

UNITED THERAPEUTICS Corp  
Form 10-K  
February 25, 2014

Use these links to rapidly review the document

[TABLE OF CONTENTS](#)

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

[Table of Contents](#)

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

---

**FORM 10-K**

(Mark One)

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

**For the fiscal year ended December 31, 2013**

**OR**

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

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

**United Therapeutics Corporation**

(Exact Name of Registrant as Specified in Its Charter)

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

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

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

**20910**  
(Zip Code)

**(301) 608-9292**

Registrant's Telephone Number, Including Area Code

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

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

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

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

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

**None**  
(Title of Class)

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

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

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

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

The aggregate market value of the Common Stock held by non-affiliates of the registrant, based on the closing price on June 28, 2013, as reported by the NASDAQ Global Select Market was approximately \$2,458,927,716.

**The number of shares outstanding of the issuer's common stock, par value \$0.01 per share, as of February 18, 2014, was 50,477,071.**

## DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for the registrant's 2014 annual meeting of shareholders scheduled to be held on June 26, 2014, are incorporated by reference in Part III of this Form 10-K.

---

Table of Contents

**TABLE OF CONTENTS**

<u>PART I</u>		
<u>Item 1.</u>	<u>Business</u>	<u>3</u>
<u>Item 1A.</u>	<u>Risk Factors</u>	<u>38</u>
<u>Item 1B.</u>	<u>Unresolved Staff Comments</u>	<u>57</u>
<u>Item 2.</u>	<u>Properties</u>	<u>57</u>
<u>Item 3.</u>	<u>Legal Proceedings</u>	<u>58</u>
<u>Item 4.</u>	<u>Mine Safety Disclosures</u>	<u>58</u>
<u>PART II</u>		
<u>Item 5.</u>	<u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	<u>59</u>
<u>Item 6.</u>	<u>Selected Financial Data</u>	<u>60</u>
<u>Item 7.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>62</u>
<u>Item 7A.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>86</u>
<u>Item 8.</u>	<u>Financial Statements and Supplementary Data</u>	<u>F-1</u>
<u>Item 9.</u>	<u>Changes In and Disagreements With Accountants on Accounting and Financial Disclosure</u>	<u>88</u>
<u>Item 9A.</u>	<u>Controls and Procedures</u>	<u>88</u>
<u>Item 9B.</u>	<u>Other Information</u>	<u>88</u>
<u>PART III</u>		
<u>Item 10.</u>	<u>Directors, Executive Officers and Corporate Governance</u>	<u>89</u>
<u>Item 11.</u>	<u>Executive Compensation</u>	<u>90</u>
<u>Item 12.</u>	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	<u>91</u>
<u>Item 13.</u>	<u>Certain Relationships and Related Transactions, and Director Independence</u>	<u>91</u>
<u>Item 14.</u>	<u>Principal Accounting Fees and Services</u>	<u>91</u>
<u>PART IV</u>		
<u>Item 15.</u>	<u>Exhibits, Financial Statement Schedules</u>	<u>92</u>
<u>SIGNATURES</u>		<u>93</u>

Table of Contents

**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), which is administered subcutaneously (under the skin) or intravenously (in the vein) for the treatment of pulmonary arterial hypertension (PAH). The United States Food and Drug Administration (FDA) approved Remodulin in 2002 for subcutaneous administration. Subsequently, the FDA broadened its approval of Remodulin for intravenous use and for the treatment of patients who require transition from Flolan® (epoprostenol), the first FDA-approved prostacyclin therapy for PAH. Outside the United States, Remodulin is approved in 37 countries, most of which have approved both routes of administration. In 2009, the FDA approved Tyvaso® (treprostinil) Inhalation Solution (Tyvaso), an inhaled prostacyclin therapy for the treatment of PAH. In December 2013, the FDA approved Orenitram™ (treprostinil) Extended-Release Tablets (Orenitram), which we expect to make commercially available in mid-2014. We are also conducting pre-clinical studies of a self-injectable form of treprostinil, which we refer to as TransCon treprostinil. Our wholly-owned subsidiary Lung Biotechnology Inc., formerly known as Lung LLC, is developing another prostacyclin analogue we licensed from Toray Industries, Inc. (Toray) called beraprost, for treatment of PAH both as an oral tablet known as 314d and as an extended release injection we refer to as TransCon beraprost.

*Phosphodiesterase Type 5 (PDE-5) Inhibitor.* PDE-5 inhibitors act to inhibit the degradation of cyclic guanosine monophosphate (cyclic GMP) in cells. Cyclic GMP is activated by nitric oxide (NO), a naturally occurring substance in the body that mediates the 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 exclusive U.S. commercialization rights to Adcirca from Eli Lilly and Company (Lilly) in 2008. In 2009, the FDA approved Adcirca for the treatment of PAH.

*Monoclonal Antibody (MAb).* 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 (NCI) of the United States National Institutes of Health (NIH). In December 2013, our marketing authorization application (MAA) for this antibody was accepted for review by the European Medicines Agency (EMA) and we plan to file a biologics license application (BLA) with the FDA during the first half of 2014.

*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 National Institute of Allergy and Infectious Diseases (NIAID) of the NIH for studies directed at the development of a broad spectrum antiviral drug based on our glycobiology antiviral platform. During the first half of 2014, we plan to begin enrolling a phase I clinical trial of our lead antiviral candidate, an alpha-glucosidase inhibitor called UV-4B, for the treatment of dengue.

*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

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

## Table of Contents

(PLX) cells for the treatment of PAH. We commenced a phase I clinical study in Australia in 2013.

*Lung Transplantation.* The only reported cure for PAH is a lung transplant. Using the xenotransplantation technology we acquired through our July 2011 acquisition of Revivicor Inc. and several regenerative medicine technologies that we have licensed, we are in the early pre-clinical stage of developing engineered lungs and lung tissue for transplant into patients suffering from PAH and other lung diseases. We are also developing technologies to increase the supply of donor lungs through collaborations with two ex-vivo lung perfusion companies.

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

Through 2013, we have generated revenues primarily from the sale of Remodulin, Tyvaso and Adcirca (which we refer to as our commercial products). Despite the planned commercial launch of Orenitram in mid-2014, we expect that sales of Remodulin, Tyvaso and Adcirca will continue to be our primary sources of revenues for the next several years. 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 contracted specialty pharmaceutical distributors in the United States and 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:

<b>Product</b>	<b>Mode of Delivery</b>	<b>Indication/Market</b>	<b>Current Status</b>	<b>Our Territory</b>
Remodulin	Continuous subcutaneous	Pulmonary arterial hypertension	Commercial in the U.S., most of Europe*, Argentina, Canada, Chile, Israel, Mexico, Peru, Puerto Rico, Saudi Arabia, South Korea, Taiwan and Venezuela; also approved in China	Worldwide
Remodulin	Continuous intravenous	Pulmonary arterial hypertension	Commercial in the U.S., Argentina, Canada, Israel, Puerto Rico, Saudi Arabia and Switzerland; also approved in most of Europe*, China, Mexico, Peru and South Korea	Worldwide
Tyvaso	Inhaled	Pulmonary arterial hypertension	Commercial in the U.S. and Puerto Rico	Worldwide
Adcirca	Oral	Pulmonary arterial hypertension	Commercial in the U.S. and Puerto Rico	United States and Puerto Rico
Orenitram	Oral	Pulmonary arterial hypertension	Approved by the FDA; commercial launch expected mid-2014	Worldwide

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

### Table of Contents

<b>Product</b>	<b>Mode of Delivery</b>	<b>Indication/Market</b>	<b>Current Status</b>	<b>Our Territory</b>
Ch14.18 MAb	Intravenous	Neuroblastoma	MAA filed with the EMA in December 2013; BLA filing with the FDA expected first half of 2014	Worldwide
Orenitram Combination Therapy	Oral	Pulmonary arterial hypertension	Phase III	Worldwide
Remodulin	Continuous intravenous via implantable pump	Pulmonary arterial hypertension	Phase III	United States, United Kingdom, France, Germany, Italy and Japan
Beraprost 314d	Oral	Pulmonary arterial hypertension	Phase III	North America, Europe, Mexico, South America, Egypt, India, South Africa and Australia
PLX Cells	Intravenous	Pulmonary arterial hypertension	Phase I	Worldwide
UV-4B	Oral	Dengue	Phase I (plan to commence enrollment first half of 2014)	Worldwide
TransCon Treprostinil	Self-Injection	Pulmonary arterial hypertension	Pre-Clinical	Worldwide
TransCon Beraprost	Self-Injection	Pulmonary arterial hypertension	Pre-Clinical	Worldwide, except Asia
Glycobiology Antiviral Agents	Oral	Broad-spectrum agents against viral infectious diseases	Pre-Clinical	Worldwide
Lung Transplantation	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.

### **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. We believe that PAH affects about 500,000 individuals worldwide. The awareness of PAH continues to grow, as we have seen increases 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.

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

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-K

*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

Table of Contents

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 cyclic GMP. Therefore, another established therapeutic approach has been to inhibit the degradation of cyclic GMP, using drugs that are known as PDE-5 inhibitors.

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

Because any or all of the three pathways may be therapeutic targets in a patient, these three classes of drugs are used alone or in combination to treat patients with PAH. We currently market drugs in two of these three classes. Remodulin and Tyvaso are prostacyclin analogues, and Adcirca is a PDE-5 inhibitor. We plan to begin selling another prostacyclin analogue, Orenitram, in mid-2014.

***Remodulin***

One of our lead products for treating PAH is Remodulin, the active pharmaceutical ingredient of which is a prostacyclin analogue known as treprostinil. We sell Remodulin to specialty pharmaceutical distributors in the United States and to pharmaceutical distributors internationally. We recognized approximately \$491.2 million, \$458.0 million and \$430.1 million in Remodulin revenues, representing 44 percent, 50 percent and 58 percent of our net revenues for the years ended December 31, 2013, 2012 and 2011, respectively. The FDA approved Remodulin as a continuous subcutaneous infusion therapy in 2002, and as a continuous intravenous infusion therapy in 2004. Remodulin is indicated to treat patients with PAH (World Health Organization (WHO) Group 1) to diminish symptoms associated with exercise. Studies establishing effectiveness included patients with New York Heart Association (NYHA) Functional Class II-IV (moderate to severe) symptoms. In 2006, the FDA expanded its approval to include transition of patients to Remodulin from Flolan, the first FDA-approved prostacyclin therapy for PAH. In 2007, the results of a prospective, open-label study demonstrated that stable patients with PAH can be safely transitioned from Flolan to intravenous Remodulin using a rapid switch protocol.

Outside of the United States, Remodulin is approved for treatment of PAH in 38 countries by continuous subcutaneous administration and in 32 countries, including 23 countries in Europe that granted approval in December 2011, by continuous intravenous administration. Applications for approval of both subcutaneous and intravenous Remodulin are under review in other countries. We continue to work toward commercializing Remodulin in new territories, including Japan (where we filed a marketing application during the third quarter of 2013) and China (where we received marketing approval in March 2013, and expect commercial launch in 2014).

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. Generic formulations of Flolan are also available. We believe subcutaneous Remodulin provides patients with a less invasive alternative to Flolan. In contrast to Flolan, Remodulin is stable at room temperature and lasts significantly longer inside the human body. These attributes allow for more convenient drug delivery to patients. Unlike Flolan, Remodulin can be delivered by subcutaneous infusion with a pager-sized miniature infusion pump. Subcutaneous delivery of Remodulin also eliminates the risk of central venous catheter infection and the hospitalization



Table of Contents

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 its subcutaneous formulation to be packaged as an aqueous solution, so patients do not have to mix the drug as they do with Flolan. Remodulin can be continuously infused for up to 48 hours before refilling the infusion pump, unlike Flolan, which must be mixed and refilled every 24 hours. Treprostinil, the active ingredient in Remodulin, is highly soluble in an aqueous solution, which enables us to manufacture Remodulin in highly concentrated solutions. This allows therapeutic concentrations of Remodulin to be delivered at low flow rates via miniaturized infusion pumps for both subcutaneous and intravenous infusion. Lastly, Remodulin does not require the patient to keep the drug cool during infusion. This eliminates the need for cooling packs or refrigeration to keep Remodulin stable, as is required with Flolan due to Flolan's chemical instability at room temperature.

In 2008, the FDA approved Teva Pharmaceuticals Industries Ltd.'s (Teva) version of generic epoprostenol (the active ingredient in Flolan) for the treatment of PAH, which has all of the attributes of Flolan discussed above. Also in 2008, the FDA approved another intravenous version of epoprostenol, which is currently marketed by Actelion Pharmaceuticals Ltd (Actelion) under the name Veletri®. Veletri is stable at room 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. Actelion also markets Tracleer® and Opsumit®, both ETRAs, and Ventavis®, an inhaled prostacyclin.

In February 2012, we received notice of an abbreviated new drug application (ANDA) by Sandoz Inc. (Sandoz) requesting FDA approval to market a generic version of the 10 mg/mL strength of Remodulin. In December 2012, we received notice that Sandoz had amended its previously filed ANDA to request additional approval to market generic versions of the 1 mg/mL, 2.5 mg/mL, and 5 mg/mL strengths of Remodulin. For further details, see the sections below entitled *Governmental Regulation Hatch-Waxman Act and Item 3. Legal Proceedings*.

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 infusion site pain related to use of subcutaneous Remodulin may instead use intravenous Remodulin. Intravenous Remodulin is delivered continuously 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. General side effects associated with Remodulin include diarrhea, jaw pain, vasodilation and edema.

*International Regulatory Review of Subcutaneous and Intravenous Remodulin*

Remodulin is approved in 38 countries outside the United States. In 32 of these countries, it is approved for both subcutaneous and intravenous use. In the other six countries, Remodulin is approved for subcutaneous use only.

We used the mutual recognition process, described more fully below in *Governmental Regulation Marketing Pharmaceutical Products Outside the United States*, to obtain approval of subcutaneous Remodulin in most countries in the European Union (EU). The mutual recognition process for subcutaneous Remodulin was completed in 2005, with positive decisions received from 23 member countries of the EEA. 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. In December 2011, we received regulatory approval of intravenous Remodulin by the French regulatory agency, *L'Agence Nationale de Sécurité du Médicament et des Produits de Santé* (ANSM), as the reference member state for the mutual recognition process. This approval allows us to market

Table of Contents

intravenous Remodulin in the EEA countries where subcutaneous Remodulin has already been approved and where we have obtained pricing approval and approval of our risk management plan (RMP).

In Europe, an 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 have implemented an RMP focused on minimizing the known risks of central venous catheter-related blood stream infections associated with intravenous administration. To date, our RMP for intravenous Remodulin has been approved in 13 EEA countries, with pricing approval in ten of these.

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 physician 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.

In March 2013, the China Food and Drug Administration approved intravenous and subcutaneous Remodulin for PAH in the People's Republic of China, and we expect a commercial launch by our local distributor in 2014. We filed a marketing application for Remodulin during the third quarter of 2013 in Japan and, assuming a favorable review, expect regulatory approval and commercial launch by our local distributor in 2014.

*Intravenous Remodulin Administered via Implantable Pump*

A majority of the patients who die of PAH in the United States each year have not initiated treatment with an infused prostacyclin analogue, which is a complex and burdensome form of medical therapy. In 2009, we entered into an agreement with exclusive rights in the United States, UK, France, Germany, Italy and Japan, with Medtronic, Inc. (Medtronic) to develop its proprietary intravascular infusion catheter to be used with Medtronic's SynchroMed® II implantable infusion pump and related infusion system components (together referred to as the Medtronic System) in order to deliver Remodulin for the treatment of PAH. If the Medtronic System is successful, it could reduce many of the patient burdens associated with infused prostacyclin analogues. In the second half of 2013, Medtronic completed the *DelIVery* clinical trial, which we funded, in order to study the safety of the Medtronic System while administering Remodulin. The primary objective of the study was to demonstrate a rate of catheter-related complications below 2.5 per 1,000 patient-days while using the Medtronic System to deliver Remodulin. In September 2013, Medtronic informed us that this primary objective was met ( $p < 0.0001$ ). In addition to the clinical study, Medtronic must complete other stability, compatibility and technical assessments of the Medtronic System, including modifications to its hardware and software, and address any outstanding regulatory issues. Upon completion of these activities by Medtronic, we anticipate Medtronic will make preparations to file a premarket approval application (PMA) seeking FDA clearance for the catheter and labeling changes, and will address any FDA feedback, to enable the use of the Medtronic System with Remodulin. In tandem, we plan to seek FDA approval of a supplement to Remodulin's label to allow the use of Remodulin with the Medtronic System.

In certain countries in Europe, an implantable pump distributed by OMT GmbH & Co. KG is used to deliver intravenous Remodulin to some patients.

*Tyvaso*

We commenced commercial sales of Tyvaso in the United States in 2009. We sell Tyvaso to the same specialty pharmaceutical distributors in the United States that distribute Remodulin. For the years

Table of Contents

ended December 31, 2013, 2012 and 2011, we recognized approximately \$438.8 million, \$325.6 million and \$240.4 million in Tyvaso revenues, representing 39 percent, 36 percent and 32 percent, respectively, of our net revenues.

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 (Bayer) 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 package insert, each Ventavis inhalation consists of four to ten minutes of continuous inhalation via the nebulizer.

In contrast to iloprost, treprostinil (the active ingredient in Tyvaso) has a longer half-life. Tyvaso is administered four times a day, by inhaling up to twelve 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, once a day, a single ampule containing that day's supply of Tyvaso is emptied into the Tyvaso Inhalation System. 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 was 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. Patients in this study also saved an average of approximately 1.4 hours per day when administering Tyvaso compared to Ventavis.

*Regulatory Approval of Tyvaso*

In 2009, the FDA approved Tyvaso for the treatment of PAH using the Tyvaso Inhalation System. Tyvaso is indicated to improve exercise ability in patients with PAH (WHO Group 1), which includes multiple etiologies such as idiopathic and heritable PAH, as well as PAH associated with connective tissue diseases. Studies establishing effectiveness included predominately patients with NYHA Functional Class III symptoms.

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.

Under the PMCs, we committed to modify certain aspects of the Tyvaso Inhalation System. We also agreed to perform a usability analysis incorporating the evaluation and prioritization of user-related risk followed by a human factors study. In 2012, the FDA acknowledged we had satisfied our PMCs and approved our modifications to the Tyvaso Inhalation System. The Tyvaso Inhalation System now includes a nebulizer called TD-100, which incorporates these modifications. In addition, we are working to further improve the Tyvaso Inhalation System to make it easier for patients to use.

In accordance with our PMR, we are enrolling patients in a long-term observational study in the United States 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 assessing the safety of Tyvaso. We are required to provide the FDA with annual updates on our PMR, and to submit the results of the study by December 15, 2014. While we believe we are on schedule to complete the PMR by this deadline, any failure or delay could result in

Table of Contents

penalties, including fines or withdrawal of Tyvaso from the market, unless we are able to demonstrate good cause for the failure or delay.

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.

We are not seeking EMA approval of Tyvaso as a stand-alone treatment of PAH.

