted primarily from the following: (1) an increase of $185.6 million relating to the estimated fair value of our common stock received in connection with an accelerated share repurchase transaction; and (2) an increase of $27.3 million relating to the value of the shares we received from the exercise of a note hedge upon the conversion of our 2011 Convertible Notes.

Results of Operations

Years ended December 31, 2011 and 2010

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

	For Years Ended December 31,		Percentage Change
	2011	2010	
Cardiopulmonary products:			
Remodulin	$ 430,132	$ 403,598	6.6%
Tyvaso	240,382	151,797	58.4%
Adcirca	70,580	36,307	94.4%
Other	2,089	1,197	74.5%
Total revenues	$ 743,183	$ 592,899	25.3%

The growth in revenues for the year ended December 31, 2011, compared to year ended December 31, 2010, corresponded to the continued increase in the number of patients being prescribed our products. For the years ended December 31, 2011 and 2010, approximately 81% and 84%, respectively, of net revenues were derived from our three U.S.-based distributors.

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The table below includes a reconciliation of the accounts associated with estimated rebates, prompt-pay discounts, allowances for sales returns and distributor fees (in thousands):

	Year Ended December 31, 2011				
	Rebates	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, January 1, 2011	$ 10,503	$ 1,467	$ 482	$ 724	$ 13,176
Provisions attributed to sales in:					
Current period	41,231	15,766	923	4,677	62,597
Prior periods	2,853				2,853
Payments or credits attributed to sales in:					
Current period	(27,734)	(14,088)		(4,007)	(45,829)
Prior periods	(12,860)	(1,466)	(3)	(662)	(14,991)
Balance, December 31, 2011	$ 13,993	$ 1,679	$ 1,402	$ 732	$ 17,806

	Year Ended December 31, 2010				
	Rebates	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, January 1, 2010	$ 4,959	$ 979	$ 64	$ 637	$ 6,639
Provisions attributed to sales in:					
Current period	27,028	12,563	418	4,157	44,166
Prior periods	232				232
Payments or credits attributed to sales in:					
Current period	(18,253)	(11,147)		(3,429)	(32,829)
Prior periods	(3,463)	(928)		(641)	(5,032)
Balance, December 31, 2010	$ 10,503	$ 1,467	$ 482	$ 724	$ 13,176

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

	Year Ended December 31,		Percentage Change
	2011	2010	
Project and non-project:			
Cardiopulmonary	$ 150,501	$ 86,161	74.7%
Share-based compensation	(7,994)	45,878	(117.4)%
Other	37,508	33,267	12.7%
Total research and development expense	$ 180,015	$ 165,306	8.9%

Cardiopulmonary. The increase in cardiopulmonary program expenses of $64.3 million for the year ended December 31, 2011, compared to year ended December 31, 2010, corresponded to: (1) an increase of $46.1 million in expenses to develop beraprost-MR, which resulted in large part from our July 2011 license agreement amendment with Toray; (2) an increase of $18.3 million in connection with other cardiopulmonary projects, including a $5.0 million charge incurred in connection with the closing of our license agreement with Pluristem; and (3) an increase of $4.2 million in expenses related to our FREEDOM-C^2 and FREEDOM-M clinical trials.

Share-based compensation. The decrease in share-based compensation of $53.9 million for the year ended December 31, 2011, compared to the year ended December 31, 2010, resulted from the

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decrease in share-based compensation recognized in connection with the STAP as a result of the decline in our stock price.

Other. The increase in other research and development expenses of $4.2 million for the year ended December 31, 2011, compared to the year ended December 31, 2010, was due to an increase of $5.8 million in expenses related to our monoclonal antibody development.

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

	Year Ended December 31,		Percentage
	2011	2010	Change
Category:			
General and administrative	$ 97,785	$ 75,292	29.9%
Sales and marketing	66,405	46,123	44.0%
Share-based compensation	(7,708)	67,191	(111.5)%
Total selling, general and administrative expense	$ 156,482	$ 188,606	(17.0)%

General and administrative. The increase in general and administrative expenses of $22.5 million for the year ended December 31, 2011, compared to the year ended December 31, 2010, was driven by the following: (1) a $4.5 million increase in salaries as a result of headcount growth; (2) a $10.6 million increase in professional fees and other expenses related to our business development activities; (3) a $3.4 million increase in expenses relating to our obligations under contingent payouts to NEBU-TEC; and (4) a $2.7 million increase in general operating expenses, which corresponded to our expansion.

Sales and marketing. The increase in sales and marketing expenses of $20.3 million for the year ended December 31, 2011, compared to the year ended December 31, 2010, was attributable to increases of $9.8 million in salaries due to the expansion of our sales force and $8.4 million in professional fees and expenses incurred in connection with our marketing and advertising initiatives.

Share-based compensation. The decrease in share-based compensation of $74.9 million for the year ended December 31, 2011, compared to the year ended December 31, 2010, corresponded to a reduction in share-based compensation recognized in connection with the STAP as a result of the decline in our stock price.

Income Tax Expense. The provision for income taxes was $81.9 million for the year ended December 31, 2011 compared to $43.9 million for the year ended December 31, 2010. The increase in the provision for income taxes corresponded to the increase in pre-tax earnings. For the years ended December 31, 2011 and December 31, 2010, the effective tax rates were 27.4 percent and 28.3 percent, respectively. For each of these two years, the reduction in the effective tax rates below the applicable statutory rates resulted in large part from the generation of business tax credits relating to our drug-related research and development and activities.

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Years ended December 31, 2010 and 2009

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

	For Years Ended December 31, 2010	2009	Percentage Change
Cardiopulmonary products:			
Remodulin	$ 403,598	$ 331,579	21.7%
Tyvaso	151,797	20,268	648.9%
Adcirca	36,307	5,789	527.2%
Other	1,197	1,244	(3.8)%
Total revenues	$ 592,899	$ 358,880	65.2%

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, by 9.6 percent and 13.3 percent, 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 84% and 87%, respectively, of net revenues were derived from our three U.S.-based distributors.