*Adcirca*

We began selling Adcirca in 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 United States and Puerto Rico from Lilly in 2008. We sell Adcirca at prices established by Lilly, which are at parity with Cialis pricing and are typically set at a discount from an average wholesale price to pharmaceutical wholesalers. For the years ended December 31, 2013, 2012 and 2011, we recognized approximately \$177.0 million, \$122.5 million and \$70.6 million in Adcirca revenues, representing 16 percent, 13 percent and 9 percent, 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. NO works to relax pulmonary blood vessels by increasing intracellular levels of cyclic GMP. Because cyclic GMP is degraded by PDE-5, an established therapeutic approach in the treatment of PAH is to use PDE-5 inhibitors to increase levels of cyclic GMP 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 citrate, 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. In the fourth quarter of 2012, several companies launched generic formulations of sildenafil citrate.

*FDA Approval of Adcirca*

In 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 patients with PAH (WHO Group 1), which encompasses patients with multiple forms of PAH including etiologies such as idiopathic and heritable PAH as well as PAH associated with connective tissue diseases. Studies establishing effectiveness included predominately patients with NYHA Functional Class II-III symptoms.

*Commercial Rights to Adcirca*

In 2008, we entered into several agreements with Lilly, including a license agreement and a manufacturing and supply 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. 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. See *Patents and Other Proprietary Rights, Strategic Licenses and Market Exclusivity* below for more details on these agreements.

Table of Contents

***Orenitram (previously known as UT-15C Sustained Release Tablets or Oral Treprostinil)***

On December 20, 2013, the FDA approved Orenitram for the treatment of PAH in WHO Group 1 patients to improve exercise capacity. The primary study that established efficacy (FREEDOM-M) included predominately patients with WHO functional class II-III symptoms and etiologies of idiopathic or heritable PAH (75%) or PAH associated with connective tissue disease (19%). Orenitram's label also notes that Orenitram is probably most useful to replace subcutaneous, intravenous, or inhaled treprostinil, but this use has not yet been studied.

Orenitram is dosed twice a day with food, but the total daily dose can be divided and given three times daily with food. Orenitram is available in four strengths: 0.125 mg, 0.25 mg, 1 mg and 2.5 mg. The dose of Orenitram should be increased as tolerated to achieve optimal clinical response. The maximum dose is determined by the individual patient's tolerability.

*Regulatory Approval of Orenitram*

In December 2011, we submitted to the FDA a new drug application (NDA) for the approval of Orenitram for treatment of PAH. Our NDA included the results of three phase III studies:

*Monotherapy Study (FREEDOM-M):* A 12-week study of PAH patients who were not on any approved background therapy. In June 2011, we announced that the FREEDOM-M 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 Orenitram improved their six-minute walk distance by a median of 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 the placebo. The median change from baseline at week 12 was 25 meters for patients receiving Orenitram and -5 meters for patients receiving the placebo.

*Combination Therapy Studies (FREEDOM-C and FREEDOM-C<sup>2</sup>):* Two separate 16-week studies 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-C and FREEDOM-C<sup>2</sup> trials were completed in 2008 and 2011, respectively, and neither achieved statistical significance for its primary endpoint of improvement in six-minute walk distance at week 16 (p=0.072 and p=0.089, respectively).

In October 2012, the FDA issued a complete response letter in which it declined to approve our NDA. In January 2013, we resubmitted our NDA to address the concerns raised in the FDA's complete response letter. In March 2013, we received a second complete response letter from the FDA declining to approve our NDA. To address the concerns raised in the FDA's second complete response letter, we filed a second resubmission of our NDA in August 2013, which was approved in December 2013.

We believe that in order for Orenitram to reach its full commercial potential, we need to complete further studies to support an amendment to Orenitram's label to indicate that Orenitram delays morbidity or mortality in patients who are on an approved oral background therapy. As such, we are enrolling up to 858 patients in a phase III clinical trial called FREEDOM-EV, which began in 2012. FREEDOM-EV is a placebo-controlled study of patients who enter the study on an approved oral background therapy, and one of the two primary endpoints of the study is the time to clinical worsening.

We currently plan to seek approval of Orenitram in Europe upon completion of the FREEDOM-EV study. In 2005, the EMA announced that Orenitram had been designated an orphan medicinal product for the treatment of PAH.

Table of Contents

***TransCon Treprostinil***

In September 2012, we signed a worldwide exclusive agreement with Ascendis Pharma A/S (Ascendis Pharma) to apply Ascendis Pharma's proprietary TransCon technology platform to our treprostinil molecule (TransCon treprostinil). We believe that the TransCon technology platform may enable a sustained release of a novel, carrier-linked product, which will significantly enhance the delivery of treprostinil by establishing a once-daily, self-injectable alternative to administering Remodulin through a continuous infusion pump for the treatment of PAH. We expect that this self-injectable form of treprostinil could enable patients to avoid the infusion site pain associated with subcutaneous Remodulin and the risk of sepsis, due to the use of an indwelling catheter, which is associated with intravenous Remodulin. We are currently conducting pre-clinical studies of TransCon treprostinil.

***Beraprost***

We have the exclusive right to develop and market a modified-release formulation of beraprost in North America, Europe, and certain other territories for the treatment of cardiovascular indications, pursuant to our license agreement with Toray, which is described below under *Patents and Other Proprietary Rights, Strategic Licenses and Market Exclusivity Toray Amended License Agreement*. Beraprost is a chemically stable, orally bioavailable prostacyclin analogue. Like natural prostacyclin and treprostinil, beraprost is believed to dilate blood vessels and prevent both platelet aggregation and proliferation of smooth muscle cells surrounding blood vessels, via a unique profile of pulmonary vascular receptor selectivity.

*314d*

We completed a phase I safety trial of a reformulated, single-isomer version of beraprost (314d) in July 2012, and the data suggested that dosing 314d four times a day would be well-tolerated. We believe that 314d and treprostinil have differing prostacyclin receptor-binding profiles, and thus could provide certain groups of patients a differing set of safety and efficacy profiles. We also believe 314d and inhaled treprostinil have complimentary pharmacokinetic and pharmacodynamic profiles, which indicates they could provide greater efficacy in combination. As such, we are enrolling a phase III study called BEAT (**BE**raprost 314d Add-on to **Ty**vaso) to evaluate the clinical benefit and safety of 314d in combination with Tyvaso for patients with PAH who show signs of deterioration on inhaled treprostinil or have a less than optimal response to inhaled treprostinil treatment. We intend to enroll 240 patients in the study, which will have a primary endpoint of time to clinical worsening.

***TransCon Beraprost***

We are developing an extended-release injection we refer to as TransCon beraprost, which incorporates the TransCon technology described above and is intended to be self-administered by PAH patients once daily. We are currently conducting pre-clinical studies with TransCon beraprost.

***Cell-Based Therapy***

In June 2011, we entered into a license agreement with Pluristem to develop and commercialize a cell-based product for the treatment of PAH 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 year ended December 31, 2011. We commenced a phase I clinical study in Australia in 2013.

Table of Contents

***Lung Transplantation***

PAH has not been reported to reoccur in end-stage patients who have received a full lung transplant. Based on available data, we believe fewer than 100 PAH patients in the United States receive a lung transplant each year (out of almost 2,000 performed) due to the shortage of available lungs for transplant, the demand for transplantable lungs by patients with other end-stage pulmonary diseases, such as chronic obstructive pulmonary disease and idiopathic pulmonary fibrosis, and delays in listing PAH patients for transplant.

In July 2011, we acquired all 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 xenotransplantation. We have focused this platform on the goal of providing transplantable lungs for human patients. We are also engaged in preclinical development of several regenerative medicine technologies for creating transplantable lung tissue and whole lungs for patients with end-stage lung disease. In 2013, we began developing technologies to increase the supply of donor lungs through collaborations with two ex-vivo lung perfusion companies.

**Products to Treat Cancer**

***Ch14.18 Antibody***

In July 2010, we entered into a Cooperative Research and Development Agreement (CRADA) with the 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 in the United States. Ch14.18 is a chimera, 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 of the NCI's phase III study were published in September 2010. In that study, 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. 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, the NCI has completed a second phase III clinical trial with 105 patients to define more clearly the safety and toxicity profile of Ch14.18 immunotherapy in children, and we have developed the commercial production capability for the antibody. The NCI studies, including a previously conducted phase III clinical trial and all other necessary studies supported by the NCI, were used as the basis for an MAA we filed in December 2013 with the EMA for approval of Ch14.18 immunotherapy in Europe for the treatment of neuroblastoma. We expect to file a BLA seeking FDA approval during the first half of 2014. As part of these filings, we must demonstrate that our production process results in a Ch14.18 drug product that is substantially equivalent to the drug product used in the NCI studies. We have received orphan drug designation for Ch14.18 from the FDA

Table of Contents

and the EMA. In lieu of a royalty payment to the NCI, we have an ongoing obligation to provide the NCI with Ch14.18 for its studies free of charge.

**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 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.

In September 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 NIAID for studies directed at the development of a broad spectrum antiviral drug based on our glycobiology antiviral platform. In addition, there are eight milestone-based options to expand the project and funding under the contract. To date, we have received contract modifications exercising four of these options, bringing total committed contract funding to approximately \$25.7 million. We recognize revenue under this contract to the extent of costs incurred, plus a proportionate amount of fee earned.

We plan to begin enrolling patients in a phase I clinical trial of our lead antiviral candidate, an alpha-glucosidase inhibitor called UV-4B, for treatment of dengue during the first half of 2014.

**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). As Medicomp did not represent a core component of our business, we sold Medicomp in March 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 in our consolidated statements of operations for the year ended December 31, 2011.

**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. Our sales and marketing teams consisted of approximately 160 employees as of December 31, 2013. We have divided our domestic sales force into two teams. One team sells Remodulin and Tyvaso and will sell Orenitram, while the other team sells Adcirca. For Remodulin and Tyvaso, the efforts of our sales and marketing teams are supplemented in the United States by specialty pharmaceutical distributors. Our U.S.-based 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 those territories where Remodulin is approved. We are working with our international distributors to expand Remodulin sales into other countries in which they have distribution rights.



Table of Contents

***Domestic Distribution of Commercial Products***

*Remodulin and Tyvaso*

We have entered into separate, non-exclusive distribution agreements with Accredo Health Group, Inc. (Accredo) and CVS Caremark (Caremark) to distribute both Remodulin and Tyvaso. In April 2012, Express Scripts, Inc., the parent company of CuraScript Inc. (CuraScript), then one of our contracted specialty pharmaceutical distributors, completed its acquisition of Medco Health Solutions, Inc., the parent company of Accredo. As a result, CuraScript's operations have been integrated into Accredo, and in December 2013 we consolidated our distribution agreements with the two organizations into one contract. Thus far, the merger has not affected our business and we do not expect the merger to materially affect our business in the future.

Our Remodulin and Tyvaso distribution agreements with Accredo and Caremark include automatic term renewals for additional one-year periods subject to notice of termination. We update our distribution agreements from time to time to reflect changes in the regulatory environment. Such changes have not had a significant impact on our operations or our relationships with our distributors, and tend to occur in the ordinary course of business. In addition, we compensate Accredo and Caremark on a fee-for-service basis for certain ancillary services. 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.

These 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 these 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.

We have generally increased the price of Tyvaso by 4.9 percent annually, with the last such price increase becoming effective on January 1, 2014. We have not increased the price of Remodulin since 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 *Patents and Other Proprietary Rights, Strategic Licenses and Market Exclusivity* below for more details), Lilly manufactures Adcirca and distributes it via its wholesaler network, which includes Accredo and Caremark, 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, product returns 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 its retail pricing, which has been and is expected to be at price parity with Cialis. Since receiving FDA approval of Adcirca, Lilly has generally increased the net wholesale price of Adcirca two or three times each year. During 2012, Lilly increased the net wholesale price of Adcirca by 9.0 percent in January and July. During 2013, Lilly increased the net wholesale price of Adcirca by 9.5 percent in January and July and by 9.0 percent in December.

Table of Contents

*Orenitram*

We plan to sell Orenitram in the United States to specialty pharmaceutical distributors under arrangements similar to those we have in place for Tyvaso and Remodulin. We are negotiating the terms of these arrangements and expect to make Orenitram commercially available in mid-2014.

***International Distribution of Remodulin***

We currently sell subcutaneous and intravenous Remodulin outside the United States to various 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, hospital or health plan on a case-by-case basis. We are working on expanding our sales of Remodulin into new territories through our existing network of distributors.

**Patents and Other Proprietary Rights, Strategic Licenses and Market Exclusivity**

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. Many of these proprietary rights stem from licenses and other strategic relationships with third parties. In addition to intellectual property rights, U.S. and international regulatory authorities often provide periods of market exclusivity for manufacturers of biopharmaceutical products.

Patents provide the owner with a right to exclude others from practicing an invention. Patents may cover the active ingredients, uses, formulations, doses, administrations, delivery mechanisms, manufacturing processes and other aspects of a product. The period of patent protection for any given product may depend on the expiration date of various patents and may differ from country to country according to the type of patents, the scope of coverage and the remedies for infringement available in a country. Most of our commercial products and investigational compounds are protected by patents with varying terms.

***Remodulin, Tyvaso and Orenitram Proprietary Rights***

We have a number of issued patents and pending patent applications covering the stable prostacyclin analogue known as treprostinil, which is the active pharmaceutical ingredient in Remodulin, Tyvaso and Orenitram.

In January 1997, we acquired patents covering the use of treprostinil for PAH from GlaxoSmithKline PLC (formerly Glaxo Wellcome, Inc.) (Glaxo) in exchange for certain payments including a royalty on sales of any product containing treprostinil. As of October 2014, all of these patents will have expired, as will our royalty payment obligation to Glaxo. The U.S. patent acquired from Glaxo is listed in the Orange Book for Remodulin, Tyvaso and Orenitram.

In October 1997, we filed patent applications for a new synthesis and production method for treprostinil in the United States, Europe and various other countries. This application resulted in the grant of three patents in the United States, all of which expire in October 2017, as well as granted patents in a number of other countries, expiring in October 2018. This synthesis application remains pending in Canada. One of the U.S. patents from this family is listed in the Orange Book for Remodulin, Tyvaso and Orenitram.

We continue to conduct research into new methods to synthesize treprostinil and have filed a number of additional patent applications relating to production of treprostinil, several of which have

Table of Contents

already been granted in the United States. One such patent was granted last year and is now listed in the Orange Book for Remodulin, Tyvaso and Orenitram, expiring in 2028.

In addition to the treprostinil patents noted above, we have additional patents specific to our individual treprostinil-based products, including the following:

*Remodulin.* We have been granted three U.S. patents covering an improved diluent for Remodulin, which will expire in 2028 and 2029. Two of these patents are listed in the FDA Orange Book, and we expect the third will be listed as well.

*Tyvaso.* We have been granted two U.S. patents, as well as patents in other countries for Tyvaso that cover methods of treating PAH by inhaled delivery. These patents will expire in the United States in 2018 and in various countries throughout the world in 2020.

*Orenitram.* Our patents for Orenitram cover methods of use for treating PAH, orally administered formulations, controlled moisture storage and production methods, as well as those covering controlled release formulations licensed to us by Supernus Pharmaceuticals Inc. (Supernus). These patents will expire in the United States between 2024 and 2031 and in various countries throughout the world between 2024 and 2027.

We have additional pending U.S. and international patent applications relating to Remodulin, Tyvaso and Orenitram.

*Orange Book*

In seeking approval of a drug through an NDA or upon issuance of new patents following approval of an NDA, applicants are required to submit to the FDA each patent whose claims cover the applicant's product or a method of using the product. Each of the patents submitted is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. See *Governmental Regulation Hatch-Waxman Act* below for further details. Remodulin currently has five Orange Book-listed patents with expiration dates ranging from 2014 to 2029. Tyvaso currently has five Orange Book listed patents with expiration dates ranging from 2014 to 2028. Orenitram currently has eight Orange Book listed patents with expiration dates ranging from 2014 to 2031. Additional patent applications are pending, and if granted, may be eligible for listing in the Orange Book.

*Regulatory Exclusivity*

In June 2010, the FDA granted orphan drug designation for Tyvaso. This designation 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. As a result of FDA approval of our NDA for Orenitram as a new dosage form, Orenitram has three years of market exclusivity for PAH expiring in December 2016. A request for orphan drug designation for Orenitram is pending with the FDA.

*Generic Challenge*

In February 2012, we received notice of an ANDA filed by Sandoz requesting FDA approval to market a generic version of the 10 mg/mL strength of Remodulin. On December 7, 2012, we received notice that Sandoz had amended its previously filed ANDA to request additional approval to market generic versions of the 1 mg/mL, 2.5 mg/mL, and 5 mg/mL strengths of Remodulin. For further details, see *Item 3. Legal Proceedings*. There can be no assurance that we will prevail in our defense of our patent rights, or that additional challenges from other ANDA filers will not surface with respect to Remodulin or our other treprostinil-based products. Our existing patents could be invalidated, found unenforceable or found not to cover a generic form of Remodulin, Tyvaso or Orenitram. If any ANDA

Table of Contents

filer were to receive approval to sell a generic version of Remodulin, Tyvaso or Orenitram and/or prevail in any patent litigation, the affected product would become subject to increased competition and our revenue would decrease.

*Supernus License*

In 2006, we entered into an exclusive license agreement with Supernus to use certain of its technologies in producing Orenitram. Under the agreement, we will pay Supernus certain amounts upon the achievement of specified milestones based on the development of Orenitram and a \$2.0 million milestone payment upon its commercial launch. In addition, the agreement provides that we will pay a royalty to Supernus based on net worldwide sales. 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.

*NEBU-TEC Agreement of Sale and Transfer*

In 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 €2.5 million as of December 31, 2013). The transaction closed in 2009 after we received FDA approval for Tyvaso. Through 2013, we managed all aspects of the manufacturing process for the Tyvaso Inhalation System and NEBU-TEC supplied the labor to assemble the devices in a facility we leased in Germany. In December 2013, we ceased manufacturing at the NEBU-TEC leased facility and are using a U.S.-based manufacturer to produce the Tyvaso Inhalation System.

*Lilly Agreements Related to Adcirca*

In 2008, we entered into several agreements with Lilly regarding Adcirca, including a license agreement, a manufacturing and supply agreement, and a stock purchase agreement.

*License Agreement*

Under the terms of the license agreement, Lilly granted us an exclusive license for the right to develop, market, promote and commercialize Adcirca for the treatment of pulmonary hypertension in the United States and Puerto Rico. In exchange for the license, we paid Lilly a \$25.0 million license fee in 2008. We also agreed to pay Lilly royalties equal to five percent of our net sales of Adcirca in the United States and Puerto Rico, as a pass through of Lilly's third-party royalty obligations, for so long as Lilly is required to make such payments.

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

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

Table of Contents

terminate upon a material breach by the other party of the license agreement or the manufacturing and supply agreement, described above.

The U.S. patent for Adcirca for the treatment of pulmonary hypertension will expire in November 2017.