The table below includes a reconciliation of the accounts associated with estimated rebates, prompt-pay discounts, allowances for sales returns and distributor fees (in thousands):

	Year Ended December 31, 2010				
	Rebates	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, January 1, 2010	$ 4,959	$ 979	$ 64	$ 637	$ 6,639
Provisions attributed to sales in:					
Current period	27,028	12,563	418	4,157	44,166
Prior periods	232				232
Payments or credits attributed to sales in:					
Current period	(18,253)	(11,147)		(3,429)	(32,829)
Prior periods	(3,463)	(928)		(641)	(5,032)
Balance, December 31, 2010	$ 10,503	$ 1,467	$ 482	$ 724	$ 13,176

	Year Ended December 31, 2009				
	Rebates	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, January 1, 2009	$ 3,326	$ 544	$	$ 226	$ 4,096
Provisions attributed to sales in:					
Current period	12,157	7,414	64	1,703	21,338
Prior periods					
Payments or credits attributed to sales in:					
Current period	(6,350)	(6,435)		(1,194)	(13,979)
Prior periods	(4,174)	(544)		(98)	(4,816)
Balance, December 31, 2009	$ 4,959	$ 979	$ 64	$ 637	$ 6,639

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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	
Project and non-project:			
Cardiopulmonary	$ 86,161	$ 61,574	39.9%
Share-based compensation	45,878	36,294	26.4%
Other	33,267	22,500	47.9%
Total research and development expense	$ 165,306	$ 120,368	37.3%

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 by the following: (1) an increase of $12.8 million in expenses incurred in connection with our FREEDOM-M and FREEDOM-C^2 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 as a result of the increase in our stock price.

Other. The increase of $10.8 million in other research and development expenses during the year ended December 31, 2010, compared to those for the year ended December 31, 2009, resulted from an increase in personnel, depreciation and overhead costs supporting our research 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.

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

	For Years Ended December 31,		Percentage Change
	2010	2009	
Category:			
General and administrative	$ 75,292	$ 67,010	12.4%
Sales and marketing	46,123	40,745	13.2%
Share-based compensation	67,191	64,139	4.8%
Total selling, general and administrative expense	$ 188,606	$ 171,894	9.7%

General and administrative. During the year ended December 31, 2010, general and administrative expense increased $8.3 million compared to the year ended December 31, 2009, for the following reasons: (1) increases of $4.5 million and $3.8 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. These increases were offset, in part, by a decrease in impairment charges of $5.1 million.

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Sales and marketing. The increase in sales and marketing expenses of $5.4 million for the year ended December 31, 2010, compared to the year ended December 31, 2009, related to increases of $4.4 million in payroll-related expenses as a result of the growth of our sales force.

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 $43.9 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.

Liquidity and Capital Resources

We have funded our operations principally through sales of our commercial products and, from time-to-time, other third-party financing arrangements. We believe that our current liquidity is sufficient to fund 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 in the future and believe we have the ability to do so. See *Item 1A Risk Factors We have had periods in which we incurred losses and may not maintain profitability* and *Item 1A Risk Factors We may fail to meet our own projected revenues, as well as third-party projections for our revenues or profits*.

Operating Cash Flows and Working Capital

Net cash provided by operating activities was $250.2 million for the year ended December 31, 2011, compared to $211.5 million for the year ended December 31, 2010. The increase in operating cash flows of $38.7 million was driven by increases of $112.0 million in net income and $37.0 million in non-cash license fees to Toray. These increases were offset in part by a $129.7 million reduction in share-based compensation.

At December 31, 2011, we had working capital of $349.9 million, compared to $335.8 million at December 31, 2010. The increase in working capital at December 31, 2011 of $14.1 million resulted from the decrease in the current portion of convertible notes of $236.0 million, offset by a corresponding decrease in cash and cash equivalents and short-term investments of $223.6 million. These decreases reflect in large part the impact of the maturity and conversion of the 2011 Convertible Notes.

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 relates to the portion of long-term financing arrangements that will be due within one year.

In addition, at December 31, 2011, we had approximately $343.5 million of long-term (meaning the security will mature more than one year from December 31, 2011) marketable securities that could be liquidated if necessary to fund our operations.

Lastly, there were approximately 5.1 million vested stock options outstanding at December 31, 2011, with a weighted average exercise price of $36.79 per share. These vested stock options, if exercised, would provide us with additional liquidity.

Construction Projects

During the second quarter of 2011, we began construction to expand our facility in Research Triangle Park, North Carolina (RTP Facility). The expansion of our RTP Facility is intended to provide

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additional warehousing, packaging and office space to accommodate projected growth. We expect to complete the approximately 180,000 square-foot expansion in mid-2012 at an anticipated cost of $74.0 million, which includes construction, equipment and other related costs. In June 2011, we amended a January 2011 construction-management agreement with DPR Construction (DPR) to provide that construction costs cannot exceed a guaranteed maximum price, which is currently set at $50.6 million. DPR will be responsible for any cost overruns that are in excess of the guaranteed maximum price. If the ultimate cost of the project is less than the guaranteed maximum, we will share a portion of the savings with DPR. In addition, DPR must pay us liquidated damages in the event that construction has not been substantially completed by June 2012. Both the guaranteed maximum price and the substantial completion date remain subject to further change in the event of any agreed-upon changes to the scope of work.

In September 2010, we began the construction of an office building to serve as an extension of our Silver Spring facilities. We anticipate total project costs of approximately $58.0 million, which includes the costs of construction and other related costs, and expect to complete this office facility during the first quarter of 2012. In March 2011, we entered into an agreement with DPR to manage this construction project. Under the terms of the agreement, construction costs will not exceed a guaranteed maximum price of approximately $45.3 million, which is subject to change based on agreed-upon changes to the scope of work. DPR will be responsible for covering any cost overruns that are in excess of the guaranteed maximum price. If the ultimate cost of the project is less than the guaranteed maximum, we will share a portion of the savings with DPR.

During the year ended December 31, 2011, we spent approximately $43.1 million related to these construction projects.

Share Tracking Award Plans

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 between 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 requirements under the STAP into 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 individual grants. In February 2012, we increased the number of available STAP awards by 2.0 million awards, primarily to accommodate anticipated grants under our long-term incentive bonus and compensation plan during 2012.

Convertible Notes

2011 Convertible Notes

In October 2006, we issued at par value $250.0 million 2011 Convertible Notes which matured on October 15, 2011. Upon maturity, the aggregate conversion value, which was determined over the consecutive twenty trading-day period beginning on October 17, 2011was $277.3 million. Accordingly, we paid the note holders the outstanding principal amount of the notes totaling $250.0 million in cash and issued 650,827 shares of common stock for the remaining aggregate conversion value.

2016 Convertible Notes

On October 17, 2011, we issued at par $250.0 million of 2016 Convertible Notes. We received $242.5 million in net proceeds from the offering after deducting fees paid to the initial purchaser (Deutsche Bank Securities, Inc.) and our offering expenses. We used the net proceeds to fund: (1) an accelerated share repurchase transaction at a cost of $212.0 million as described in *Note 10 Stockholders' Equity Share Repurchase*; and (2) the convertible note hedge and warrant transactions at

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a net cost of $33.3 million, as described in *Note 8 Debt Convertible Note Hedge and Warrant Transactions* to our consolidated financial statements included in this Annual Report on Form 10-K.

Terms of the 2016 Convertible Notes are substantially similar to those of the 2011 Convertible Notes. Interest will be payable semi-annually, in arrears, on March 15th and September 15th of each year. The initial conversion price is $47.69 per share and the number of shares of our common stock underlying the debt is approximately 5.2 million shares.

Conversion can occur: (1) any time after June 15, 2016; (2) during any calendar quarter that follows a calendar quarter in which the price of our common stock exceeds 130% 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 2016 Convertible Notes is less than 95% of the closing price of our common stock multiplied by the then current number of shares underlying the 2016 Convertible Notes; (4) upon specified distributions to our shareholders; (5) in connection with certain corporate transactions; or (6) in the event that our common stock ceases to be listed on the NASDAQ Global Select Market, the NASDAQ Global Market, or the New York Stock Exchange, or any of their respective successors.

Upon conversion, holders of our 2016 Convertible Notes are entitled to receive: (1) cash equal to the lesser of the principal amount of the notes or the conversion value (the number of shares underlying the 2016 Convertible Notes multiplied by the then-current conversion price per share); and (2) to the extent the conversion value exceeds the principal amount of the notes, shares of our common stock. In the event of a change in control, as defined in the indenture under which the 2016 Convertible Notes have been issued, holders can require us to purchase all or a portion of their 2016 Convertible Notes for 100 percent of the principal amount plus any accrued and unpaid interest.

Mortgage Financing

In December 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. 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, at maturity, we will owe the remaining principal balance of approximately $66.6 million. 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, 2011. 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 June 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

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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, 2011, we were in compliance with the preceding covenants.

Toray License Obligations

Pursuant to a March 2007 amendment to our license agreement for the development of beraprost-MR, we issued 400,000 shares of our common stock to Toray. Terms of these outstanding shares 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. The July 2011 amendment to the license agreement carried forward the original terms relating to these shares. To date, Toray has not notified us that it intends to require us to repurchase these shares.

As part of the July 2011 amendment to our license, we agreed to pay Toray $50.0 million in equal, non-refundable payments over a five-year period ending in 2015 in exchange for a reduction in royalty rates. As of December 31, 2011, the outstanding balance of this obligation was $40.0 million.

Obligations Under License Agreements

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

We have entered into other license rights arrangements under which we are required to make milestone payments upon the achievement of certain developmental and commercialization objectives and royalty payments upon the commercialization of related licensed technology.

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.

Contractual Obligations

At December 31, 2011, we had the following contractual obligations (in thousands):

		Payments Due by Period			
	Total	Less than 1 year	1-3 Years	3-5 Years	More than 5 Years
2016 Convertible Notes(1)	$ 250,000	$	$	$ 250,000	$
Mortgage Loans(2)	72,655	1,208	67,914	3,533	
Obligations under construction commitments(3)	93,009	93,009			
Operating lease obligations	19,296	3,305	6,097	5,668	4,226
Obligations under the STAP(4)	55,477	55,282	130	65	
Obligations under the SERP(5)	32,952			21,142	11,810
Purchase commitments	52,074	22,074	20,000	10,000	
Milestone payments and contingent payments under acquisition agreements(6)	27,628	7,031	3,814	10,492	6,291
Total(7)	$ 603,091	$ 181,909	$ 97,955	$ 300,900	$ 22,327

(1) Assumes payment of the principal balance of the 2016 Convertible Notes, which is to be repaid in cash will occur at the contractual maturity date.

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(2) Includes a $70.0 million mortgage loan which contains prepayment provisions. The timing of related principal payments assumes that the prepayment option will not be exercised during the term of this loan.

(3) Represents total budgeted expenditures for our construction projects, including amounts that are not under contractual commitments at December 31, 2011.

(4) Estimated based on the intrinsic value of outstanding STAP awards expected to vest as of December 31, 2011, assuming that awards will be exercised immediately upon vesting. Refer to *Note 7 Share Tracking Award Plans* to our consolidated financial statements included in this Annual Report on Form 10-K for further details.

(5) Consists of actuarially derived, estimated future payouts of benefits. Refer to *Note 13 Employee Benefit Plans Supplemental Executive Retirement Plan* to our consolidated financial statements included in this Annual Report on Form 10-K for comprehensive disclosures.