*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, product returns 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 \$125.0 million payment to Lilly in 2008. 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.

*Stock Purchase Agreement*

Under the terms of the stock purchase agreement, in 2008, we issued 6.3 million shares of our common stock to Lilly from treasury for an aggregate purchase price of \$150.0 million.

*Toray Amended License Agreement*

In 2000, we licensed from Toray the exclusive right to develop and market beraprost for cardiovascular indications. Beraprost is a chemically stable oral prostacyclin analogue in a sustained release formulation, which produces \$300 million in sales annually in Japan primarily for the treatment of cardiovascular indications. As amended, this license gives us exclusive rights to develop beraprost and its variants throughout North America, Europe, and certain other territories.

*Significant Agreement Terms*

In 2007, we issued 400,000 shares of our common stock to Toray in exchange for the cancellation of Toray's existing right under the 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 \$27.21 per share. The 2007 amendment also provided for certain milestone payments during the development period and upon receipt of regulatory approval for beraprost in the United States or the European Union.

In 2011, we amended our license agreement with Toray. The amendment did not materially change the terms of our license agreement, 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 an obligation and a corresponding charge to research and development expense of \$46.3 million, which represented the present value of the related payments discounted by our estimated current cost of debt. Toray has the right to terminate the license agreement in the event of a change of control of our company under certain circumstances.

Table of Contents

***Pluristem License Agreement***

In June 2011, we entered into a license agreement with Pluristem for exclusive worldwide rights to develop and commercialize a cell-based product for the treatment of PAH 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. The agreement provides for additional milestone payments to Pluristem at various stages, as well as royalties on commercial sales.

***National Cancer Institute***

In July 2010, we entered into a CRADA with the NCI to collaborate on the late-stage development and regulatory agency submissions of Ch14.18 for children with high-risk neuroblastoma and patients with other cancers. For further details, refer to the section above entitled *Products to Treat Cancer Ch14.18 Antibody*.

***Ascendis Pharma A/S***

In September 2012, we signed an exclusive agreement with Ascendis Pharma to apply Ascendis Pharma's proprietary TransCon technology platform to our treprostinil and beraprost molecules. Under the agreement, we may be required to make future development-related milestone payments and royalty payments based on commercial sales. For further details, refer to the sections above entitled *TransCon Treprostinil* and *TransCon Beraprost*.

***Oxford***

We maintain a research agreement with Oxford to develop antiviral compounds. Research under this agreement is performed by Oxford Glycobiology Institute, which is headed by a member of our Board of Directors and our scientific advisory board. Under the terms of the agreement, we are required to fund related research activities and make milestone payments for the successful completion of clinical trials. We are also obligated to pay royalties to Oxford equal to a percentage of our net sales from any discoveries and products developed by Oxford. Milestone payments and royalties are subject to reduction depending upon third-party contributions to discoveries and/or third-party licenses necessary to develop products. In August 2010, the term of the research agreement was extended through September 2016. In connection with the extension of the term, we agreed to pay Oxford a total of \$2.9 million (using the then-prevailing exchange rate) in 60 equal installments. As of December 31, 2013, approximately \$1.7 million remains outstanding under this 2010 agreement. In addition, in December 2012, we amended our agreement with Oxford, under which we agreed to pay Oxford an additional \$871,000 in the aggregate (using the exchange rate as of the amendment date) in 36 equal installments for additional work supporting the development of our virology platform which began in January 2013. For additional details regarding our virology program, please see the section above entitled *Products to Treat Infectious Diseases Glycobiology Antiviral Agents*.

***Medtronic***

In 2009, we entered into an exclusive agreement with Medtronic, which was amended in May 2011, to collaborate on the development and commercialization of Medtronic's proprietary intravascular infusion catheter to be used with Medtronic's Synchronomed II implantable infusion pump and related infusion system components (together referred to as the Medtronic System) in order to deliver Remodulin for the treatment of PAH in the U.S., UK, Canada, France, Germany, Italy and Japan. Under the amended agreement, we have been working together at our expense to develop the Medtronic System, conduct a clinical trial and obtain regulatory approval for the use of Remodulin with the Medtronic System. If this development program is successful, our agreement provides that,

Table of Contents

upon commercialization, we will purchase infusion pumps and supplies from Medtronic and will also pay a royalty to Medtronic based on net sales of Remodulin for use in the Medtronic System within the exclusive territories, subject to certain adjustments specified in the agreement. The Medtronic System will be exclusive to Remodulin so long as we purchase a minimum percentage of our annual requirement for implantable pump systems from Medtronic. We will be solely responsible for all marketing and promotion of the Medtronic System for the delivery of Remodulin for the treatment of PAH in the exclusive territories.

*Other*

We are party to various other license agreements relating to therapies under development. These license agreements require us to make payments based on a percentage of sales, if we are successful in commercially developing these therapies, and may require other payments upon the achievement of certain milestones.

**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 (both clinical and pre-clinical studies and manufacturing). Research and development expenses during the years ended December 31, 2013, 2012 and 2011 totaled approximately \$299.3 million, \$173.4 million and \$180.0 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. Research and development expense is significantly impacted by fluctuations in our stock price, due to the cash payment obligations created by our share-based compensation programs. For further details, see *Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations Operating Expenses Share-Based Compensation*.

**Production and Supply**

We synthesize treprostinil, the active ingredient in Remodulin and Tyvaso, and treprostinil diolamine, the active ingredient in Orenitram, at our facility in Silver Spring, Maryland. In 2011, we received FDA approval to produce finished Tyvaso and Remodulin at our Silver Spring facility. In 2012, we received a Good Manufacturing Practice certificate from the U.K. Medicines and Health Products Regulatory Agency to produce Remodulin and Tyvaso in our Silver Spring facility.

We produce Orenitram, and warehouse and distribute Remodulin, Tyvaso and Orenitram, at our facility in Research Triangle Park, North Carolina (RTP Facility).

Baxter Pharmaceutical Solutions, LLC (Baxter) currently produces Remodulin for us. In 2009, we amended our contract with Baxter to extend the contract term through the end of 2013. In July 2013, we entered into a three-year commercial supply agreement with Baxter. In 2009, we also agreed with Baxter that Remodulin will be produced in larger quantities using a different set of equipment than the currently approved process. The FDA approved the new equipment and process in January 2014, and EMA approval is pending. In 2011, the FDA approved Jubilant Hollister-Stier Contract Manufacturing and Services as an additional Remodulin producer. To date, we have not utilized Jubilant Hollister-Stier to manufacture Remodulin.

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 (3) analyze other products we develop. We are working to obtain FDA approval of a third party to serve as an additional producer of Orenitram.

Table of Contents

We intend to use our own facilities to produce our primary supply of Remodulin, Tyvaso and Orenitram, 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 demand.

Under our manufacturing and supply agreement with Lilly, Lilly manufactures Adcirca for us. For further detail, see the section above entitled *Lilly Agreements Related to Adcirca Manufacturing and Supply Agreement*.

Until December 2013, our German facility manufactured the nebulizer used in our Tyvaso Inhalation System. Beginning in 2014, Minnetronix Inc., which received FDA approval to manufacture the Tyvaso Inhalation System in 2010, will be the sole manufacturer of the system.

In July 2012, we received FDA approval for a modified inhalation device (TD-100) for the Tyvaso Inhalation System based on the results of the completed PMCs related to the inhalation device. In 2013, the TD-100 was incorporated into the Tyvaso Inhalation System. In December 2012, we increased our reserves for inventory obsolescence by \$8.9 million based on the estimated cost of inhalation devices in inventory that we expected not to be salable as a result of the then-pending commercial release of TD-100.

Although we believe that third parties could provide similar products, services and materials, there are few companies that could replace our existing third-party producers and suppliers. A change in supplier or producer could cause a delay in the production, 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 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 2008, Teva announced that the FDA approved its version of generic epoprostenol for the treatment of PAH. In 2008, GeneraMedix Inc. (GeneraMedix) received FDA approval for its version of epoprostenol, which is stable at room temperature. In 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 2010;

*Ventavis and Ilomedin®*. Approved in 2004 in the United States and in 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 in Europe as Iloprost. In 2007, CoTherix was acquired by Actelion, the manufacturer and distributor of Tracleer and Opsumit® and the distributor of Veletri. Iloprost is also marketed by Bayer in certain countries outside the United States in an intravenous form known as Ilomedin;



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

### Table of Contents

*Tracleer*. The first oral ETRA class drug to be approved for PAH. Tracleer (bosentan) was approved in 2001 in the United States and in 2002 in Europe. Tracleer is marketed worldwide by Actelion;

*Letairis*®. Approved in 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 2008, Glaxo received marketing authorization from the EMA for Letairis in Europe, where it is known as Volibris®;

*Revatio*. Approved in 2005 in the United States, Revatio (sildenafil citrate) is also an oral therapy and is marketed by Pfizer. Revatio contains sildenafil citrate, the same active ingredient as Viagra, and is the first PDE-5 inhibitor to be approved for PAH;

*Generic sildenafil citrate*. In the fourth quarter of 2012, several companies began marketing generic formulations of sildenafil citrate;

*Opsumit*. Approved in October 2013 in the United States and December 2013 in the European Union, Opsumit (macitentan) is an oral ETRA developed by Actelion for the treatment of PAH; and

*Adempas*®. Approved in August 2013 in the United States, Adempas (riociguat) is a soluble guanylate cyclase stimulator, which targets a similar vasodilatory pathway as PDE-5 inhibitors and is approved for chronic thromboembolic pulmonary hypertension and PAH. Adempas is an oral therapy marketed by Bayer. In February 2013, Bayer announced that it had filed an MAA for the approval of Adempas for the treatment of PAH in Europe.

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

*Selexipag*, an oral prostacyclin receptor agonist 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 for the treatment of PAH. Novartis Pharmaceuticals Corporation (Novartis) completed a phase III trial of Gleevec for the treatment of PAH in September 2011. During the third quarter of 2012, Novartis withdrew its NDA in order to submit additional data to the FDA and during the first quarter of 2013 withdrew the MAA it had filed with the EMA.

Oral therapies (such as Adcirca, Revatio, generic sildenafil citrate, 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. For example, in February 2012, we received notice of an ANDA filed by Sandoz requesting FDA approval to market a generic version of the 10 mg/mL strength of Remodulin. On December 7, 2012, we received notice that Sandoz had amended its previously filed ANDA to request additional approval to market generic

Table of Contents

versions of the 1 mg/mL, 2.5 mg/mL, and 5 mg/mL strengths of Remodulin. For further details, see the sections below entitled *Governmental Regulation Hatch-Waxman Act* and *Item 3. Legal Proceedings*.

In addition, certain Revatio patents expired in 2012, leading several manufacturers to launch generic formulations of sildenafil citrate, which physicians could prescribe for the treatment of PAH. Generic sildenafil citrate's lower price, relative to Adcirca, could lead to an erosion of Adcirca's market share and limit its growth potential. Although we believe Adcirca's once-daily dosing regimen provides a significant competitive advantage over generic sildenafil citrate's dosing regimen of three times per day, we expect government payers and private insurance companies to favor over time the use of the less expensive generic sildenafil citrate instead of Adcirca.

Orenitram is the first oral prostacyclin analogue therapy approved for PAH in the United States. We anticipate that it will face competition with existing oral PAH therapies, and will be regarded as a less invasive and more convenient alternative therapy to Tyvaso and Remodulin.

We compete with the developers, manufacturers and distributors of all of the PAH products noted above 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, manufacturing 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. In the United States, failure to comply with requirements under the Federal Food, Drug, and Cosmetic Act (FDC Act), the Public Health Service Act (PHSA), and other federal statutes and regulations, may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending NDAs or 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

Table of Contents

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. Absent FDA objection within 30 days after submission of an IND, the IND becomes effective and 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. 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 criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be approved by an institutional review board (IRB). 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 demonstrate 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 United States. 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 \$2.1 million, and the manufacturer and/or sponsor of an approved NDA or BLA is also subject to annual product and establishment fees, currently exceeding \$104,000 per product and \$554,000 per

Table of Contents

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 may instead ask for additional information, in which case, the application must be resubmitted with the requested information. The FDA has agreed to certain performance goals in the review of new drug applications. Most such applications for non-priority drugs are reviewed within ten to twelve months, while most applications for priority review drugs are reviewed in six to eight months. 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 information submitted during FDA review, including information intended to clarify information already provided or to address any deficiencies identified 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 the FDA's current Good Manufacturing Practices (cGMP) and GCP is satisfactory and the NDA or BLA contains data that provide substantial evidence that the pharmaceutical product is safe and effective for purposes of the indication studied.

In the United States, after the FDA evaluates the NDA or BLA 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. A Class 1 resubmission may contain only limited information such as labeling, safety updates, stability updates, or minor analysis updates or clarifying information and is subject to a two-month review period. All other resubmissions are categorized as Class 2 and are subject to a six-month review period. Even after such a resubmission, the FDA may decide that the application does not satisfy the regulatory criteria for approval.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA or BLA 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 or certification for 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 cGMP 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

Table of Contents

withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

***Disclosure of Clinical Trial Information***

Sponsors of clinical trials of FDA-regulated drugs and other products are required to register and disclose certain clinical trial information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial. This clinical trial information is then made public as part of the sponsor's registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Competitors may use this publicly-available information to gain knowledge regarding the progress of development programs.

***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 a rare disease or condition affecting fewer than 200,000 people in the United States. Orphan drug designation must be requested before submitting an NDA or BLA. 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 or BLA applicant to receive orphan drug designation and FDA approval for a particular active ingredient to treat a particular disease is entitled to a seven-year exclusive marketing period in the United States for that product, for that indication. During the seven-year period, the FDA may not approve any other application 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 or the inability of the NDA or BLA holder for the product with orphan drug exclusivity to assure availability of sufficient quantities of the drug to meet the needs of patients with the rare disease or condition. 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 or BLA 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. A request for orphan drug designation for Orenitram is pending.

***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

Table of Contents

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 requested time frame. 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 passed 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 providing protection to brand pharmaceuticals by extending their patent protection, in some cases, to compensate for patent life lost during the product development and approval process and providing 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 whose claims cover 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 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 an NDA for a new chemical entity, 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

Table of Contents

submission contains a Paragraph IV certification, in which case the submission may be made four years following the original product approval. Following approval of an application to market a drug that contains previously approved active ingredients 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, the FDC Act 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 for a patent that will expire on October 6, 2014.

In February 2012, we received notice of an ANDA filed by Sandoz requesting FDA approval to market a generic version of the 10 mg/mL strength of Remodulin. On December 7, 2012, we received notice that Sandoz had amended its previously filed ANDA to request additional approval to market generic versions of the 1 mg/mL, 2.5 mg/mL, and 5 mg/mL strengths of Remodulin. For further details, see *Item 3. Legal Proceedings*.

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

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

Section 505(b)(2) NDAs may 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 in which the applicant relies, at least in part, on information from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may eliminate the need to conduct certain preclinical or clinical studies, if it can establish that reliance on studies conducted for a previously-approved product is scientifically appropriate. 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,

Table of Contents

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 their approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting promotion of off-label uses, and a company that is found to have engaged in off-label promotion may be subject to significant liability.

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 an NDA or BLA or supplement thereto before the change can be implemented. An NDA or 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 cGMP requirements after approval. Manufacturers and certain of their contractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies, to assess compliance with cGMP requirements. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMP. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards or if previously unrecognized problems are subsequently discovered.

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

Outside of the United States, our ability to market our products is also contingent upon receiving marketing authorizations from regulatory authorities. The foreign regulatory approval process may include some or all of the risks associated with the FDA review and approval process set forth above. The requirements governing the conduct of clinical trials and marketing authorization vary widely from country to country.



Table of Contents

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 and EEA 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 EEA 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 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, and do not currently intend to resubmit it, 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 applications to market new drug products. Instead, biological products are approved for marketing under provisions of the PHSA via a BLA. However, the application process and requirements 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

Table of Contents

the creation and enforcement of regulations to prevent the introduction, or spread, of communicable diseases in the United 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 Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (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 must be shown through analytical studies, animal studies, and at least one clinical study absent a waiver. 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, intricacies 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 that 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 approval of 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. Cell and tissue based products may also be subject to the same approval standards, including demonstration of safety and efficacy, as other biologic and drug products, if they meet certain criteria such as if the cells or tissues are more than minimally manipulated or if they are intended for a non-homologous use (a use different from the cell's origin).

Table of Contents

*U.S. Regulation of Medical Devices*

Medical devices are also subject to FDA approval and extensive regulation under the FDC Act. Under the FDC Act, 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 listing; reporting of adverse medical events; 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 approval application (PMA), an expensive, lengthy and uncertain process requiring many years to complete. Most Class II and Class III medical devices may only be marketed in the United States if the FDA has approved a PMA application for the device or cleared the device in response to a 510(k) submission. There is also an alternative pathway to approval of a PMA or clearance of a 510(k) for low or moderate risk devices that are not classified and for which no predicate device exists, known as de novo classification.

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 marketed device, also referred to as a "predicate" 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 IDE 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:

finances, injunctions, and civil penalties;

recall or seizure of products;

Table of Contents

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.

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 as a combination product, and was cleared by the FDA subject to compliance with the QSR as it applies to combination products. In July 2012, we received FDA approval for a modified Tyvaso Inhalation System using an updated nebulizer (TD-100) based on the results of the completion of the QSR compliance commitments.

***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 jointly funded and 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. Orenitram will also be reimbursed under Medicare Part D. 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, exclusion of our products from reimbursement under the federal healthcare programs, or debarment, and expose us to liability under federal and state false claims laws. We estimate that between 35-50% of Remodulin, Tyvaso and Adcirca sales in the United States are reimbursed under the Medicare and Medicaid programs.

Table of Contents

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

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

The federal False Claims Act prohibits any person from, among other things, 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 material to a false claim. Many pharmaceutical and other healthcare companies have been prosecuted under the False Claims Act 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 the False Claims Act. The majority of states also have statutes or regulations similar to the federal anti-kickback statute and False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment.

In December 2013 we received a subpoena from the Office of the Inspector General of the Department of Health and Human Services reflecting a civil investigation by the United States Department of Justice, principally represented by the United States Attorney's Office for the District of Maryland. The subpoena requests documents regarding Remodulin, Tyvaso and Adcirca, including our marketing practices relating to these products. For further details, see *Item 3. Legal Proceedings*.

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 distribution of drugs and drug samples, 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***

PPACA is intended to expand healthcare coverage within the United States. 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 2010, and the volume of rebated drugs has been expanded to include beneficiaries in Medicaid managed care organizations, effective as of March 2010. The PPACA also imposes an annual fee on pharmaceutical manufacturers, based on the

Table of Contents

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 2010, which could increase the amount of the Medicaid drug rebates paid to states.

As noted above under *Governmental Regulation Biologics*, 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 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. Manufacturers were required to begin collecting the information on August 1, 2013, with the first reports due on March 31, 2014. 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 required to be made publicly available by the Secretary of Health and Human Services in a searchable format beginning September 30, 2014. 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 these statutes or specific intent to violate them. 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 Act.

***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 706 employees as of February 7, 2014. The success of our business is highly dependent on attracting and retaining highly talented and qualified personnel.

**Industry Segments and Geographic Areas**

Prior to the sale of Medicomp in March 2011, we operated in two business segments: pharmaceuticals and telemedicine. Since March 2011, our core business has been 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.

Table of Contents**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 with 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>.

**EXECUTIVE OFFICERS OF THE REGISTRANT**

The following is a list, as of February 25, 2014, 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.	59	Chairman, Chief Executive Officer and Director
Roger Jeffs, Ph.D.	52	President, Chief Operating Officer and Director
John M. Ferrari	59	Chief Financial Officer
Paul A. Mahon, J.D.	50	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 SiriusXM Satellite Radio. 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 PAH. 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, regulatory, pharmacovigilance 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. 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

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

### Table of Contents

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.

### **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. These statements, which are based on our beliefs and expectations as to future outcomes, include, among others, statements relating to the following:

Expectations of revenues, expenses, profitability, and cash flows;

The sufficiency of current and future working capital to support operations;

Our ability to obtain financing;

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

The maintenance of domestic and international regulatory approvals;

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

The expected commercial launch and related sales, distribution and revenue recognition of Orenitram (treprostinil) Extended-Release Tablets (Orenitram);

The timing and outcome of clinical studies and related regulatory filings, including: (1) our plans to complete our FREEDOM-EV study of Orenitram by the end of 2016; (2) our aim to obtain United States Food and Drug Administration (FDA) approval for Orenitram as a combination therapy before the end of 2017; (3) our plan to file for approval for Orenitram in Europe upon the completion of the FREEDOM-EV study; (4) our program with Medtronic Inc. (Medtronic) to develop an implantable pump to administer Remodulin; and (5) our plan to begin a phase I clinical study of our lead antiviral candidate, UV-4B, during the first half of 2014;

The expected likelihood and timing of regulatory submissions and approvals for drug candidates under development and the timing of related sales, including (1) our expected filing of a biologics license application for Ch14.18 with the FDA during the first half of 2014; and (2) our pending approval of Remodulin in Japan, and potential commercial launch of Remodulin in Japan and China in 2014;

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

The impact of competing therapies, including generic products (such as generic sildenafil) and newly-developed therapies, on sales of our commercial products;



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

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 for our products, 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 the patents we own or license;

Table of Contents

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

Our expectations regarding the subpoena by the Office of Inspector General of the U.S. Department of Health and Human Services relating to Remodulin, Tyvaso and Adcirca, including our marketing practices relating to these products, and the related investigation by the United States Department of Justice;

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.

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.

Table of Contents

**Risks Related to Our Business**

**We rely heavily on sales of Remodulin, Tyvaso and Adcirca to generate revenues and support our operations.**

Sales of Remodulin, Tyvaso and Adcirca comprise virtually all of our revenues. A wide variety of events, many of which are described in other risk factors below, could cause sales of these products to decline. For instance, we would be unable to sell any of these products if their regulatory approvals were withdrawn. Any substantial change in the prescribing practices or dosing patterns of patients using Remodulin, Tyvaso or Adcirca due to combination or competing therapies, side effects, adverse events, deaths or any other reasons could decrease related revenues. We also face potential generic competition. For example, during the fourth quarter of 2012, generic sildenafil became commercially available, which could negatively affect future market demand for Adcirca. In addition, we rely on third parties to produce, market, distribute and sell Remodulin, Tyvaso and Adcirca. The inability of any one of these third parties to perform these functions satisfactorily could result in a reduction in sales. We are also increasingly internalizing elements of our production process for Remodulin and Tyvaso, and any failure to effectively manage our internal production processes could result in an inability to meet patient demand. Because we are highly dependent on sales of Remodulin, Tyvaso and Adcirca, a reduction in sales of any one of these products could have a negative and material adverse impact on our operations.

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

To obtain regulatory approvals from the FDA and international regulatory agencies such as the EMA, we must conduct clinical trials demonstrating that our products are safe and effective. In the past, several of our product candidates failed or were discontinued at various stages in the development process. Moreover, we may need to amend ongoing trials or the FDA and 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. Approval of a new drug application (NDA) could be subject to delays if the FDA determines that it cannot review or approve the NDA as submitted. In such a case, the FDA would issue a refuse-to-file letter or a complete response letter outlining 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 of these deficiencies adequately and consequently would be unable to obtain FDA approval to market the product candidate.

In addition, we have commenced a phase III clinical trial, FREEDOM-EV, which is a study of Orenitram in combination with other approved pulmonary arterial hypertension (PAH) therapies. One primary endpoint of the study is time to clinical worsening. In addition, the primary endpoint of our phase III BEAT study of 314d is time to clinical worsening. We have not previously conducted a study with a time to clinical worsening primary endpoint. Our inexperience with this type of trial design may impact our ability to conduct these trials appropriately and achieve positive results, or complete the trials within our anticipated timetable. In particular, failure to prove the efficacy of Orenitram in combination with other PAH therapies could materially limit the commercial potential of Orenitram and impede our growth.

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.

Table of Contents

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;

We fail to reach agreement with the FDA or non-U.S. regulatory agencies regarding the scope or design of our clinical trials;

Patients do not enroll in our studies at the rate we expect;

We are unable to obtain approval from institutional review boards (IRBs) to conduct clinical trials at their respective sites;

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

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 FDA good clinical practice (GCP) regulations and similar regulations outside the United States;

Patients experience severe side effects during treatment or die during our trials because of adverse events related to the trial drug, advanced disease, or other medical complications; 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 counterparts have substantial discretion over the approval process for pharmaceutical products. As such, these regulatory agencies may not agree that we have demonstrated the requisite level of product safety and efficacy to grant approval.

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

We compete with well-established drug companies for, among other things, funding, licenses, expertise, personnel, clinical trial patients and investigators, consultants and third-party collaborators. We also compete with these companies for market share. Most of these competitors have substantially greater financial, marketing, manufacturing, sales, distribution and technical resources, and a larger number of approved products, than we do. These competitors also possess greater experience in areas critical to success such as research and development, clinical trials, sales and marketing and regulatory matters. There are several treatments that compete with our commercial therapies, as well as several other therapies under development, including late-stage investigational products that have been 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®, Adempas® (riociguat), Opsumit® (macitentan), generic epoprostenol and generic sildenafil. 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 in combination 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 can negatively impact our operating results.



Table of Contents

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

Other companies may introduce new products that may render all or some of our technologies and products obsolete or noncompetitive. For example, both Adempas and Opsumit were recently approved by the FDA for treatment of PAH. Our commercial therapies have to compete with numerous investigational products currently in development, including 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 negatively impact our sales.**

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. An estimated 35-50% of Remodulin, Tyvaso and Adcirca sales in the United States are reimbursed under the Medicare and Medicaid programs. In the United States, the European Union and other potentially significant markets for our products, government payers and/or third-party payers are increasingly attempting to limit or regulate the price of medicinal products and frequently challenge the pricing of new and expensive drugs. Our prostacyclin analogue products (Remodulin and Tyvaso) are expensive therapies. We also expect Orenitram to be an expensive therapy, as we plan to establish a price comparable to that of Tyvaso. Consequently, it may be difficult for our specialty pharmaceutical distributors or wholesalers to obtain adequate reimbursement for our products from third-party payers to motivate such distributors or wholesalers to support our products. Alternatively, third-party payers may reduce the amount of reimbursement for our products based on changes in pricing of other therapies for PAH. If third-party payers do not approve our products for reimbursement, or limit reimbursements, patients and physicians could choose competing products that are approved for reimbursement or provide lower out-of-pocket costs.

In the United States, the federal government and others are increasingly focused on analyzing the impact of various regulatory programs on the federal deficit, which could result in increased pressure on federal programs to reduce costs. In addition, financial pressures may cause the federal government or other third-party payers to seek cost containment more aggressively through mandatory discounts or rebates on our products, policies requiring the automatic substitution of generic products, more rigorous requirements 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 health care programs could have a material adverse effect on our business and results of our 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. Countries in Europe are under increasing pressure to reduce the cost of health care. Changes to current reimbursement policies may adversely affect our ability to sell our products or 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. Furthermore, international governments expect prices of prescription pharmaceuticals to decline over the life of the product or as prescription volumes increase. In addition, in December 2011, we received marketing approval for the intravenous use of Remodulin in most of

Table of Contents

the countries that are members of the European Economic Area (EEA); however, we are in the process of obtaining approval of our risk management plan on a country-by-country basis, and must obtain pricing approval in each of these member countries before we can market Remodulin. Delays in obtaining these approvals could impact our future sales growth. Additionally, in granting pricing approval for the intravenous use of Remodulin, a member country may approve a lower reimbursement price for intravenous Remodulin than for subcutaneous Remodulin, or reduce the reimbursement price for both methods of administering Remodulin. Any regulatory action reducing the reimbursement rates for intravenous and subcutaneous Remodulin could have a material adverse effect on our revenues, results of operations and our business.

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

We must be able to produce sufficient quantities of our commercial products to satisfy the growing demand for our products. 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 and Tyvaso, and treprostinil diolamine, the active ingredient in Orenitram, in our Silver Spring, Maryland facility using raw materials and advanced intermediate compounds supplied by vendors. We produce Remodulin, Tyvaso and Orenitram at our own facilities and rely on third parties for additional production capacity. Beginning in December 2013, we now rely on Minnetronix, Inc. as the sole manufacturer of the Tyvaso Inhalation System. We substantially rely on third parties to adhere to and maintain production processes in accordance with all applicable regulatory requirements. If any of these critical third-party production and supply arrangements are interrupted for compliance issues or other reasons, we may not have sufficient inventory to meet future demand. In addition, any change in suppliers and/or service providers could interrupt the production of our commercial products and impede the progress of our commercial launch plans and clinical trials.

In addition, the internalization of our production process also subjects us to risks as we engage in increasingly complex production processes. For example, Remodulin, Tyvaso and Ch14.18 must be formulated in a sterile environment and we have limited experience with sterile manufacturing on a commercial scale. In addition, Ch14.18 is a monoclonal antibody as with all biologic products, monoclonal antibodies are inherently more difficult to produce than our treprostinil-based products and involve increased risk of viral and other contaminants.

Additional risks we face with our production strategy include the following:

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. We are limited in our ability to exercise 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 are in compliance 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 or subject to recalls;

If we had to replace our own production operations or a third-party 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 and biologic products is complex;

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

Table of Contents

The supply of materials and components necessary to produce and package our products may become scarce or unavailable. Disruptions to the supply of these materials could delay the production 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 can 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. Interruptions in our production process 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 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 involve third parties extensively to assist us in: (1) producing our commercial products; (2) conducting clinical trials; (3) obtaining regulatory approvals; (4) conducting pharmacovigilance-related and product complaint activities, including drug safety, reporting adverse events and product complaints; and (5) marketing and distributing our products. The involvement of third parties is necessary because we do not possess the internal capacity, and in certain cases the expertise, to perform all of these functions. Accordingly, the success of these third parties in performing their contractual obligations is critical to our operations.

For risks relating to the involvement of third parties in our production process, see the risk factor above, entitled *Our production strategy exposes us to significant risks*.

We rely on Accredo Health Group, Inc. (Accredo) and CVS Caremark (Caremark) to 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 achieve acceptable profit margins on our products, they may reduce or discontinue the sale of our products. Furthermore, if our distributors devote fewer resources to sell our products or are unsuccessful in their sales efforts, our revenues may decline materially.

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 wholesale price of Adcirca, which generally moves in parity with the wholesale price Lilly sets for Cialis® (both of these products contain the same active ingredient). Lilly generally increases the price of both Cialis and Adcirca twice per year. Changes in Lilly's wholesale prices could adversely impact demand or reimbursement for Adcirca, particularly in light of the commercial availability of generic sildenafil, the active ingredient in Revatio, which could be prescribed in lieu of Adcirca.

In addition, any change in service providers could interrupt the 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.

We rely heavily on third-party contract research organizations, clinical investigative sites and other third-parties to conduct our clinical trials. In addition, the success of certain products we are



Table of Contents

developing will depend on clinical trials sponsored by third parties. Failure by any third party to conduct or assist us in conducting clinical trials in accordance with study protocols, quality controls and GCP, and to submit associated regulatory filings, could limit or prevent our ability to rely on results of those trials in seeking regulatory approvals.

We are heavily reliant on Medtronic, Inc. (Medtronic) for the success of our program to develop an implantable pump to deliver intravenous Remodulin. Medtronic has recently completed a clinical study in this regard, and is conducting other stability, compatibility and technical assessments of its implantable pump system. We are substantially reliant on Medtronic to complete these assessments, to complete necessary regulatory filings and respond to FDA inquiries, and to maintain appropriate quality controls relating to the system. As such, we can provide no assurances as to the timing or likelihood of the Remodulin implantable pump program's success.

**Our operations must comply with extensive laws and regulations in the United States 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 regulatory approval process is particularly uncertain for our lung transplantation programs, which include the development of xenotransplantation, regenerative medicine and cell-based products. The manufacture, distribution, advertising and marketing of these products are also subject to extensive regulation, including strict pharmacovigilance and adverse event and medical device reporting requirements. Any future product approvals we receive could be accompanied by significant restrictions on the use or marketing of a given product. Furthermore, our product candidates may fail to receive marketing approval on a timely basis, or at all. If granted, product approvals can be withdrawn for failure to comply with regulatory requirements, such as 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 up to and 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 avoid the use of our products even after we have resolved the issues that led to such regulatory action.

For example, in December 2013 we received a subpoena from the Office of the Inspector General (OIG) of the Department of Health and Human Services reflecting a civil investigation by the United States Department of Justice, principally represented by the United States Attorney's Office for the District of Maryland. The subpoena requests documents regarding Remodulin, Tyvaso and Adcirca, including our marketing practices relating to these products. We are cooperating with the investigation, which has and will continue to increase our legal expenses, and will require significant management time and attention. We are not aware that a claim, litigation or assessment has been asserted in connection with the subpoena. However, such subpoenas are often associated with previously filed qui tam actions brought under the federal and state false claims acts. Qui tam actions are lawsuits brought by private plaintiffs on behalf of the federal government, and often state governments, for alleged federal or state false claims act violations, with potential liability including mandatory treble damages

Table of Contents

and significant per-claim penalties, currently set at \$5,500 to \$11,000 per false claim. We may currently be subject to investigation in connection with qui tam actions filed under seal. We also cannot predict what actions, if any, may be taken against us or our employees by the OIG, the Department of Justice, other governmental entities, or any third parties in connection with such investigation, nor can we predict or determine the outcome of the government's investigation or reasonably estimate the amount or range of amounts of fines, damages, restitutions or penalties that might result from a settlement or an adverse outcome. As a result of the investigation we may also be subject to exclusion of our products from reimbursement under the federal healthcare programs, debarment, or a corporate integrity agreement, and certain of our employees may also be subject to exclusion or debarment. Any of these risks and uncertainties, including the conduct of the investigation itself, could adversely affect our revenues, results of operations, cash flows and financial condition.

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

After our products receive regulatory approval, they remain subject to ongoing regulatory requirements, which can impact, among other things, product labeling, manufacturing practices, pharmacovigilance and adverse event and medical device reporting, complaint processing, storage, distribution, advertising and promotion, and record keeping. If we do not comply with applicable regulations, the range of possible sanctions may include: (1) adverse publicity, (2) product recalls or seizures, (3) fines, (4) total or partial suspensions of production and/or distribution, (5) suspension of marketing applications, and (6) enforcement actions, including injunctions and civil suits or criminal prosecution. 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 an unacceptable safety risk, regulatory authorities could withdraw the product's approval, suspend production or place other marketing restrictions on that product. 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 and other regulators to those specific indications and conditions for which clinical safety and efficacy have been demonstrated.**

Any regulatory approval of our products is limited to 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.

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, suspension or withdrawal of an approved product from the market, product recalls, fines, disgorgement of money, operating restrictions, civil lawsuits, injunctions or criminal prosecution.

Table of Contents

**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.**

There are various laws in jurisdictions around the world that restrict particular marketing practices in the pharmaceutical and medical device industries. These laws include, but are not limited to, anti-kickback and false claims statutes, the Foreign Corrupt Practices Act and the UK Bribery Act. 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 and financial condition. Furthermore, we have significantly expanded our sales and marketing staff. Any expansion of sales and marketing efforts can increase the risks of noncompliance with these laws. Furthermore, the growth in our operations outside the U.S., both directly and through third-party distributors, also has increased these risks.

In the United States, the federal health care program anti-kickback statute prohibits, among other activities, knowingly and willfully offering, paying, soliciting, or receiving compensation to induce, or in return for, the purchase, lease, order or arranging the purchase, lease or order of any health care product or service reimbursable under any federally financed health-care program. 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. 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 compensation intended to induce prescriptions, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not always meet all of the criteria for safe harbor protection.

The federal False Claims Act prohibits any person from knowingly presenting or causing to be presented a false statement material to a false claim. 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 free product. Other companies have been prosecuted for causing false claims to be submitted because of these companies' marketing of a product for unapproved, and thus non-reimbursable, uses. Potential liability under the federal False Claims Act includes mandatory treble damages and significant per-claim penalties, currently set at \$5,500 to \$11,000 per false claim. The majority of states also have statutes or regulations similar to the federal anti-kickback statute and False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs; furthermore, in several states, these statutes and regulations 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, debarment, criminal fines, and imprisonment.

In December 2013 we received a subpoena from the OIG of the Department of Health and Human Services reflecting a civil investigation by the United States Department of Justice, principally represented by the United States Attorney's Office for the District of Maryland. The subpoena requests documents regarding Remodulin, Tyvaso and Adcirca, including our marketing practices relating to these products. For further details, see *Item 3. Legal Proceedings*.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (PPACA), also imposed new reporting requirements for pharmaceutical and device manufacturers with regard to payments or other transfers of value made to physicians and teaching hospitals. 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. Manufacturers must make these first reports for information collected in 2013

Table of Contents

by March 31, 2014. Such information is to be made publicly available by the Secretary of Health and Human Services in a searchable format beginning September 30, 2014.

Failure to submit required information may result in civil monetary penalties of up to \$150,000 per year (and up to \$1.0 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. This amendment provides that a person or entity no longer needs to have knowledge these statutes or specific intent to violate them. 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 Act.

If not preempted by this federal law, several states currently 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, Connecticut 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 will 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 broad measure intended to expand health care 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 law will significantly impact the pharmaceutical industry; however, the full effects of the PPACA will be unknown until all of these provisions are implemented and the Centers for Medicare and 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 health care 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 prostacyclin analogues, such as intravenous Remodulin, 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 the Remodulin package insert, and the occurrence of sepsis is familiar to physicians who prescribe intravenously administered therapies. Concerns about bloodstream infections may affect a physician's decision to prescribe or a patient's willingness to use intravenous Remodulin.

**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

Table of Contents

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, generally 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 impede the operations of our business.