(6) Based on our estimates of the timing and probability of achieving milestones specified under our various license arrangements and paying out contingent consideration as specified in our acquisition agreements.

(7) As of December 31, 2011, we had $1.7 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 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: (1) estimated rebates, (2) prompt payment discounts and (3) service fees to our distributors. Calculating these sales allowances involves the use of significant estimates and judgment and information from external sources.

We derive our provisions for rebates from an analysis of historical levels of rebates to both state Medicaid agencies and commercial 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.

We estimate prompt pay discounts based on observed payment behavior. Our distributors have routinely taken advantage of these discounts and we expect them to continue to do so.

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We pay our distributors for contractual services rendered and base related provisions on contracted rates applied to the estimated units of service provided by distributors for a given financial reporting period.

Our distributors do not have return rights; however, we provide exchange rights in the event that product is damaged during shipment, or expires. Exchanges for damaged product are highly infrequent. In the event that 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 damaged product has been replaced. Replacement generally occurs within several days after we are notified of the damage. Furthermore, the number of product exchanges due to expiration has been minimal because we sell Remodulin and Tyvaso with a remaining shelf life in excess of one year and our distributors typically carry a 30- to 60-day supply of our products at any given time. 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 closely track inventory levels in the distribution channels.

The financial effects of exchange rights for Remodulin have been immaterial and we expect the volume of exchanges to be consistent with historical levels. 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.

We recognize sales of Adcirca net of: (1) estimated rebates (including discounts required under Medicare Part D); (2) prompt pay discounts; (3) allowances for product returns; and (4) wholesaler fees. We estimate our liability for rebates based on an analysis of historical levels of rebates to both Medicaid and commercial third-party payers. In addition, we determine our obligation for prescription drug discounts required for Medicare Part D patients within the coverage gap based on estimations of the number of Medicare Part D patients and the period such patients will remain within the coverage gap. We base our estimates for prompt pay discounts on observed customer payment behavior and expectations regarding the future utilization of such discounts. We derive estimates relating to the allowance for returns from published industry data specific to specialty pharmaceuticals and will continue to do so until we have sufficient historical data on which to base our allowance. In addition, we compare patient prescription data for Adcirca to sales of Adcirca on a quarterly basis to ensure a reasonable relationship between prescription and sales trends. To date, we have not identified any unusual patterns in the volume of prescriptions relative to sales that would warrant reconsideration of,

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or adjustment to, the methodology we currently employ to estimate our allowance for returns. Lastly, wholesaler fees are based on contractual percentages of sales to wholesalers.

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 in which the fair value is lower than the carrying value, we periodically review whether related impairments 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 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

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include estimating the amounts and timing of expected cash flows and determining a suitable discount rate.

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 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 in our consolidated financial statements.

Intangible Assets and Goodwill

In connection with transactions that we account for as business combinations, we typically recognize intangible assets, based on their acquisition-date fair value, and goodwill, representing the excess of the fair value of the consideration transferred, over the estimated fair value of assets acquired and liabilities assumed. Measuring the acquisition-date fair value of intangible assets involves the use of significant judgment and estimates with respect to determining, among other inputs: (1) the timing and amounts of cash flows and operating profits for potential product candidates; (2) the timing and probability of regulatory approvals for product candidates under development; (3) the useful lives of potential product candidates; and (4) appropriate discount rates.

We are required to test goodwill and indefinite-lived intangible assets 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, 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 fair value.

We also test our amortizable intangible assets for impairment when conditions suggest that the carrying value of intangible assets may not be recoverable. Evaluating intangible assets for impairment requires judgment, particularly in determining the undiscounted cash flows used in evaluating recoverability. Such projections require forward-looking assumptions that may include 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

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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. Changes in the discount rate can significantly increase or decrease our SERP obligation. For instance, a reduction in the discount rate would increase our projected benefit obligation and result in an actuarial loss. Consequently, we could be required to recognize additional pension expense on our consolidated statements of operations related to the actuarial loss in future periods if certain thresholds are met. 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 assumptions. Changes in any of these assumptions can also affect the measurement of the SERP obligation.

Recently Issued Accounting Standards

In September 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2011-08, *Intangibles Goodwill and Other (Topic 350) Testing Goodwill for Impairment* (ASU 2011-08). ASU 2011-08 gives reporting entities the option to assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying value. If the "more likely than not" threshold is not met, then the two-step impairment test would not be required. ASU 2011-08 also includes examples of factors that entities should consider when performing qualitative assessments that supersede previous examples included under Accounting Standards Codification Topic 350 of circumstances entities should consider when testing goodwill for impairment between annual tests. ASU 2011-08 will be effective for annual impairment tests performed for fiscal years beginning after December 15, 2011. We do not expect the adoption of ASU 2011-08 to have any impact on our consolidated financial statements.

In June 2011, the FASB issued ASU No. 2011-05, *Comprehensive Income (Topic 220) Presentation of Comprehensive Income* (ASU 2011-05). ASU 2011-05 eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity. Instead, ASU 2011-05 requires entities to report all non-owner changes in stockholders' equity in either a single continuous statement of comprehensive income, or in two separate, but consecutive statements. ASU 2011-05 does not change the items that must be reported in other comprehensive income, or when an item must be reclassified to net income. In December 2011, the FASB issued ASU 2011-12, *Comprehensive Income (Topic 220):Presentation of Comprehensive Income Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05* (ASU 2011-12). ASU 2011-12 defers indefinitely provisions contained in ASU 2011-05 that revise existing presentation requirements for reclassification adjustments from comprehensive income as the FASB deliberates this issue at a future date. During the deferral period, reporting entities will continue to follow existing guidance under ASC Topic 220, *Comprehensive Income*, with respect to the disclosure of reclassifications adjustments. Both

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ASU 2011-12 and ASU 2011-05 are effective for fiscal years, and interim periods within those years, beginning after December 15, 2011 and ASU 2011-05 requires retrospective application. Other than the presentational changes to our basic consolidated financial statements that will be required under ASU 2011-05, the adoption of ASU 2011-05 is not expected to have any impact on our consolidated financial statements.