**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, produce and sell the products covered by such agreements 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 those which we have commercialized and are developing further. These intellectual property rights have either been contractually licensed to us or have been acquired by us. Under each of our product license agreements, we are granted a license to intellectual property owned by others that covers a drug or other product. Under each of our purchase agreements, we have rights to certain intellectual property. We may be required to license 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 licenses or purchase agreements are terminated, we may lose our rights to develop, make and sell the products to which such licenses or agreements relate;

Our license and purchase agreements generally provide the licensor or seller with the right to terminate the agreement in the event of a breach 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 we have rights to breaches its obligation or otherwise fails to maintain the intellectual property licensed, 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 license 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. 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 relates. For example, Lilly also has authority over all regulatory activities and has the right to determine the net wholesale price for Adcirca.

Table of Contents

**Our intellectual property rights may not effectively deter competitors from developing competing products that, if successful, could have a material adverse effect on 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 use of tadalafil, the active ingredient in Remodulin, Tyvaso and Orenitram, for treating PAH will expire in October 2014. Three of our U.S. patents covering our current methods of synthesizing and producing tadalafil expire in October 2017, and a fourth will expire in 2028. We also have been granted one patent in the European Union and one patent in Japan, each of which covers our tadalafil synthesis and production methods and will expire in October 2018. Our three U.S. patents covering an improved diluent for Remodulin will expire in 2028 and 2029. Our patents for Tyvaso covering methods of treating PAH by inhaled delivery will expire in the United States and in various countries throughout the world in 2018 and 2020, respectively. Our patents for Orenitram covering methods of use for treating PAH, orally administered formulations, controlled moisture storage and production methods and controlled release formulations will expire in the United States between 2024 and 2031 and in various countries throughout the world in 2024. The U.S. patent for Adcirca for the treatment of pulmonary hypertension will expire in 2017.

We continue to conduct research into new methods to synthesize tadalafil and have pending U.S. and international patent applications and patents relating to such methods. However, we cannot be sure that these additional patents will affect the possibility or timing of competitors' efforts to bring products to market, or that additional patent applications will result in new patents. Upon the expiration of any of our patents, competitors may develop generic versions of our products and may market those generic versions at a lower price 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. In addition, we may be forced to incur substantial costs to defend the intellectual property rights conferred by our patents. 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 may 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 two abbreviated new drug application (ANDA) filings by a generic drug company. The outcome of current or future challenges with respect to the validity, enforceability or scope of our patents could significantly reduce revenues from Remodulin.**

In February 2012, we received a Paragraph IV Certification Notice Letter (Original Notice Letter) from Sandoz advising that Sandoz had submitted an ANDA to the FDA requesting approval to market a generic version of the 10 mg/mL strength of Remodulin. In December 2012, we received notice (Second Notice Letter) that Sandoz had amended its previously filed ANDA, to request approval to market generic versions of the 1 mg/mL, 2.5 mg/mL, and 5 mg/mL strengths of Remodulin. In the Notice Letters, Sandoz states that it intends to market a generic version of Remodulin before the expiration of certain of our patents that expire in 2014, 2017 and 2029.

Table of Contents

We responded to the Original Notice Letter by filing a lawsuit in March 2012 against Sandoz in the U.S. District Court for the District of New Jersey alleging patent infringement. We responded to the Second Notice Letter by filing an additional lawsuit in January 2013 for patent infringement in the U.S. District Court for the District of New Jersey.

The current status of our litigation with Sandoz is further described in *Part I, Item 3. Legal Proceedings*, contained elsewhere in this Annual Report on Form 10-K.

There can be no assurance that we will prevail in our defense of our patent rights, or that additional challenges from other ANDA filers will not surface with respect to Remodulin or our other treprostinil-based products. Our existing patents could be invalidated, found unenforceable or found not to cover a generic form of Remodulin, Tyvaso or Orenitram. If any ANDA filer were to receive approval to sell a generic version of Remodulin, Tyvaso or Orenitram and/or prevail in any patent litigation, the affected product would become subject to increased competition and our revenue would decrease.

**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. Payment of royalties would negatively affect our profits; furthermore, if we chose to contest these allegations, we could be subject to costly and time-consuming litigation or could lose 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, distracting to our operations, costly and may conclude unfavorably for us. In addition, 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 determined to be valid or enforceable, 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 to which we currently do not hold licenses are necessary for us to manufacture, use or sell our products, we would need to obtain necessary licenses to prevent infringement. 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. Otherwise, we would be responsible for the cost of these licenses. Royalty payments and other fees under these licenses would erode 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 to avoid infringing a third-party patent, we would be unable to continue to manufacture or sell related products.

If a third party commences 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.

**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. We may not be able to maintain our current product liability 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

Table of Contents

significantly exceed our liability insurance coverage, we may experience financial hardship or potentially be forced out of business.

**If we fail to attract and retain key management and qualified scientific and technical personnel, we may not be able to achieve our business objectives.**

Members of our management team, including our founder, Chairman and Chief Executive Officer, Dr. Martine Rothblatt, and our President and Chief Operating Officer, Dr. Roger Jeffs, play a critical role in defining our business strategy and maintaining our corporate culture. The loss of the services and leadership of Dr. Rothblatt, Dr. Jeffs or any other members of our senior management team could have an adverse effect on our business. We do not maintain key person life insurance on our senior management team members. In addition, effective succession planning is important to our long-term success. Failure to identify and retain adequate replacements for members of our senior management team and to transfer knowledge effectively could impede the achievement of our business objectives. Our future success also depends on our ability to attract and retain qualified scientific and technical personnel. Competition for skilled scientific and technical personnel in the biotechnology and pharmaceutical industries is intense. Furthermore, our compensation arrangements may not be sufficient to attract new qualified scientific and technical employees or retain such core employees. If we fail to attract and retain such employees, we may not be successful in developing and commercializing new therapies for PAH and other diseases.

**Improper handling of hazardous materials used in our activities could expose us to significant remediation 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 and future environmental laws and regulations can require significant costs; furthermore, we can be subject to substantial fines and penalties in the event of noncompliance. 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 the manner in which such hazardous waste is disposed of by our contractors. 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 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 and expanding our offices, laboratories and production facilities, and we are currently seeking regulatory approvals for certain facilities. However, our facilities could be insufficient to meet future demand for our products. Conversely, we may have excess capacity at our facilities if future demand falls short of our projections, 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 until we possess sufficient post-launch sales experience.



Table of Contents

**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 instance, upon maturity or conversion of our 1.0 percent Convertible Senior Notes due September 15, 2016 (2016 Convertible Notes), subject to certain provisions, we must repay our investors in cash up to the principal balance of \$250.0 million. Further, in certain circumstances constituting a fundamental change under the 2016 Convertible Notes, we may be required to repurchase the 2016 Convertible Notes for cash. In addition, awards granted under our Share Tracking Award 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 may 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 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.

**Information technology security breaches and other disruptions could compromise our information and expose us to legal responsibility which would cause our business and reputation to suffer.**

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our suppliers, customers and business partners, and personally identifiable information. The secure maintenance of this information is critical to our operations and business strategy. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Such breaches could compromise sensitive and confidential information stored on our networks and expose such information to public disclosure, loss or theft. Any access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, disruption of our operations, and damage to our reputation which could adversely affect our business.

Table of Contents

**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 relate to operating performance. The following table sets forth the high and low closing prices of our common stock for the periods indicated:

		<b>High</b>	<b>Low</b>
January 1, 2013	December 31, 2013	\$ 114.51	\$ 51.64
January 1, 2012	December 31, 2012	\$ 58.91	\$ 40.42
January 1, 2011	December 31, 2011	\$ 70.70	\$ 37.21

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

Failure to meet estimates or expectations of securities analysts;

Quarterly and annual financial results;

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, including in particular, the development of new, competing PAH therapies;

Announcements by us or others regarding generic challenges to the intellectual property relating to our products, including the ANDA filed by Sandoz relating to certain of our Remodulin patents and to our pending lawsuit defending our patent 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 our operations;

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

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

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

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.

Table of Contents

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

Many securities analysts publish quarterly and annual projections of our revenues and profits. Such projections are inherently subject to uncertainty. As a result, actual revenues and profits may fail to meet these projections. Even minor variations in reported revenues and profits compared to securities analysts' expectations could have a significant adverse 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 settlement of warrants relating to the hedging transaction relating to our 2016 Convertible Notes. 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.

Any sales of common stock issued to holders of our 2016 Convertible 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 our common stock.**

In recent years, our Board of Directors has authorized several programs to repurchase our common stock, including a \$420.0 million share repurchase program effective during the two-year period that began on March 4, 2013. The price of our common stock may, in part, reflect expectations that our repurchase program will be fully consummated. Our share repurchase program does not obligate us to acquire any specific number of shares. If we fail to meet analyst or investor expectations regarding our repurchase program, our stock price may decline.

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

The counterparty to the convertible note hedge transaction we entered into in connection with the issuance of our 2016 Convertible Notes (call options) will subject us to counterparty risk in that the counterparty may default on fulfilling its obligations under the call options. Our exposure to the credit risk of the counterparty will not be secured by any collateral. Recent global 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. 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 stock due to our obligation to deliver shares subsequent to the conversion of the notes. We cannot provide any assurances as to the future financial stability or viability of the counterparty to our convertible note hedge transaction.

Table of Contents

**Provisions of Delaware law and our amended and restated certificate of incorporation, second amended and restated by-laws, shareholder rights plan, 2016 Convertible Notes, convertible note hedge transaction and employment and license agreements, among other things, 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 convertible note hedge transaction could require us to make substantial payments to the counterparty or may increase the price of our common stock. The costs or any increase in stock price that may arise from terminating or unwinding the transaction 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 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 prior consent of the counterparties to these agreements if we are contemplating a change of control. If these counterparties withhold consent, related agreements could be terminated and we would lose related license rights. For example, both Lilly and Toray have the right to terminate our license agreements relating to Adcirca and beraprost, 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.

Table of Contents

**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 232,000 square foot combination laboratory and office building complex in Silver Spring, Maryland that serves as our corporate headquarters and is used for the synthesis of treprostinil, the active ingredient in Remodulin and Tyvaso, and treprostinil diolamine, the active ingredient in Orenitram, as well as the production of Remodulin and Tyvaso and our Ch14.18 monoclonal antibody. We also own several other buildings in Silver Spring used principally for office and laboratory space and we lease and own warehouse space near Silver Spring.

**North Carolina** We own a 380,000 square foot combination manufacturing facility and office building in Research Triangle Park, North Carolina (RTP facility), which is occupied by our clinical research and development, commercialization and our logistics and manufacturing personnel. We warehouse and distribute Remodulin, Tyvaso and Orenitram and produce Orenitram at this location. In June 2012, we acquired a 132-acre property containing approximately 312,000 square feet of building space adjacent to our RTP facility, which we intend to use for future expansion. We have begun building out a portion of the property to house research, development and production facilities relating to our lung regeneration program.

**Europe** We own an office building near London, England which serves as our European headquarters. We also own a building in Oxford, England. In Germany, we lease a warehouse where we maintain inventory of components of our Tyvaso Inhalation System.

**District of Columbia** We own two adjacent buildings in Washington, D.C., which serve as office space.

**Florida** We own an office building in Satellite Beach, Florida. In addition, we lease office space in Melbourne, Florida.

Certain of our Maryland and North Carolina properties serve as collateral under our \$70.0 million Credit Agreement with Wells Fargo Bank, National Association and Bank of America, N.A. For further details, see *Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Capital Resources Mortgage Financing*.

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.

Table of Contents

**ITEM 3. LEGAL PROCEEDINGS**

*Sandoz Inc.*

In February 2012, we received a Paragraph IV Certification Notice Letter (the Original Notice Letter) from Sandoz Inc. (Sandoz) advising that Sandoz had submitted an abbreviated new drug application (ANDA) to the FDA requesting approval to market a generic version of the 10 mg/mL strength of Remodulin. In December 2012, we received notice (the Second Notice Letter) that Sandoz had amended its previously filed ANDA to request additional approval to market generic versions of the 1 mg/mL, 2.5 mg/mL, and 5 mg/mL strengths of Remodulin. In the Original Notice Letter and the Second Notice Letter, Sandoz stated that it intends to market a generic version of Remodulin before the expiration of the following patents relating to Remodulin: 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. Each of these patents is listed in the FDA's Orange Book.

We responded to the Original Notice Letter by filing a lawsuit in March 2012 against Sandoz in the U.S. District Court for the District of New Jersey alleging patent infringement. We responded to the Second Notice Letter by filing an additional lawsuit in January 2013 for patent infringement in the U.S. District Court for the District of New Jersey. Sandoz has filed its answer to our complaints in both lawsuits, and has also filed counterclaims in each action alleging that the patents at issue in the litigation are invalid or will not be infringed by the commercial manufacture, use or sale of the proposed product described in Sandoz's ANDA submission. We have filed answers to the counterclaims in both lawsuits.

Under the Hatch-Waxman Act, the FDA is automatically precluded from approving Sandoz's ANDA with respect to each concentration of Remodulin for up to 30 months from receipt of the Notice Letter corresponding to such concentration or until the issuance of a district court decision that is adverse to us, whichever occurs first. We intend to vigorously enforce our intellectual property rights relating to Remodulin.

*Department of Health and Human Services Subpoena*

In December 2013, we received a subpoena from the Office of the Inspector General (OIG) of the Department of Health and Human Services reflecting a civil investigation by the United States Department of Justice, principally represented by the United States Attorney's Office for the District of Maryland. The subpoena requests documents regarding Remodulin, Tyvaso and Adcirca, including our marketing practices relating to these products. We are cooperating with the investigation. We are not aware that a claim, litigation or assessment has been asserted in connection with the subpoena. However, we cannot predict what actions, if any, may be taken by the OIG, the Department of Justice, other governmental entities, or any third parties in connection with such investigation.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

Table of Contents**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:

		2013		2012	
		High	Low	High	Low
January 1	March 31	\$ 62.57	\$ 51.64	\$ 50.99	\$ 45.54
April 1	June 30	\$ 69.31	\$ 59.64	\$ 49.38	\$ 40.42
July 1	September 30	\$ 79.58	\$ 66.10	\$ 58.30	\$ 49.87
October 1	December 31	\$ 114.51	\$ 80.03	\$ 58.91	\$ 44.99

**Number of Holders**

As of February 18, 2014, there were 39 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.

**Comparison of Five-Year Total Cumulative Shareholder Return**

The following chart shows the performance from December 31, 2008 through December 31, 2013 of United Therapeutics common stock, compared with an investment in the stocks represented in each of the NASDAQ U.S. Benchmark TR Index, the NASDAQ U.S. Stock Market Index, the NASDAQ ICB: 4577 Pharmaceuticals Index and the NASDAQ Pharmaceutical Stock Index, assuming the investment of \$100 at the beginning of the period and the reinvestment of dividends, if any. NASDAQ OMX, which supplies us with total return data for the comparative indexes, has historically used total return data prepared by the Center for Research in Security Prices (CRSP). Effective January 2014, NASDAQ OMX has replaced total return values prepared by CRSP with its own NASDAQ OMX Global Index data. As a result of this change, the NASDAQ U.S. Stock Market Index has been replaced with the NASDAQ U.S. Benchmark TR Index, and the NASDAQ Pharmaceutical Stock Index has been replaced with the NASDAQ ICB: 4577 Pharmaceuticals Index.



Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-K

Table of Contents

**ITEM 6. SELECTED FINANCIAL DATA**

The following selected consolidated financial data should be read in conjunction with our consolidated financial statements and the notes accompanying the consolidated financial statements and *Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations* included in this Annual Report on Form 10-K. The historical results are not necessarily indicative of results to be expected for future periods. The following information is presented in thousands, except per share data.

	Year Ended December 31,				
	2013	2012	2011	2010	2009
<b>Consolidated Statements of Operations Data:</b>					
Revenues	\$ 1,116,984	\$ 916,076	\$ 743,183	\$ 592,899	\$ 358,880
Operating expenses:					
Research and development	299,348	173,387	180,015	165,306	120,368
Selling, general and administrative	394,010	201,746	156,482	188,606	171,894
Cost of product sales	131,127	119,297	88,904	67,674	40,861
Total operating expenses	824,485	494,430	425,401	421,586	333,123
Operating income	292,499	421,646	317,782	171,313	25,757
Total other (expense) income, net	(13,596)	19,025	(18,665)	(16,162)	(7,134)
Income from continuing operations before income tax	278,903	440,671	299,117	155,151	18,623
Income tax (expense) benefit	(104,343)	(136,229)	(81,874)	(43,945)	695
Income from continuing operations	174,560	304,442	217,243	111,206	19,318
Income (loss) from discontinued operations, net of tax(1)			625	(5,290)	144
Net income	\$ 174,560	\$ 304,442	\$ 217,868	\$ 105,916	\$ 19,462
Net income per common share:					
Basic(2)	\$ 3.49	\$ 5.84	\$ 3.81	\$ 1.89	\$ 0.37
Diluted(2)	\$ 3.28	\$ 5.71	\$ 3.67	\$ 1.78	\$ 0.35
Weighted average number of common shares outstanding:					
Basic(2)	50,076	52,093	57,163	56,142	53,314
Diluted(2)	53,231	53,280	59,395	59,516	56,133

	Year Ended December 31,				
	2013	2012	2011	2010	2009
<b>Consolidated Balance Sheet Data:</b>					
Cash, cash equivalents and marketable investments(3)	\$ 1,136,668	\$ 784,931	\$ 747,378	\$ 759,932	\$ 378,120
Total assets	2,087,567	1,626,595	1,518,079	1,431,635	1,051,544
Debt	286,182	276,323	266,835	305,968	250,599
Retained earnings (deficit)	728,040	553,480	249,038	31,170	(74,746)
Total stockholders' equity	1,259,274	1,083,981	948,488	883,886	653,009

(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

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

### Table of Contents

Medicomp, Inc. have been included within discontinued operations for each of the years presented prior to the sale of the subsidiary. 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 11 *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.

Table of Contents

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

The following discussion should be read in conjunction with our consolidated financial statements and related notes to the consolidated financial statements included in this Annual Report on Form 10-K. The following discussion contains forward-looking statements made pursuant to the safe harbor provisions of Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. These statements are based on our 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®, Orenitram , 314d, TransCon treprostinil and TransCon beraprost):* 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 (cyclic GMP) in cells. Cyclic GMP is activated by nitric oxide (NO), a naturally occurring substance in the body that mediates the relaxation of vascular smooth muscle;

*Monoclonal antibody for oncologic applications (Ch14.18 MAb):* an antibody that treats 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;

*Cell-based therapy:* a cell-based product known as PLacental eXpanded (PLX) cells we are developing for the treatment of pulmonary hypertension; and

*Lung transplantation:* engineered lungs and lung tissue, which we are developing using xenotransplantation and regenerative medicine technologies, for transplantation in patients suffering from pulmonary arterial hypertension (PAH) and other lung diseases. We are also developing technologies to increase the supply of donor lungs through collaborations with two ex-vivo lung perfusion companies.

We concentrate substantially all of our research and development efforts on the preceding key therapeutic programs. We currently market and sell the following commercial products: (1) Remodulin (treprostinil) Injection (Remodulin); (2) Tyvaso (treprostinil) Inhalation Solution (Tyvaso); and (3) Adcirca (tadalafil) tablets (Adcirca). In December 2013, the United States Food and Drug Administration (FDA) approved Orenitram (treprostinil) Extended-Release Tablets (Orenitram) for the treatment of PAH in World Health Organization (WHO) Group 1 patients to improve exercise capacity. We expect to begin selling Orenitram in mid-2014 as we are currently preparing for commercial launch.

Remodulin is approved in the United States for subcutaneous (under the skin) and intravenous (in the vein) administration, including for the treatment of patients requiring transition from Flolan® (epoprostenol sodium) for Injection. Remodulin has also been approved in various countries outside of the United States.



Table of Contents

Tyvaso is an inhaled treatment for PAH approved in the United States using the same active ingredient as Remodulin and Orenitram. Adcirca and Orenitram are both orally-administered therapies. We acquired exclusive commercialization rights to Adcirca in the United States and Puerto Rico from Eli Lilly and Company (Lilly). Tyvaso, Adcirca and Orenitram offer more convenient routes of administration than Remodulin, and are capable of reaching a broader range of patients who suffer from PAH in various stages of the disease. In addition, we are developing the following products for the treatment of PAH: an implantable pump delivery system for Remodulin, an extended release, once-daily injectable form of treprostinil (TransCon treprostinil), an oral formulation of the prostacyclin analogue beraprost (314d) and an extended release, once-daily injection of beraprost (TransCon beraprost).

***Revenues***

Sales of Remodulin, Tyvaso and Adcirca comprise substantially all of our revenues. Despite the planned commercial launch of Orenitram in 2014, we anticipate that we will remain substantially reliant on sales of Remodulin, Tyvaso and Adcirca for the next several years as our principal sources of revenue. We have entered into separate, non-exclusive distribution agreements with Accredo Health Group, Inc. (Accredo) and CVS Caremark (Caremark) in the United States, to distribute both Remodulin and Tyvaso. In April 2012, Express Scripts, Inc., the parent company of CuraScript Inc. (CuraScript), then one of our specialty pharmaceutical distributors, completed its acquisition of Medco Health Solutions, Inc., the parent company of Accredo. As a result, CuraScript's operations have been integrated into Accredo's, and in December 2013 we consolidated our distribution agreements with the two organizations into one contract. We also sell Remodulin to distributors internationally. Adcirca is sold through Lilly's pharmaceutical wholesaler network on our behalf. Furthermore, Lilly determines the wholesale price at which we may sell Adcirca.

We require our specialty pharmaceutical distributors to maintain reasonable levels of inventory reserves as the interruption of Remodulin or Tyvaso therapy can be life threatening. Our specialty pharmaceutical distributors typically place monthly orders based on estimates of future demand and contractual minimum inventory requirements. As a result, sales of Remodulin and Tyvaso, our most significant sources of revenue, can vary depending on the timing and magnitude of these orders and may not precisely reflect patient demand.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (PPACA), contains broad provisions that will be implemented over the next several years. Since its enactment in 2010, we have not been materially impacted by the PPACA. However, the potential long-term impact of the PPACA on our business is inherently difficult to predict, as many details regarding the implementation of this legislation have not yet been determined. The impact of the PPACA depends in part on the issuance of final regulations and how this legislation will affect insurance companies and their relationships with drug manufacturers.

We recognize revenues net of: (1) estimated rebates; (2) prompt pay discounts; (3) allowances for sales returns; and (4) distributor fees. We estimate our liability for rebates based on an analysis of historical levels of rebates to both Medicaid and commercial third-party payers and considering the impact of sales trends, changes in government and commercial rebate programs and any anticipated changes in our products' pricing. In addition, we determine our obligation for prescription drug discounts required for Medicare Part D patients within the coverage gap based on estimates 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 related estimates on observed historical customer payment behavior. Prior to 2013, we derived estimates relating to our allowance for returns of Adcirca from published industry data specific to specialty pharmaceuticals and, beginning in 2013, from actual return data accumulated since launch. This change in the methodology for estimating returns of Adcirca resulted in a \$3.1 million reduction

Table of Contents

of our allowance for returns associated with Adcirca for the twelve-month period ending December 31, 2013. We also compare patient prescription data for Adcirca to sales 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 our methodology. Tyvaso and Remodulin are distributed under separate contracts with substantially similar terms, which include exchange rights in the event that product is damaged during shipment or expires. The allowance for exchanges for Remodulin and Tyvaso is based on the historical rate of product exchanges, which has been negligible and immaterial. As such, we do not record reserves for exchanges for either Remodulin or Tyvaso at the time of sale. Furthermore, we anticipate minimal exchange activity in the future for both products since we sell Remodulin and Tyvaso with a remaining shelf life in excess of one year and our distributors typically carry a thirty- to sixty-day supply of our products at any given time. Lastly, we pay our distributors for contractual services rendered and accrue for related fees based on contractual rates applied to the estimated units of service provided by distributors for a given financial reporting period.

We expect to commercially launch Orenitram in mid-2014. We anticipate selling Orenitram to specialty pharmaceutical distributors under substantially the same terms and conditions as our distribution agreements for Remodulin and Tyvaso. Consequently, we anticipate that the recognition of related sales will be net of estimated rebates, discounts, applicable sales allowances, if any, and service fees.

*Generic Competition*

We disclose in *Part I, Item 3. Legal Proceedings* of this Annual Report on Form 10-K that we are engaged in litigation with Sandoz Inc. (Sandoz) contesting its abbreviated new drug applications (ANDAs) seeking FDA approval to market generic versions of Remodulin before the expiration of certain U.S. patents in October 2014, October 2017 and March 2029. There can be no assurance that we will prevail in our defense of our patent rights, or that additional challenges from other ANDA filers will not surface with respect to Remodulin or our other treprostini-based products. Our existing patents could be invalidated, found unenforceable or found not to cover a generic form of Remodulin, Tyvaso or Orenitram. If any ANDA filer were to receive approval to sell a generic version of Remodulin, Tyvaso or Orenitram and/or prevail in any patent litigation, the affected product would become subject to increased competition and our revenue would decrease.

Certain patents for Revatio®, a PDE-5 inhibitor marketed by Pfizer, Inc., expired in 2012, leading several manufacturers to launch generic formulations of sildenafil citrate, the active ingredient in Revatio, for the treatment of PAH. Generic sildenafil's lower price relative to Adcirca could lead to an erosion of Adcirca's market share and limit its potential sales. Although we believe Adcirca's once-daily dosing regimen provides a significant competitive advantage over generic sildenafil's multiple dosing regimen, we believe that government payers and private insurance companies may favor the use of less expensive generic sildenafil over Adcirca. Thus far we have not observed any measurable impact of generic sildenafil on sales of Adcirca; however, circumstances could change over time and our revenues could be adversely impacted. The U.S. patent for Adcirca for the treatment of pulmonary hypertension will expire in 2017.

Patent expiration and generic competition for any of our commercial products could have a significant, adverse impact on our revenues, the magnitude of which is inherently difficult to predict. For additional discussion, please refer to the risk factor entitled, *Our intellectual property rights may not effectively deter competitors from developing competing products that, if successful, could have a material adverse effect on our revenues and profits*, contained in *Part I, Item 1A Risk Factors* included in this Annual Report on Form 10-K.

Table of Contents

**Cost of Product Sales**

Cost of product sales comprise: (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 original developers of these products. These agreements obligate us to pay royalties based on specified percentages of our net revenues from related products. While the royalties vary by agreement, we pay or will pay aggregate royalties on each of our current commercial products ranging from three percent to ten percent of net revenues. All royalty obligations pertaining to Remodulin and Tyvaso will expire in October 2014; consequently, we anticipate gross margins on these products to increase.

We synthesize trestatinil, the active ingredient in Remodulin and Tyvaso, and trestatinil diolamine, the active ingredient in Orenitram, and produce Remodulin and Tyvaso, at our facility in Silver Spring, Maryland. We produce Orenitram in our Research Triangle Park, North Carolina facility (RTP facility). We intend to use our own facilities to produce our primary supply of Remodulin, Tyvaso and Orenitram and to continue to contract with third parties to supplement our production capacity and mitigate the risk of shortages. We believe we have ample supply of Orenitram to support the drug's commercial launch, expected to occur in mid-2014. Lastly, we engage a third-party contract manufacturer to produce the Tyvaso Inhalation System.

Lilly manufactures Adcirca. We take title to Adcirca upon its manufacture and bear any losses related to the storage, distribution and sale of Adcirca.

**Operating Expenses**

Since our inception, we have devoted substantial resources to our various clinical trials and other research and development efforts, which are conducted both internally and through third parties. From time to time, we also license or acquire additional technologies and compounds to be incorporated into our development pipeline.

*Share-Based Compensation*

Our operating expenses and net income are often materially impacted by the recognition of share-based compensation expense (benefit) associated with our share tracking award plans (STAP) and stock option grants containing a performance requirement. The fair value of STAP awards and stock options grants are measured using inputs and assumptions under the Black-Scholes-Merton model that can materially impact the amount of compensation expense for a given period.

STAP awards are classified as liabilities and their fair value must be re-measured at the end of each financial reporting period until the awards are no longer outstanding. Changes in our STAP-related liability resulting from such re-measurements are recorded as adjustments to share-based compensation expense (benefit) and can create substantial volatility within our operating expenses from financial reporting period to period. Some or all of the following factors, among others, can cause substantial volatility in the amount of share-based compensation expense (benefit) recognized in connection with the STAP from period to period: (1) volatility in the price of our common stock (specifically, increases in the price of our common stock will result in an increase in our STAP liability and related compensation expense, while decreases in our stock price will generally result in a reduction in our STAP liability and related compensation expense); (2) changes in the number of outstanding awards; (3) changes in both the number of vested and partially vested awards; and (4) the probability of meeting a performance condition, if any.

If we meet annual contractual performance requirements tied to growth in our market capitalization, our Chief Executive Officer will be granted stock options at year-end, which vest



Table of Contents

immediately upon grant. We accrue compensation expense for her estimated stock option grants when we determine that it is probable that the performance criteria will be met. These preceding factors may cause volatility in our operating expenses and net income from financial reporting period to period.

**Major Research and Development Projects**

Our major research and development projects focus on: (1) the use of prostacyclin analogues and other therapies, as well as lung transplantation technologies, to treat cardiopulmonary diseases; (2) monoclonal antibodies to treat a variety of cancers; and (3) glycobiology antiviral agents to treat infectious diseases.

*Cardiopulmonary Disease Projects*

*Remodulin*

In 2009, we entered into an agreement with exclusive rights in the United States, United Kingdom, France, Germany, Italy and Japan, with Medtronic, Inc. (Medtronic) to develop its proprietary intravascular infusion catheter to be used with Medtronic's SynchroMed® II implantable infusion pump and related infusion system components (together referred to as the Medtronic System) in order to deliver Remodulin for the treatment of PAH. If the Medtronic System is successful, it could reduce many of the patient burdens and other complications associated with infused prostacyclin analogues. With our funding, Medtronic recently completed the *DelIVery* clinical trial, in order to study the safety of the Medtronic System while administering Remodulin. The primary objective was to demonstrate a rate of catheter-related complications below 2.5 per 1,000 patient-days while using the Medtronic System to deliver Remodulin. In September 2013, Medtronic informed us that this primary objective was met ( $p < 0.0001$ ). In addition to the clinical study, Medtronic must complete other stability, compatibility and technical assessments of the Medtronic System, including modifications to its hardware and software, and address any outstanding regulatory issues. Upon completion of these activities by Medtronic, we anticipate Medtronic will make preparations to file a premarket approval application seeking FDA clearance for the catheter and labeling changes, and will address any FDA feedback, to enable the use of the Medtronic System with Remodulin. In tandem, we plan to seek FDA approval of a supplement to Remodulin's label to allow the use of Remodulin with the Medtronic System.

*Tyvaso*

We launched commercial sales of Tyvaso in 2009 following its approval by the FDA. In connection with Tyvaso's 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 voluntary commitments.

In accordance with our PMR, we are enrolling patients in a long-term observational study in the United States that includes 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 assessing the safety of Tyvaso. We are required to update the FDA annually on our PMR, and to submit the results of the study by December 15, 2014.

In 2012, the FDA acknowledged that we had satisfied our PMCs and approved modifications to the Tyvaso Inhalation System. The Tyvaso Inhalation System now includes a nebulizer called TD-100, which incorporates these modifications. In addition, we are working to further improve the Tyvaso Inhalation System to improve and simplify patient use.

Table of Contents

*Orenitram (previously known as UT-15C Sustained Release Tablets or Oral Treprostinil)*

On December 20, 2013, the FDA approved Orenitram for the treatment of PAH in WHO Group 1 patients to improve exercise capacity. The primary study that supported efficacy of Orenitram was a 12-week monotherapy study (FREEDOM-M) in which PAH patients were not on any approved background therapy. Analysis of the FREEDOM-M results demonstrated that patients receiving Orenitram improved their six-minute walk distance by a median of approximately 23 meters ( $p=0.0125$ ) compared to patients receiving placebo. The median change from baseline at week 12 was 25 meters for patients receiving Orenitram and -5 meters for patients receiving placebo.

We also conducted two phase III studies of Orenitram in combination with other therapies, called FREEDOM-C and FREEDOM-C<sup>2</sup>. These were 16-week studies 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-C and FREEDOM-C<sup>2</sup> trials were completed in 2008 and 2011 respectively, and neither achieved statistical significance for its primary endpoint of improvement in six-minute walk distance at week 16 ( $p=0.072$  and  $p=0.089$ , respectively).

Orenitram's label notes that Orenitram has not been shown to improve exercise capacity in patients on background vasodilator therapy, and that Orenitram is probably most useful to replace subcutaneous, intravenous, or inhaled treprostinil, but use of these forms has not been studied.

We believe that in order for Orenitram to reach its full commercial potential, we need to complete further studies to support an amendment to Orenitram's label to indicate that Orenitram delays morbidity or mortality in patients who are on an approved oral background therapy. As such, we are enrolling up to 858 patients in a phase III clinical trial called FREEDOM-EV, which began in 2012. FREEDOM-EV is a placebo-controlled study of patients who enter the study on an approved background therapy, and one of the two primary endpoints of the study is the time to clinical worsening.

We expect to seek approval of Orenitram in Europe upon completion of the FREEDOM-EV study. In 2005, the European Medicines Agency (EMA) announced that Orenitram had been designated an orphan medicinal product for the treatment of PAH.

*TransCon Treprostinil*

In September 2012, we signed an exclusive agreement with Ascendis Pharma A/S (Ascendis Pharma) to apply Ascendis Pharma's proprietary TransCon technology platform to our treprostinil molecule. We believe that the TransCon technology platform may enable a sustained release of a novel, carrier-linked product, which will significantly enhance the delivery of treprostinil by establishing a once-daily, self-injectable alternative to administering Remodulin through a continuous infusion pump for the treatment of PAH. We expect that this self-injectable form of treprostinil could enable patients to avoid the infusion site pain associated with subcutaneous Remodulin and the risk of sepsis, due to the use of an indwelling catheter, which is associated with intravenous Remodulin. We are currently conducting pre-clinical studies of TransCon treprostinil.

*314d and TransCon Beraprost*

We have been studying various formulations of beraprost since 2000. We completed a phase I safety trial of a reformulated, single-isomer version of beraprost (314d) in July 2012, and the data suggested that dosing 314d four times a day was safe. We believe that 314d and treprostinil have differing prostacyclin receptor-binding profiles and thus could provide benefit to certain groups of patients with differing sets of safety and efficacy profiles. We also believe inhaled treprostinil and 314d have complimentary pharmacokinetic and pharmacodynamic profiles, which indicates they could provide greater efficacy in combination. As a result, we are enrolling a phase III study called BEAT

Table of Contents

(**BE**raprost 314d Add-on to Tyvaso) to evaluate the clinical benefit and safety of 314d in combination with Tyvaso for patients with PAH who show signs of deterioration on inhaled treprostinil or have a less than optimal response to inhaled treprostinil treatment. We intend to enroll 240 patients in the study, which will have a primary endpoint of time to clinical worsening.

In addition, we are developing an extended-release injection we refer to as TransCon beraprost, which incorporates the TransCon technology described above under *TransCon Treprostinil* and is intended to be self-administered by PAH patients once daily.

*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 PAH using Pluristem's proprietary cell technology known as PLacental eXpanded (PLX) cells. We commenced a phase I clinical study in Australia in 2013.

*Lung Transplantation*

The only reported "cure" for PAH is a lung transplant. Only a few hundred PAH patients receive a lung transplant each year due to the shortage of available lungs for transplant and the demand for transplantable lungs in patients with PAH and other end-stage pulmonary diseases, such as chronic obstructive pulmonary disease and idiopathic pulmonary fibrosis.

In July 2011, we acquired all 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 xenotransplantation. We have focused this platform on the goal of providing transplantable lungs for human patients.

We are also engaged in preclinical development of several regenerative medicine technologies for creating transplantable lung tissue and whole lungs for patients with end-stage lung disease.

In 2013, we began developing technologies to increase the supply of donor lungs through collaborations with two ex-vivo lung perfusion companies.

From inception to December 31, 2013, we spent \$990.6 million on all of our current and former cardiopulmonary disease programs.

*Cancer-Related Projects*

*Ch14.18 Antibody*

In July 2010, we entered into a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI) of the United States National Institutes for Health (NIH) to collaborate on the late-stage development and regulatory approval process for 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 neuroblastoma by targeting GD2, a glycolipid on the surface of tumor cells. Under the terms of the CRADA, the NCI has completed necessary studies and we obtained the ability to develop Ch14.18 for commercial production. Collectively, related NCI/NCI supported studies and our production data were used as the foundation for the marketing application authorization (MAA) filing which the European Medicines Agency (EMA) accepted in December 2013. In addition, we intend to file a biologics license application (BLA) during the first half of 2014 seeking FDA approval. We previously received orphan drug designation for Ch14.18 from both the FDA and the EMA.

We have spent \$107.2 million from inception to December 31, 2013, on all of our current and former cancer programs.

Table of Contents

***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 stages of testing for the treatment of a wide variety of viruses. Through our research agreement with Oxford, we are also supporting the research of 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.

In September 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 National Institute of Allergy and Infectious Diseases (NIAID) of the NIH for studies directed toward the development of a broad spectrum antiviral drug with a primary indication for dengue and a secondary indication for influenza, based on our glycobiology antiviral platform. There are eight milestone-based options to expand the project and funding under the contract. To date, we have received contract modifications exercising four of these options, increasing total committed contract funding to approximately \$25.7 million. We recognize revenue under this contract to the extent of allowable costs incurred, plus a proportionate amount of fees earned. Related revenues are included under the caption *Other Revenues* on our consolidated statements of operations located elsewhere in this Annual Report on Form 10-K.

Pursuant to our contract with NIAID, we plan to begin enrolling a phase I clinical trial of our lead antiviral candidate, an alpha-glucosidase inhibitor called UV-4B, for the treatment of dengue during the first half of 2014.