In May 2011, the FASB issued ASU 2011-04, *Fair Value Measurement (Topic 820) Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs* (ASU 2011-04). ASU 2011-04 amends certain fair value principles to improve comparability between GAAP and International Financial Reporting Standards regarding fair value measurements and disclosures. In addition, ASU 2011-04 requires entities to disclose, among others: (1) quantitative information about the significant unobservable inputs used for Level 3 measurements; (2) qualitative information regarding the sensitivity of Level 3 measurements to changes in related unobservable inputs; and (3) the amounts of any transfers between Levels 1 and 2 of the fair value hierarchy and the reasons for those transfers. ASU 2011-04 will become effective during interim and annual periods beginning after December 15, 2011. Other than the additional disclosure requirements with respect to fair value measurements, we do not expect the adoption of ASU 2011-04 to impact our consolidated financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As of December 31, 2011, we have invested $584.3 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 interest rates increase, the market value of a debt investment would be expected to decrease. Conversely, as interest 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 hold these investments to maturity so that they can be redeemed at their stated or face value. At December 31, 2011, our investments in debt securities issued by corporations and federally-sponsored agencies had a weighted average stated interest rate of approximately 0.52 percent. These investments mature at various times through 2013 and many are callable annually.

During sustained periods of instability and uncertainty in the financial markets, we could be exposed to additional investment-related risks that could materially affect the value and liquidity of our investments. 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 maintain a conservative investment approach in that we invest exclusively in highly-rated securities with relatively short maturities that we believe do not expose us to undue risks. 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

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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, 2011 and 2010, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2011. 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, 2011 and 2010, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2011, 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, 2011, 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 28, 2012 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

McLean, Virginia
February 28, 2012

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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, 2011, 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, 2011, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2011 consolidated financial statements of United Therapeutics Corporation, and our report dated February 28, 2012, expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

McLean, Virginia
February 28, 2012

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UNITED THERAPEUTICS CORPORATION

Consolidated Balance Sheets

(In thousands, except share and per share data)

	December 31,	
	2011	**2010**
Assets		
Current assets:		
Cash and cash equivalents	$ 162,676	$ 252,162
Marketable investments	240,803	374,921
Accounts receivable, net of allowance of none for 2011 and 2010	88,680	73,707
Other current assets	6,188	6,840
Prepaid expenses	9,928	8,752
Inventories, net	45,981	35,520
Deferred tax assets	8,199	12,585
Total current assets	562,455	764,487
Marketable investments	343,899	132,849
Marketable investments and cash restricted	5,123	5,122
Goodwill and other intangible assets, net	22,087	9,861
Property, plant, and equipment, net	366,046	306,044
Deferred tax assets, net	190,745	202,135
Other assets	27,724	11,137
Total assets	$ 1,518,079	$ 1,431,635
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 47,257	$ 16,146
Accrued expenses	57,227	50,280
Convertible notes		235,968
Other current liabilities	108,093	126,292
Total current liabilities	212,577	428,686
Convertible notes	194,180	
Mortgages payable	71,452	68,929
Other liabilities	80,500	39,252
Total liabilities	558,709	536,867
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 shares authorized, 61,506,063 and 60,017,546 shares issued, and 53,609,645 and 57,555,893 shares outstanding at December 31, 2011 and 2010, respectively	615	600
Additional paid-in capital	992,718	928,690
Accumulated other comprehensive loss	(10,885)	(9,175)
Treasury stock at cost, 7,896,418 and 2,461,653 shares at December 31, 2011 and 2010, respectively	(282,998)	(67,399)
Retained earnings	249,038	31,170

Total stockholders' equity	948,488	883,886
Total liabilities and stockholders' equity	$ 1,518,079	$ 1,431,635

See accompanying notes to consolidated financial statements.

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UNITED THERAPEUTICS CORPORATION

Consolidated Statements of Operations

(In thousands, except per share data)

	Year Ended December 31,		
	2011	**2010**	**2009**
Revenues:			
Net product sales	$ 741,094	$ 591,702	$ 357,636
Other	2,089	1,197	1,244
Total revenue	743,183	592,899	358,880
Operating expenses:			
Research and development	180,015	165,306	120,368
Selling, general and administrative	156,482	188,606	171,894
Cost of product sales	88,904	67,674	40,861
Total operating expenses	425,401	421,586	333,123
Operating income	317,782	171,313	25,757
Other (expense) income:			
Interest income	3,450	2,939	5,146
Interest expense	(21,367)	(19,710)	(12,875)
Equity loss in affiliate	(119)	(160)	(141)
Other, net	(629)	769	736
Total other (expense) income, net	(18,665)	(16,162)	(7,134)
Income from continuing operations before income taxes	299,117	155,151	18,623
Income tax (expense) benefit	(81,874)	(43,945)	695
Income from continuing operations	217,243	111,206	19,318
Discontinued operations			
Income (loss) from discontinued operations, net of tax	7	(5,290)	144
Gain on disposal of discontinued operations, net of tax	618		
Income (loss) from discontinued operations	625	(5,290)	144
Net income	$ 217,868	$ 105,916	$ 19,462
Net income per common share:			
Basic			
Continuing operations	$ 3.80	$ 1.98	$ 0.36
Discontinued operations	0.01	(0.09)	0.01
Net income per basic common share	$ 3.81	$ 1.89	$ 0.37
Diluted			
Continuing operations	$ 3.66	$ 1.87	$ 0.34
Discontinued operations	0.01	(0.09)	0.01
Net income per diluted common share	$ 3.67	$ 1.78	$ 0.35

Weighted average number of common shares outstanding:			
Basic	57,163	56,142	53,314
Diluted	59,395	59,516	56,133

See accompanying notes to consolidated financial statements.