We have spent \$75.4 million from inception to December 31, 2013, on all of our current and former infectious disease programs.

**Future Prospects**

The extent of our future success is dependent on how well we achieve the following objectives: (1) in the near term, continued sales growth of our current commercial products by increasing our market share and launching enhancements designed to improve patient care, such as implantable pumps for Remodulin and a once-daily, self-injectable form of tadalafil and/or beraprost; (2) in the medium term, augmenting our near-term product growth through: (a) the approval and launch of Orenitram for use in combination with Adcirca and other oral therapies at earlier stages of PAH, and (b) commercial launch and sales of one or more of our antiviral drug candidates to the government and private sectors; and (3) in the long term, supplementing our oral, inhaled and infused PAH therapy revenues by introducing transplantable cells, tissues and organs that may provide effective treatment for PAH and other end-stage lung diseases.

Our ability to achieve these objectives and sustain our growth and profitability will depend on many factors including among others: (1) the timing and outcome of clinical trials and regulatory approvals for products we develop; (2) the timing of commercial launch of new products; (3) the pricing of and demand for our products and services; (4) reimbursement of our products by public and private health 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 ongoing challenge to our Remodulin patents by a generic drug company.

We may need to construct additional facilities to support the development and commercialization of our products. For example, the development of broad-spectrum anti-viral drugs, cell therapies and transplantable lungs and lung tissues will require the design and construction of sophisticated facilities that will need to comply with stringent regulatory requirements related to these programs. In 2013, we commenced construction of additional research and development facilities and office space, including

Table of Contents

those needed for our lung transplantation programs. The extent to which we fully develop any of these facilities will depend on the progress of our pre-clinical and clinical development in our various earlier stage programs.

We operate in a highly competitive market in which a small number of pharmaceutical companies control a majority of the available PAH therapies. These pharmaceutical companies are well established in the market and possess 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 attempt to market in the future.

**Financial Position**

Cash and cash equivalents and current and non-current marketable investments (excluding restricted amounts) at December 31, 2013 were \$1,136.7 million, compared to approximately \$784.9 million as of December 31, 2012. The increase in cash and cash equivalents of \$351.8 million resulted principally from: (1) the increase in revenues for the year ended December 31, 2013; (2) \$145.6 million and \$72.3 million less in expenditures relating to share repurchases and construction, respectively; and (3) the timing, volume and magnitude of operating expenditures relative to 2012.

Accounts receivable at December 31, 2013, was \$126.3 million, compared to \$116.6 million at December 31, 2012. The \$9.7 million increase reflects an approximately 22 percent increase in sales during the quarter ended December 31, 2013, compared to the quarter ended December 31, 2012, and the timing of invoicing and cash collections.

Other assets at December 31, 2013 were \$53.3 million compared to \$26.8 million at December 31, 2012. The \$26.5 million increase was driven by \$30.8 million of investments in two privately-held lung perfusion companies during 2013.

Current convertible notes increased by \$215.8 million, with a corresponding decrease to long-term convertible notes of \$204.7 million (net of amortization), as of December 31, 2013 compared with December 31, 2012, as a result of the reclassification of our 1.0 percent Convertible Senior Notes due September 15, 2016 (2016 Convertible Notes) from long-term status to short-term status because the notes became convertible at the election of their holders. Refer to Note 8 *Debt - Convertible Notes Due 2016* included in this Annual Report on Form 10-K for details.

Mortgages payable - current increased by \$65.3 million to \$66.6 million at December 31, 2013 from \$1.3 million at December 31, 2012, as a result of the reclassification of \$66.5 million outstanding relating to the 2010 Credit Agreement with Wells Fargo Bank, National Association and Bank of America, N.A. (Wells mortgage loan), from long-term to short-term status as the outstanding loan will be due in full in December 2014. Accordingly, there was a corresponding decrease in mortgage payable - noncurrent, from \$70.3 million at December 31, 2012 to \$3.7 million at December 31, 2013. Refer to Note 8 *Mortgage Financing - Wells Fargo Bank* included in this Annual Report on Form 10-K for details.

The Share Tracking Award plans liability increased by \$212.6 million from \$75.4 million at December 31, 2012 to \$288.0 million at December 31, 2013 as a result of a 112 percent appreciation in the price of our common stock during 2013.

Temporary equity at December 31, 2013 was \$45.0 million, compared to \$10.9 million at December 31, 2012. The \$34.2 million increase in temporary equity corresponded to the reclassification of the equity component (equal to the unamortized discount) of our 2016 Convertible Notes from additional paid-in capital as of December 31, 2013, since our 2016 Convertible Notes are now convertible at the election of their holders. For further details refer to Note 10 *Temporary Equity* to the consolidated financial statements included in this Annual Report on Form 10-K.

Table of Contents

Additional paid-in capital increased by \$41.4 million from \$1,015.8 million at December 31, 2012 to \$1,057.2 million at December 31, 2013. The increase was comprised of the following elements: (1) \$36.9 million of share-based compensation, primarily related to our Chief Executive Officer's year end stock option grant based on the terms of her employment agreement; and (2) \$35.9 million in proceeds and related tax benefits received from stock option exercises. These increases were offset in part by the reclassification of \$34.2 million to temporary equity as disclosed above.

Treasury stock was \$513.4 million at December 31, 2013, compared to \$471.0 million at December 31, 2012. The increase of \$42.4 million corresponded to our repurchase of approximately 709,000 shares of our common stock. Refer to Note 11 *Stockholders' Equity Share Repurchases* to the consolidated financial statements contained in this Annual Report on Form 10-K for further details.

**Results of Operations***Years ended December 31, 2013 and 2012*

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

	Year Ended December 31,		Percentage Change
	2013	2012	
Cardiopulmonary products:			
Remodulin	\$ 491,179	\$ 457,969	7.3%
Tyvaso	438,793	325,614	34.8%
Adcirca	176,972	122,540	44.4%
Other	10,040	9,953	0.9%
 Total revenues	 \$ 1,116,984	 \$ 916,076	 21.9%

The growth in revenues for the year ended December 31, 2013, compared to the year ended December 31, 2012, corresponded to the continued increase in the number of patients being treated with our products.

For the years ended December 31, 2013 and 2012, approximately 76 percent and 78 percent, respectively, of total revenues were derived from sales of Remodulin and Tyvaso to U.S.-based specialty pharmaceutical distributors. Remaining revenues were derived primarily from sales of Adcirca and sales of Remodulin to our international distributors.

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-K

Table of Contents

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, 2013				
	Rebates	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, January 1, 2013	\$ 15,207	\$ 2,115	\$ 3,350	\$ 1,281	\$ 21,953
Provisions attributed to sales in:					
Current period	81,938	24,154	1,254	7,008	114,354
Prior periods	997		(1,530)	3	(530)
Payments or credits attributed to sales in:					
Current period	(59,225)	(21,654)		(5,916)	(86,795)
Prior periods	(16,442)	(2,115)	(212)	(1,284)	(20,053)
Balance, December 31, 2013	\$ 22,475	\$ 2,500	\$ 2,862	\$ 1,092	\$ 28,929

	Year Ended December 31, 2012				
	Rebates	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, January 1, 2012	\$ 13,993	\$ 1,679	\$ 1,402	\$ 732	\$ 17,806
Provisions attributed to sales in:					
Current period	53,674	18,682	1,717	6,089	80,162
Prior periods	(949)	6	381	31	(531)
Payments or credits attributed to sales in:					
Current period	(39,559)	(16,567)		(4,808)	(60,934)
Prior periods	(11,952)	(1,685)	(150)	(763)	(14,550)
Balance, December 31, 2012	\$ 15,207	\$ 2,115	\$ 3,350	\$ 1,281	\$ 21,953

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

	Year Ended December 31,		Percentage Change
	2013	2012	
<b>Project and non-project:</b>			
Cardiopulmonary	\$ 116,137	\$ 122,350	(5.1)%
Share-based compensation expense	134,706	11,237	1,098.8%
Other	48,505	39,800	21.9%
Total research and development expense	\$ 299,348	\$ 173,387	72.6%

*Cardiopulmonary.* The decrease in cardiopulmonary program expenses of \$6.2 million for the year ended December 31, 2013, compared to the year ended December 31, 2012, resulted from a \$6.1 million decrease in expenses relating to work on our TransCon once-daily injectable prostacyclin analogues program.

*Share-based compensation.* The increase in share-based compensation of \$123.5 million for the year ended December 31, 2013, compared to the year ended December 31, 2012, resulted from the approximately 112 percent appreciation in the price of our common stock during the year ended December 31, 2013, compared to the approximately 13 percent appreciation in the price of our common stock price during the year ended December 31, 2012.



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

### Table of Contents

*Other.* The increase in other research and development expenses of \$8.7 million for the year ended December 31, 2013, compared to the year ended December 31, 2012, was attributable to a \$5.1 million increase in expenditures for our development of Ch14.18 and \$2.5 million in support expenses not allocated to specific projects.

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

Category:	Year Ended December 31,		Percentage Change
	2013	2012	
General and administrative	\$ 140,235	\$ 116,899	20.0%
Sales and marketing	73,871	67,220	9.9%
Share-based compensation expense	179,904	17,627	920.6%
<b>Total selling, general and administrative expense</b>	<b>\$ 394,010</b>	<b>\$ 201,746</b>	<b>95.3%</b>

*General and administrative.* The increase in general and administrative expenses of \$23.3 million for the year ended December 31, 2013, compared to the year ended December 31, 2012, was driven by the following: (1) a \$9.2 million increase in grants to non-affiliated, non-profit organizations that provide financial assistance to patients with PAH due to the growth of patients using our products, in particular, Adcirca; (2) \$6.9 million and \$5.8 million increases in operating expenses and salaries and other compensation-related expenses, respectively, associated with the general expansion of our business, including headcount; and (3) a \$6.3 million increase in consulting and professional fees related to ongoing legal matters. These increases were offset in part by a one-time \$6.8 million impairment charge on an acquired contract-based intangible asset we recognized during the year ended December 31, 2012.

*Sales and marketing.* The increase in sales and marketing expenses of \$6.7 million reflects the following increases: (1) a \$4.2 million increase in marketing activities; and (2) \$2.4 million in salaries and other compensation-related expenses as we expanded our sales personnel during 2013.

*Share-based compensation.* The increase in share-based compensation of \$162.3 million for the year ended December 31, 2013, compared to the year ended December 31, 2012, corresponded to the approximately 112 percent appreciation in the price of our common stock during the year ended December 31, 2013, compared to the approximately 13 percent appreciation in our stock price during the year ended December 31, 2012.

#### *Other (expense) Income Other, net*

Other, net income was \$635,000 for the year ended December 31, 2013, compared to other, net income of \$31.7 million for the year ended December 31, 2012. The \$31.1 million decrease was driven by the recognition of a gain of approximately \$31.0 million from the collection of insurance proceeds during 2012. Refer to Note 21 *Litigation Lexington Insurance Company* to the consolidated financial statements contained in this Annual Report on Form 10-K.

#### *Income Tax Expense*

The provision for income taxes was \$104.3 million for the year ended December 31, 2013 compared to \$136.2 million for the year ended December 31, 2012. For the years ended December 31, 2013 and December 31, 2012, the effective tax rates were approximately 37 percent and 31 percent, respectively. The increase in the effective tax rate for the year ended December 31, 2013, resulted from certain non-deductible executive compensation expenses, driven primarily by the increase in our STAP liability as

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

### Table of Contents

a result of the appreciation in our stock price. For complete details refer to Note 13 *Income Taxes* contained in this Annual Report on 10-K.

### *Years ended December 31, 2012 and 2011*

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

	Year Ended December 31,		Percentage Change
	2012	2011	
<b>Cardiopulmonary products:</b>			
Remodulin	\$ 457,969	\$ 430,132	6.5%
Tyvaso	325,614	240,382	35.5%
Adcirca	122,540	70,580	73.6%
Other	9,953	2,089	376.4%
Total revenues	\$ 916,076	\$ 743,183	23.3%

The growth in revenues for the year ended December 31, 2012, compared to the year ended December 31, 2011, corresponded to the continued increase in the number of patients being treated with our products.

For the years ended December 31, 2012 and 2011, approximately 78 percent and 81 percent, respectively, of net revenues were derived sales of Remodulin and Tyvaso to U.S.-based specialty pharmacy distributors. Remaining revenues were derived primarily from sales of Adcirca and sales of Remodulin to our international distributors. Other revenues increased by \$7.9 million, reflecting the recognition of approximately \$6.9 million of revenue from our contract with NIAID and \$2.0 million of deferred revenue upon the termination of a third-party license agreement to which our subsidiary, Revivicor, Inc. was a party, and the resulting termination of our performance obligation.

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, 2012				
	Rebates	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, January 1, 2012	\$ 13,993	\$ 1,679	\$ 1,402	\$ 732	\$ 17,806
Provisions attributed to sales in:					
Current period	53,674	18,682	1,717	6,089	80,162
Prior periods	(949)	6	381	31	(531)
Payments or credits attributed to sales in:					
Current period	(39,559)	(16,567)		(4,808)	(60,934)
Prior periods	(11,952)	(1,685)	(150)	(763)	(14,550)
Balance, December 31, 2012	\$ 15,207	\$ 2,115	\$ 3,350	\$ 1,281	\$ 21,953

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-K

Table of Contents

	Year Ended December 31, 2011					Total
	Rebates	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees		
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	

*Cost of Product Sales*

The cost of product sales as a percentage of product revenues increased to 13.0 percent for the year ended December 31, 2012 compared to 12.2 percent for the year ended December 31, 2011. During the fourth quarter of 2012, we increased our reserves for inventory obsolescence by \$8.9 million, which represents the cost of the inhalation devices incorporated into our Tyvaso Inhalation System expected to be rendered obsolete based on the pending commercial release of our improved inhalation device, the TD-100.

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

Project and non-project:	Year Ended December 31,		Percentage Change
	2012	2011	
Cardiopulmonary	\$ 122,350	\$ 150,501	(18.7)%
Share-based compensation (benefit) expense	11,237	(7,994)	240.6%
Other	39,800	37,508	6.1%
Total research and development expense	\$ 173,387	\$ 180,015	(3.7)%

*Cardiopulmonary.* The decrease in cardiopulmonary program expenses of \$28.2 million for the year ended December 31, 2012, compared to the year ended December 31, 2011, corresponded to a \$55.7 million decrease in expenses relating to the development of beraprost, as during the year ended December 31, 2011 we recognized a \$46.3 million charge relating to our July 2011 amended license agreement with Toray. This decrease was partially offset by the increases of: (1) \$16.9 million in expenses relating to work on our self-injectable prostacyclin analogues program; (2) \$5.4 million in expenses associated with our development of an implantable pump for Remodulin; and (3) \$4.1 million relating to our work to develop engineered lungs and lung tissue for transplantation.

*Share-based compensation.* The increase in share-based compensation of \$19.2 million for the year ended December 31, 2012, compared to the year ended December 31, 2011, resulted from the approximately 13 percent appreciation in the price of our common stock during the year ended December 31, 2012, compared to the approximately 25 percent decline in our stock price during the year ended December 31, 2011.



Table of Contents

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

Category:	Year Ended December 31,		Percentage Change
	2012	2011	
General and administrative	\$ 116,899	\$ 97,785	19.5%
Sales and marketing	67,220	66,405	1.2%
Share-based compensation (benefit) expense	17,627	(7,708)	328.7%
<b>Total selling, general and administrative expense</b>	<b>\$ 201,746</b>	<b>\$ 156,482</b>	<b>28.9%</b>

*General and administrative.* The increase in general and administrative expenses of \$19.1 million for the year ended December 31, 2012, compared to the year ended December 31, 2011, was driven by the following: (1) the recognition of a \$6.8 million impairment loss relating to a contract-based intangible asset as described in Note 17 *Acquisitions Revivicor, Inc.* to the consolidated financial statements contained in our Annual Report on Form 10-K for the year ended December 31, 2012; (2) a \$6.3 million increase, principally in grants to non-affiliated, not-for-profit organizations that provide financial assistance to patients with PAH; and (3) an increase of \$5.4 million in depreciation expense as a result of the expansion of our corporate headquarters in Maryland and our facilities in North Carolina in 2012.

*Share-based compensation.* The increase in share-based compensation of \$25.3 million for the year ended December 31, 2012, compared to the year ended December 31, 2011, corresponded to the approximately 13 percent appreciation in the price of our common stock during the year ended December 31, 2012, compared to the approximately 25 percent decline in our stock price during the year ended December 31, 2011.

*Other (expense) Income Other, net*

Other, net income was \$31.7 million for the year ended December 31, 2012, compared to other, net (expense) of \$748,000 for the year ended December 31, 2011. The \$32.5 million increase was driven by the recognition of an approximately \$31.0 million gain from insurance proceeds. Refer to Note 21 *Litigation Lexington Insurance Company* to the consolidated financial statements contained in this Annual Report on Form 10-K.

*Income Tax Expense*

The provision for income taxes was \$136.2 million for the year ended December 31, 2012 compared to \$81.9 million for the year ended December 31, 2011. The increase of \$54.3 million in the provision for income taxes corresponded to the increase in pre-tax earnings. For the years ended December 31, 2012 and December 31, 2011, the effective tax rates were approximately 31 percent and 27 percent, respectively. Our effective tax rate increased in 2012 compared to 2011 as a result of a reduction in the generation of general business credits. For both 2012 and 2011, the reduction in the effective tax rates reflects our domestic manufacturing deduction and our generation of general business tax credits. For complete details refer to Note 13 *Income Taxes* contained in this Annual Report on 10-K.

**Liquidity and Capital Resources**

We have funded our operations principally through sales of our commercial products and, from time-to-time, third-party financing arrangements. We believe that our current liquidity is sufficient to

Table of Contents

fund ongoing operations and future business plans as we expect continued growth in demand for our commercial products. 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 and we may seek other forms of financing.

***Cash Flows and Working Capital 2013 Compared to 2012***

*Operating*

Net cash provided by operating activities was \$425.3 million for the year ended December 31, 2013, compared to net cash provided of \$323.6 million for the year ended December 31, 2012. The \$101.6 million increase in net operating cash flows was driven by a \$290.7 million increase in share-based compensation primarily as a result of the 112 percent increase of our stock price during the year ended December 31, 2013. This increase in non-cash expense was partially offset by decreases of \$129.9 million in net income and a \$50.9 million decrease in other liabilities, consisting primarily of \$40.6 million and \$24.1 million increases in cash paid relating to income taxes and STAP award exercises, respectively, during the year ended December 31, 2013 compared to 2012.

*Investing*

Net cash used in investing activities was \$295.0 million for the year ended December 31, 2013, compared to \$163.4 million for the year ended December 31, 2012. The \$131.6 million increase in net cash used in investing activities reflects an increase in cash used to purchase \$180.8 million of held-to-maturity investments, net of maturities and \$30.8 million used to purchase investments in privately-held investments. These increases in cash used for investing were offset by a \$72.3 million decrease in construction related expenditures in 2013 as compared to 2012, as we had completed our major construction projects in Silver Spring, Maryland and Research Triangle Park, North Carolina in early 2012. Our ability to invest an additional \$180.8 million in to held-to-maturity investments was also due in part to the \$145.6 million reduction in repurchases of our common stock during 2013 as compared to 2012.