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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)	Stockholders' Equity
	Shares	Amount					
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
Conversion of convertible notes	63		3		(4)		(1)
Exercise of stock options	3,335,114	33	83,313				83,346
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
Net income						217,868	217,868
Foreign currency translation adjustments				(1,709)			(1,709)
Unrealized gain on available-for-sale securities				6			6
Unrealized loss on pension liability				(7)			(7)
Total other comprehensive income				(1,710)		217,868	216,158
Shares received as part of Medicomp sale					(2,750)		(2,750)
Conversion of 2011 convertible notes and exercise of convertible note hedge	650,827	7	27,287		(27,294)		
Issuance of 2016 convertible notes (Note 8)			56,192				56,192
2016 convertible note hedge and warrants, net of tax (Note 8)			(29,069)				(29,069)
Share repurchase (Note 10)			(26,211)		(185,555)		(211,766)
Exercise of stock options	837,690	8	23,955				23,963
Tax benefit from exercises of non-qualified stock options			11,347				11,347
Share-based compensation			527				527
Balance, December 31, 2011	61,506,063	$ 615	$ 992,718	$ (10,885)	$ (282,998)	$ 249,038	$ 948,488

See accompanying notes to consolidated financial statements.

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UNITED THERAPEUTICS CORPORATION

Consolidated Statements of Cash Flows

(In thousands)

	Year Ended December 31,		
	2011	**2010**	**2009**
Cash flows from operating activities:			
Net income	$ 217,868	$ 105,916	$ 19,462
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	20,535	17,920	11,394
Provisions for bad debt and inventory obsolescence	5,180	2,398	4,675
Share-based compensation (benefit) expense	(15,715)	113,942	101,015
Impairments		7,688	4,494
Expense associated with outstanding license fees	37,049		
Amortization of debt discount and issue costs	19,359	16,839	15,714
Current and deferred tax expense (benefit)	81,432	41,923	(1,038)
Amortization of discount or premium on investments	4,474	2,574	1,551
Equity loss in affiliate and other	2,614	967	(1,848)
Excess tax benefits from share-based compensation	(11,347)	(23,826)	(4,406)
Changes in assets and liabilities:			
Accounts receivable	(16,158)	(23,452)	(21,956)
Inventories	(16,055)	(9,196)	(9,061)
Prepaid expenses	(2,107)	(587)	3,422
Other assets	(3,626)	(4,776)	(196)
Accounts payable	16,656	(2,734)	(3,645)
Accrued expenses	3,595	25,612	9,203
Other liabilities	(93,559)	(59,676)	(29,057)
Net cash provided by operating activities	250,195	211,532	99,723
Cash flows from investing activities:			
Purchases of property, plant and equipment	(35,977)	(18,640)	(95,400)
Purchases of held-to-maturity investments	(815,684)	(662,225)	(310,634)
Maturities of held-to-maturity investments	733,876	421,528	249,083
Sales of trading investments		36,200	
Acquisitions	(3,547)		(3,568)
Restrictions on cash	(1)	13,901	(2,099)
Net cash used in investing activities	(121,333)	(209,236)	(162,618)
Cash flows from financing activities:			
Principal payments of debt	(251,039)		
Proceeds received from issuance of debt	250,000	70,000	
Payments of transaction costs related to issuance of debt	(7,535)	(1,055)	
Payment for convertible note hedge and warrants, net	(33,250)		
Payment of lease obligation		(31,442)	
Payment for an accelerated share repurchase transaction (Note 10)	(212,000)		
Proceeds from exercise of stock options	24,398	85,427	32,071
Excess tax benefits from share-based compensation	11,347	23,826	4,406
Net cash (used in) provided by financing activities	(218,079)	146,756	36,477
Effect of exchange rate changes on cash and cash equivalents	(269)	2,758	(2,682)
Net (decrease) increase in cash and cash equivalents	(89,486)	151,810	(29,100)
Cash and cash equivalents, beginning of year	252,162	100,352	129,452

Cash and cash equivalents, end of year	$ 162,676	$ 252,162	$ 100,352
Supplemental cash flow information:			
Cash paid for interest	$ 4,103	$ 1,818	$ 1,250
Cash paid for income taxes	$ 46,939	$ 22,683	$ 23,931
Non-cash investing and financing activities:			
Acquisitions non-cash consideration	$ 5,873	$	$ 4,776
Non-cash additions to property, plant and equipment	$ 23,063	$ 2,445	$ 2,571
Issuance of common stock upon conversion of convertible notes	$ 27,294	$	$
Assumption of mortgage in connection with the acquisition of property	$ 3,736	$	$

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 otherwise requires, the terms "we," "us," "our," and similar terms refer to United Therapeutics Corporation and its consolidated subsidiaries.

Our lead product, Remodulin® (treprostinil) Injection (Remodulin), was first approved in 2002 by the United States Food and Drug Administration (FDA) and has also been approved for use in countries outside of the United States. We sell Remodulin in the United States and in various other countries around the world. In 2009, we received FDA approval for Tyvaso® (treprostinil) Inhalation Solution (Tyvaso) and Adcirca® (tadalafil) tablets (Adcirca), both of which we market 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. The operating results of Medicomp, Inc. for each of the three years in the three-year period ended December 31, 2011 have been reclassified and presented within discontinued operations on our consolidated statements of operations. This change in presentation had no impact on net income as previously reported. We did not recast our consolidated balance sheet at December 31, 2010 or our consolidated statements of stockholders' equity or cash flows for years ended December 31, 2010 and 2009 to reflect the classification of Medicomp, Inc. as a discontinued operation as the impact is not significant to those statements (refer to Note 18 *Sale of Medicomp, Inc.*).

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. However, because the use of estimates involves an inherent degree of uncertainty, 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 (including those relating to our acquisitions), 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 our marketable investments and 1.0% Convertible Senior Notes due September 15, 2016 (2016 Convertible Notes) are reported in Notes 4 *Marketable Investments* and 5 *Fair Value Measurements*, respectively.

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

The recorded value of our $70.0 million 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 8 *Debt Mortgage Financing Wells Fargo*.

Fair Value Measurements

Fair value is a market-based measurement, not an entity-specific measurement. The objective of a fair value measurement is to estimate the price to sell an asset or transfer a liability in an orderly transaction between market participants at the measurement date under current market conditions. Such transactions to sell an asset or transfer a liability are assumed to occur in the principal market for that asset or liability, or in the absence of the principal market, the most advantageous market for the asset or liability.

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 to determine fair value. 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.

Marketable Investments

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

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 attributable to the estimated credit loss. In determining whether a decline in the value of an investment is other-than-temporary, we evaluate currently available factors that may include, among others: (1) general market conditions, (2) the duration and extent to which fair value has been less than the carrying value, (3) the investment issuer's financial condition and business outlook, and (4) our

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

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.

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.

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,	
	2011	**2010**
Pharmaceutical Products:		
Raw materials	$ 9,171	$ 2,788
Work in progress	14,222	18,598
Finished goods	22,588	13,098
Delivery pumps, supplies and equipment		1,036
Total inventories	$ 45,981	$ 35,520

Goodwill and Other Intangible Assets

The carrying amount of goodwill and indefinite-lived intangible assets are not amortized but subject to annual impairment testing. We evaluate goodwill and indefinite-live intangible assets 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). 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).

In February 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 carrying value of Medicomp's goodwill at December 31, 2010 and recognized a related impairment charge of $6.2 million, which has been included within the results of discontinued operations on our consolidated statement of operations for the year ended December 31, 2010.

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 carrying amount.

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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, 2011			As of December 31, 2010		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Goodwill(1)(2)	$ 8,123	$	$ 8,123	$ 2,487	$	$ 2,487
Other intangible assets(1):						
Technology, patents and tradenames	4,766	(1,999)	2,767	8,991	(5,368)	3,623
Customer relationships and non-compete agreements	4,653	(1,658)	2,995	4,762	(1,011)	3,751
Contract-based(2)	8,350	(148)	8,202			
Total	$ 25,892	$ (3,805)	$ 22,087	$ 16,240	$ (6,379)	$ 9,861

(1) Includes foreign currency translation adjustments.

(2) Refer to *Note 17 Acquisitions*.

We are amortizing other intangible assets over an estimated weighted average life of 12.1 years. Related amortization expense for the years ended December 31, 2011, 2010 and 2009, was $1.7 million, $1.6 million and $717,000, respectively. As of December 31, 2011, aggregate amortization expense relating to intangible assets for each of the five succeeding years and thereafter is estimated as follows (in thousands):

Year Ended December 31,	
2012	$ 1,834
2013	1,812
2014	1,804
2015	1,556
2016	1,060
Thereafter	5,898
	$ 13,964

Property, Plant and Equipment

Property, plant and equipment is recorded at cost and depreciated over its estimated useful life 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
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,	
	2011	**2010**
Land	$ 21,723	$ 20,236
Buildings, building improvements and leasehold improvements	249,289	239,473
Buildings under construction	72,511	7,241
Furniture, equipment and vehicles	75,801	77,287
	419,324	344,237
Less accumulated depreciation	(53,278)	(38,193)
Property, plant and equipment, net	$ 366,046	$ 306,044

Depreciation expense for the years ended December 31, 2011, 2010 and 2009 was $18.2 million, $17.6 million and $10.7 million, respectively.

Buildings under construction at December 31, 2011 and 2010 consists of direct costs relating to our construction projects, including capitalized interest. We expect to complete the expansion of our corporate headquarters located in Maryland in the first quarter of 2012 and our North Carolina facility in mid-2012. At December 31, 2011 and 2010, we capitalized interest of $842,000 and $103,000, respectively, relating to these 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 *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, 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.

We derive our provisions for rebates from an analysis of historical levels of rebates 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. Since rebate eligibility and pricing requirements can differ for Remodulin and Tyvaso, we analyze rebate data separately for each of these products.

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

We estimate prompt pay discounts based on observed payment behavior. Our distributors have routinely taken advantage of these discounts and we expect them to continue to do so.

We pay our distributors for contractual services rendered and accrue for related fees 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 is damaged during shipment or expires. Exchanges for damaged product are highly infrequent. In the event that 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 damaged product has been replaced. Replacement of damaged product generally occurs within several days after we are notified of the damage. Furthermore, the number of product exchanges due to expiration has been minimal because we sell Remodulin and Tyvaso with a remaining shelf life in excess of one year and our distributors typically carry a 30- to 60-day supply of our products at any given time. In addition, we closely track inventory levels in the distribution channels and 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.

The financial effects of exchange rights for Remodulin have been immaterial and we expect the volume of exchanges to be consistent with historical levels. 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 and the level of product exchanges for Tyvaso has been less than that of Remodulin, we expect that exchanges of Tyvaso will continue to be less than or comparable to exchanges 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 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 to customers, and 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.

We recognize sales of Adcirca net of: (1) estimated rebates (including discounts required under Medicare Part D); (2) prompt pay discounts; (3) allowances for product returns; and (4) wholesaler fees. We estimate our liability for rebates based on an analysis of historical levels of rebates to both Medicaid and commercial third-party payers. In addition, we determine our obligation for prescription

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

drug discounts required for Medicare Part D patients within the coverage gap based on estimations of the number of Medicare Part D patients and the period such patients will remain within the coverage gap. We base our estimates for prompt pay discounts on observed customer payment behavior and expectations regarding the future utilization of such discounts. We derive estimates relating to the allowance for returns from published industry data specific to specialty pharmaceuticals and will continue to do so until we have sufficient historical data on which to base our allowance. In addition, we compare patient prescription data for Adcirca to sales of Adcirca on a quarterly basis to ensure a reasonable relationship between prescription and sales trends. To date, we have not identified any unusual patterns in the volume of prescriptions relative to sales that would warrant reconsideration of, or adjustment to, the methodology we currently employ to estimate our allowance for returns. Lastly, wholesaler fees are based on contractual percentages of sales to wholesalers.

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 in-house or contracted production activities 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, 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 Award Plans, 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.

Generally, the fair value of a stock option grant is measured on its grant date and related compensation expense is recognized ratably over the requisite service period. Compensation expense is recognized in its entirety based on the grant-date fair value for stock option awards that vest immediately upon issuance. Compensation expense is accrued for performance-based stock option grants when we determine it is probable that the performance criteria will be met.

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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, 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 highly-rated securities with relatively short maturities that we believe do not subject us to undue investment risk. At any given time, our trade receivables are concentrated among a small number of principal customers. If any of these financial institutions, issuers or customers fail to perform their obligations under the terms of these financial instruments, our maximum exposure to potential losses would equal amounts reported on our consolidated balance sheets.

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

Concentration of products, revenues and customers

During the years ended December 31, 2011, 2010 and 2009, net sales of Remodulin accounted for 58%, 68% and 92%, respectively, of our total net revenues. Net sales of Remodulin in the United States to our three distributors comprised 49%, 59% and 81%, respectively, of our total net revenues. In addition, these three U.S.-based distributors are our sole customers for Tyvaso. Net sales of Tyvaso during the years ended December 31, 2011, 2010 and 2009 comprised 32%, 26% and 6% of our net revenues.

At December 31, 2011 and 2010, 68% and 77%, 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, 2011, 2010 and 2009, we derived 61%, 65% and 71% of our total net product revenues from one customer. Estimated net revenues from that customer were as follows (in thousands):

	Year Ended December 31,		
	2011	2010	2009
Accredo Health Group, Inc.	$ 455,504	$ 387,251	$ 253,314

3. Recently Issued Accounting Standards

In September 2011, the FASB issued Accounting Standards Update (ASU) No. 2011-08, *Intangibles Goodwill and Other (Topic 350) Testing Goodwill for Impairment* (ASU 2011-08). ASU 2011-08 gives reporting entities the option to assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying value. If the "more likely than not" threshold is not met, then the two-step impairment test would not be required. ASU 2011-08 also includes examples of factors that entities should consider when performing qualitative assessments that supersede previous examples included under Accounting Standards Codification Topic 350 of circumstances entities should consider when testing goodwill for impairment between annual tests. ASU 2011-08 will be effective for annual impairment tests performed for fiscal years beginning after December 15, 2011. We do not expect the adoption of ASU 2011-08 to have any impact on our consolidated financial statements.

In June 2011, the FASB issued ASU No. 2011-05, *Comprehensive Income (Topic 220) Presentation of Comprehensive Income* (ASU 2011-05). ASU 2011-05 eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity. Instead, ASU 2011-05 requires entities to report all non-owner changes in stockholders' equity in either a single continuous statement of comprehensive income, or in two separate, but consecutive statements. ASU 2011-05 does not change the items that must be reported in other comprehensive income, or when an item must be reclassified to net income. In December 2011, the FASB issued ASU 2011-12, *Comprehensive Income (Topic 220):Presentation of Comprehensive Income Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05* (ASU 2011-12). ASU 2011-12 defers indefinitely provisions contained in ASU 2011-05 that revise existing presentation requirements for reclassification

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

3. Recently Issued Accounting Standards (Continued)

adjustments from comprehensive income as the FASB deliberates this issue at a future date. During the deferral period, reporting entities will continue to follow existing guidance prior to ASU 2011-05 under ASC Topic 220, *Comprehensive Income*, with respect to the disclosure of reclassifications adjustments. Both ASU 2011-12 and ASU 2011-05 are effective for fiscal years, and interim periods within those years, beginning after December 15, 2011 and ASU 2011-05 requires retrospective application. Other than the presentational changes to our basic consolidated financial statements that will be required under ASU 2011-05, the adoption of ASU 2011-05 is not expected to have any impact on our consolidated financial statements.

In May 2011, the FASB issued ASU 2011-04, *Fair Value Measurement (Topic 820) Amendments to Achieve Common Fair Value Measurement and Disclosure Requirements in U.S. GAAP and IFRSs* (ASU 2011-04). ASU 2011-04 amends certain fair value principles to improve comparability between GAAP and International Financial Reporting Standards regarding fair value measurements and disclosures. In addition, ASU 2011-04 requires entities to disclose, among others: (1) quantitative information about the significant unobservable inputs used for Level 3 measurements; (2) qualitative information regarding the sensitivity of Level 3 measurements to changes in related unobservable inputs; and (3) the amounts of any transfers between Levels 1 and 2 of the fair value hierarchy and the reasons for those transfers. ASU 2011-04 will become effective during interim and annual periods beginning after December 15, 2011. Other than the additional disclosure requirements with respect to fair value measurements, we do not expect the adoption of ASU 2011-04 to impact our consolidated financial statements.

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, 2011	$ 308,202	$ 155	$ (170)	$ 308,187
Corporate notes and bonds at December 31, 2011	276,118	113	(442)	275,789
Total	$ 584,320	$ 268	$ (612)	$ 583,976
Reported under the following captions on the consolidated balance sheet at December 31, 2011:				
Current marketable investments	$ 240,803			
Noncurrent marketable investments	343,517			
	$ 584,320			

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

4. Marketable Investments (Continued)

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Government-sponsored enterprises at December 31, 2010	$ 282,005	$ 52	$ (152)	$ 281,905