*Financing*

Net cash used in financing activities was \$5.1 million for the year ended December 31, 2013 compared to \$169.1 million for the year ended December 31, 2012. The \$164.0 million decrease in cash used in financing activities comprised in large part the following: (1) a \$145.6 million decrease in repurchases of our common stock; (2) a \$16.1 million increase in stock-option exercises and related tax benefits; and (3) \$2.7 million in proceeds related to our employee stock purchase plan during 2013, compared to none in 2012. The increase in stock option exercises and related tax benefits and the decrease in repurchases of our common stock were all attributable to the 112 percent appreciation in the price of our common stock during 2013.

***2012 Compared to 2011***

*Operating*

Net cash provided by operating activities was \$323.6 million for the year ended December 31, 2012, compared to \$250.2 million for the year ended December 31, 2011. The increase in net operating cash flows of \$73.4 million was driven by an increase of \$84.5 million in net income, which resulted mainly from an increase in revenues for 2012 and a \$45.8 million increase in share-based compensation due to the appreciation in our stock price at December 31, 2012 compared to December 31, 2011. These increases were partially offset by a decrease of \$53.9 million in the change in accounts payable, which was attributable to customary timing variances in the receipt and payment of vendor invoices. In

Table of Contents

addition, at December 31, 2011, \$14.5 million of construction-related invoices were pending payment as compared to \$205,000 at December 31, 2012.

*Investing*

Net cash used in investing activities was \$163.4 million for the year ended December 31, 2012, compared to \$121.3 million for the year ended December 31, 2011. The increase of \$42.0 million in cash used in investing activities reflects a \$75.9 million increase in expenditures associated with: (1) the completion of our Maryland and North Carolina construction projects in 2012; and (2) the acquisition of land and property in North Carolina for planned future expansion, partially offset by a \$30.4 million increase in cash received from the maturities of investments net of purchases.

*Financing*

Net cash used in financing activities for the year ended December 31, 2012 was \$169.1 million, compared to \$218.1 million of net cash provided by financing activities for the year ended December 31, 2011. During the year ended December 31, 2011, we used \$250.0 million to pay off the aggregate principal value of our 0.50 percent Convertible Senior Notes due October 15, 2011 (2011 Convertible Notes) upon their maturity date; in addition, during October 2011, we received \$250.0 million in proceeds upon the issuance at par value, of our 2016 Convertible Notes. In connection with the issuance of our 2016 Convertible Notes, we incurred issuance costs of \$7.5 million and used \$33.3 million to fund the net cost of a convertible note hedge and warrants. There were no comparable transactions during 2012. In addition, expenditures for share repurchases decreased by \$24.0 million during the year ended December 31, 2012 compared to the year ended December 31, 2011 and proceeds received from the exercise of stock options and related tax benefits recognized decreased by \$15.9 million.

*Working Capital*

At December 31, 2013, we had working capital of \$221.3 million, compared to \$491.7 million at December 31, 2012. The decrease in working capital at December 31, 2013 of \$270.4 million resulted from (1) the \$215.8 million reclassification of our 2016 Convertible Notes from long-term to current status (for further details refer to Note 8 *Debt Convertible Notes Due 2016* contained in this Annual Report on Form 10-K); (2) a \$212.5 million increase in our current STAP liability as a result of the 112 percent appreciation in the price of our common stock during 2013; and (3) the \$66.5 million reclassification of our Wells mortgage loan to short term status from long term status, as the loan is due in full in December 2014 (refer to Note 8 *Debt Mortgage Financing Wells Fargo Bank* for details included in this Annual Report on Form 10-K). These decreases in working capital were offset in part by a \$209.3 million increase in the aggregate of "cash and cash equivalents" and "short-term marketable investments" due to the increase in our sales during the twelve months ended December 31, 2013.

In addition, at December 31, 2013, we had approximately \$447.7 million of long-term marketable securities that could be liquidated or used to collateralize borrowings against our line of credit facility, if necessary, to fund our operations.

*Line of Credit*

In September 2013, we entered into a one-year Credit Agreement with Wells Fargo Bank, National Association (Wells Fargo) providing for a \$75.0 million revolving loan facility, which may be increased by up to an additional \$75.0 million provided certain conditions are met (the 2013 Credit Agreement). We plan to use this facility for general corporate purposes. At our option, amounts borrowed under the 2013 Credit Agreement bear interest at either the one-month LIBOR plus a 0.50 percent margin, or a

Table of Contents

fluctuating base rate excluding any margin. In addition, we are subject to a monthly commitment fee at a rate of 0.06 percent per annum based on the average daily unused balance of the facility. Amounts borrowed under the 2013 Credit Agreement are secured by certain of our marketable investments. As of December 31, 2013, we have not drawn on this facility.

***Convertible Senior Notes***

In October 2011, we issued the 2016 Convertible Notes with an aggregate principal value of \$250.0 million. The 2016 Convertible Notes are unsecured, unsubordinated debt obligations that rank equally with all of our other unsecured and unsubordinated indebtedness. We pay interest at 1.0 percent per annum semi-annually on March 15 and September 15 of each year. The initial conversion price is \$47.69 per share and the number of underlying shares used to determine the aggregate consideration upon conversion 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 percent 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 percent 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.

The closing price of our common stock exceeded 130 percent of the conversion price of the 2016 Convertible Notes for more than 20 trading days during the 30 consecutive trading day period ended December 31, 2013. Consequently, the 2016 Convertible Notes are convertible at the election of their holders. As this conversion right is not within our control, the 2016 Convertible Notes have been classified as a current liability on our consolidated balance sheet at December 31, 2013. We are required to calculate this contingent conversion criteria at the end of each quarterly reporting period. Therefore, the convertibility and classification of our 2016 Convertible Notes may change depending on the price of our common stock.

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. It is our expectation, based on our understanding of the historical behavior of holders of convertible notes with similar terms and our experience from a previous issue of our senior convertible notes, that most, if not all, of our outstanding 2016 Convertible Notes will be held until maturity. We currently have sufficient cash and cash equivalents and borrowing capacity to fund any conversions.

***Mortgage Financing***

In December 2010, we entered into a Credit Agreement with Wells Fargo and Bank of America, N.A., pursuant to which we obtained a \$70.0 million mortgage loan (the 2010 Credit Agreement). The 2010 Credit Agreement matures in December 2014, with a principal payment of \$66.5 million due, and is secured by certain of our facilities in Research Triangle Park, North Carolina and Silver Spring, Maryland. Annual principal payments were based on a twenty-five year amortization schedule using a



Table of Contents

fixed rate of interest of 7.0 percent and the outstanding debt bears a floating rate of interest per annum based on the one-month LIBOR, plus a credit spread of 3.75 percent, or approximately 3.9 percent as of December 31, 2013. Alternatively, we have the option to change the rate of interest charged on the loan as specified in the 2010 Credit Agreement. We can prepay the outstanding loan balance without being subject to a prepayment premium or penalty. The 2010 Credit Agreement subjects us to financial covenants, and as of December 31, 2013, we were in compliance with these covenants. We currently have sufficient cash and cash equivalents and borrowing capacity to fund the amounts due at maturity.

***Share Tracking Award Plans***

Awards granted under our 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. At December 31, 2013, the fair value of STAP awards that could potentially be exercised during 2014 was \$217.9 million. We review the potential future cash requirements of the STAP program annually. Based on our review, we can modify our operating budgets, the metrics used in determining the number of awards to be granted, or both. We currently have sufficient cash and cash equivalents and borrowing capacity to fund any STAP awards which could be exercised during 2014 and beyond. In addition, in January 2014 our Board of Directors approved a 3.0 million increase in the number of available STAP awards to accommodate anticipated future grants of STAP awards under our long-term incentive bonus and compensation programs during 2014 and 2015.

***Share Repurchases***

In June 2012, our Board of Directors authorized the repurchase of up to \$100.0 million of aggregate repurchases of our common stock (2012 Repurchase Program). We completed the 2012 Repurchase Program by acquiring approximately 2.0 million shares of our common stock at an aggregate cost of \$100.0 million during the second half of 2012.

On February 4, 2013, we announced that our Board of Directors authorized a new share repurchase program for up to \$420.0 million in aggregate repurchases of our common stock from time to time at our discretion (2013 Repurchase Program). Repurchases under the 2013 Repurchase Program may be made in the open market or in privately negotiated transactions. The 2013 Repurchase Program is effective for a two-year period beginning on March 4, 2013 and is funded by cash generated from operations and existing cash and short-term marketable investments. As of December 31, 2013, we have repurchased approximately 708,998 shares of our common stock at a cost of \$42.4 million under this repurchase plan.

***Toray License Obligations***

Pursuant to a March 2007 amendment to our license agreement for the development of beraprost, we issued 400,000 shares of our common stock to Toray. Toray has the right to request that we repurchase these shares at their issuance price of \$27.21 per share upon 30 days prior written notice. To date, Toray has not notified us that it intends to 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, 2013, the undiscounted outstanding balance of this obligation was \$20.0 million.

Table of Contents***Obligations Under License and Assignment Agreements***

Under our assignment agreement with GlaxoSmithKline PLC, we are obligated to make royalty payments through October 2014 at a rate of ten percent of the net sales of Remodulin, Tyvaso and Orenitram once the 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. Upon commercial launch of Orenitram in 2014, we will owe Supernus Pharmaceuticals Inc. a \$2.0 million milestone payment, plus a single-digit percentage royalty based on net sales of Orenitram.

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, 2013, we had the following contractual obligations (in thousands):

	Total	Payments Due by Period			More than 5 Years
		Less than 1 year	2-3 Years	4-5 Years	
2016 Convertible Notes(1)	\$ 250,000	\$ 250,000	\$ 250,000	\$	\$
Mortgage and other loans	70,337	66,636	3,587	114	
Operating lease obligations	15,229	3,285	6,238	5,341	365
Obligations under the STAP(2)	494,633	296,710	102,782	95,141	
Obligations under the SERP(3)	52,832		23,502		29,330
Purchase commitments	24,500	14,500	10,000		
Milestone payments under license and acquisition agreements(4)	28,746	7,009	7,329	7,976	6,432
Total(5)	\$ 936,277	\$ 388,140	\$ 403,438	\$ 108,572	\$ 36,127

(1) Assumes no early conversions and that the price of our common stock will exceed the conversion value so that the full principal balance of our 2016 Convertible Notes is paid at their contractual maturity date.

(2) Estimated based on the intrinsic value of outstanding STAP awards expected to vest as of December 31, 2013, 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.

(3) Consists of actuarially derived, estimated future payouts of benefits. Refer to Note 14 *Employee Benefit Plans Supplemental Executive Retirement Plan* to our consolidated financial statements included in this Annual Report on Form 10-K for further details.

(4) Based on our estimates of the timing and probability of achieving milestones specified under our various license and acquisition agreements.

(5)

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-K

As of December 31, 2013, we had \$2.8 million in unrecognized tax benefits. The contractual obligations disclosed above exclude these amounts due to the uncertainty surrounding the amounts and timing of future payments.

Table of Contents

**Summary of Critical Accounting Policies and Estimates**

We prepare our consolidated financial statements in conformity with generally accepted accounting principles in the United States (GAAP). GAAP requires that we make estimates and assumptions that affect the amounts and timing reported in our consolidated financial statements. As we become aware of updated information or new developments, these estimates and assumptions may change and materially impact reported amounts. We consider the following accounting policies to be critical to our consolidated financial statements because they require the use of our judgment and estimates (including those that are forward-looking) in their application.

***Revenue Recognition***

*Remodulin and Tyvaso*

We market Remodulin and Tyvaso to specialty pharmaceutical distributors under materially 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 we pay to distributors. Determining sales allowances involves the use of significant estimates and judgment and may involve the use of 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 prices, sales trends and changes to 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 different routes of administration 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.

We pay our distributors for contractual services rendered and accrue for related fees based on contractual 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 rare. 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 satisfactorily replaced. Replacement generally occurs within several days after we are notified of the damage. The number of product exchanges due to expiration has been negligible because we sell Remodulin and Tyvaso with expiration dates in excess of one year and our distributors typically carry a thirty- to sixty-day supply of related inventories. In addition, we do not require, nor do we provide incentives for our distributors to assume, inventory levels of Remodulin or Tyvaso beyond that which would be considered reasonable and customary in the ordinary course of business. In addition, we monitor inventory levels closely in the distribution channels.

The financial effects of exchange rights for Remodulin and Tyvaso have been immaterial and we expect the future volume of exchanges to be consistent with historical levels. Specifically, exchanges for Remodulin and Tyvaso have comprised significantly less than one percent of the volume of units sold. Since exchanges of Remodulin and Tyvaso have been, and are expected to be, insignificant, we do not recognize a reserve for estimated exchange rights in the period of sale. Lastly, we regularly monitor

Table of Contents

exchange data for both of these therapies to ensure that our assumptions continue to be reasonable, appropriate and current.

*Adcirca*

Adcirca is manufactured for us by Lilly and distributed through Lilly's pharmaceutical wholesaler network. Specifically, Lilly handles all of the administrative functions associated with the sale of Adcirca on our behalf, including the receipt and processing of customer purchase orders, shipment of Adcirca to customers and the invoicing and collection of customer payments. In addition, sales terms for Adcirca include return rights that extend throughout the distribution channel. We recognize sales of Adcirca on a gross basis (net of allowances) upon delivery to customers due to the following factors: (1) we are responsible for the acceptability of the product sold; (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; (4) we bear the return of product risk; and (5) we assume the risk and cost of a product recall, if required.

We recognize sales of Adcirca net of: (1) estimated rebates; (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 and we consider the impact of sales trends, changes in government and commercial rebate programs and anticipated changes in Adcirca's pricing. 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. Prior to 2013, we derive estimates relating to our allowance for returns of Adcirca from published industry data specific to specialty pharmaceuticals and, beginning in 2013, from actual return data accumulated since launch. This change in the methodology for estimating returns of Adcirca resulted in a \$3.1 million reduction of our allowance for returns for the twelve-month period ending December 31, 2013. In addition, we quarterly compare patient prescription data for Adcirca to sales of Adcirca 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 wholesalers' sales.

***Share-Based Compensation***

Our share-based awards are classified as either equity (stock options and our employee stock purchase plan) or as liabilities (STAP awards). We recognize related share-based compensation expense based on the fair value of the options granted to purchase stock and on outstanding STAP 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 these securities to determine whether the related impairments 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

Table of Contents

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 an impairment charge to our consolidated statement of operations.

In addition, we classify substantially all of our 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.

***Fair Value Measurements***

We are required to disclose assets and liabilities subject to fair value measurements within a specified fair value hierarchy. The fair value hierarchy gives the highest priority to fair value measurements based on unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to fair value measurements derived through the use of unobservable inputs (Level 3 measurements). Assets and liabilities are classified within the fair value hierarchy, in their entirety, based on the lowest level input that is significant to the related fair value measurement. Determining where a particular asset or liability should be disclosed within the hierarchy involves judgment regarding the significance of inputs relative to a fair value measurement and where such inputs lie within the hierarchy. Furthermore, assets and liabilities that are not actively traded may have little or no price transparency. As such, estimating the fair value of Level 3 assets and liabilities involves the use of significant subjective assumptions that we believe market participants would consider in pricing. We often employ a discounted cash flow model to help us estimate the fair value of our Level 3 assets and liabilities. Inputs to the model that involve a significant degree of judgment include estimating the amounts and timing of expected cash flows and determining a suitable discount rate.

***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

Table of Contents

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 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. When required, 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 test our finite-lived intangible assets for impairment when conditions suggest that their carrying values may not be recoverable. Evaluating intangible assets for impairment requires judgment, particularly when determining amounts of undiscounted cash flows used in assessing recoverability and measuring the fair value of such assets, if necessary. These projections require forward-looking assumptions that may include, among others, estimates of future growth, discount rates and future business or industry conditions. Changes in our business strategy or adverse changes in market conditions could indicate one or more finite-lived intangible assets have been impaired. Therefore, we would be initially required to test such assets for recoverability. If determined unrecoverable, we would recognize an impairment charge equal to the extent the carrying value of such assets exceed their fair value.

***Pension Benefit Obligation***

Accounting for our Supplemental Executive Retirement Plan (SERP) requires that we recognize in our consolidated balance sheet a liability equal to the unfunded status of the SERP (the total estimated 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 underlying the valuation is the discount rate. The discount rate should be representative of the rate associated with high-quality, fixed-income debt securities. We must consider prevailing economic conditions and outlook, the state of the credit markets and other economic factors when determining an appropriate discount rate to employ. 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 in 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 date of retirement,

Table of Contents

rate of salary increases and withdrawal rates, among other factors. Not only can actual experience differ from actuarial assumptions, but changes in any of these assumptions can also materially affect the measurement of the SERP obligation.

**Recently Issued Accounting Standards**

We noted no recent accounting standards updates issued by the Financial Accounting Standards Board (FASB) that would have a material impact on our consolidated financial statements.

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

As of December 31, 2013, we have invested \$857.4 million in corporate-debt securities and federally-sponsored agencies. The market value of these investments varies inversely with changes in prevailing 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 date, we have not experienced significant volatility in the value of these investments. However, to address market risk, we invest in debt securities with terms no longer than three years and hold these investments to maturity so that they can be redeemed at their stated or face value. At December 31, 2013, our investments in debt securities issued by corporations and federally-sponsored agencies had a weighted average stated interest rate of approximately 0.38 percent and a weighted average maturity of 1.1 years. These investments mature at various times through 2016 and many are callable annually.

During sustained periods of instability and uncertainty in the financial markets, we may be subjected 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. In addition, we believe that we maintain a conservative investment approach in that we invest exclusively in unstructured, highly-rated securities with relatively short maturities that we believe reduce our exposure 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.



Table of Contents

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

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

<u>Report of Independent Registered Public Accounting Firm</u>	<u>F-2</u>
<u>Report of Independent Registered Public Accounting Firm on Internal Control over Financial Reporting</u>	<u>F-3</u>
<u>Consolidated Balance Sheets as of December 31, 2013 and 2012</u>	<u>F-4</u>
<u>Consolidated Statements of Operations for the years ended December 31, 2013, 2012, and 2011</u>	<u>F-5</u>
<u>Consolidated Statements of Comprehensive Earnings for the years ended December 31, 2013, 2012 and 2011</u>	<u>F-6</u>
<u>Consolidated Statements of Stockholders' Equity for the years ended December 31, 2013, 2012 and 2011</u>	<u>F-7</u>
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2013, 2012 and 2011</u>	<u>F-8</u>
<u>Notes to Consolidated Financial Statements</u>	<u>F-9</u>

Table of Contents

**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Shareholders  
United Therapeutics Corporation

We have audited the accompanying consolidated balance sheets of United Therapeutics Corporation as of December 31, 2013 and 2012, and the related consolidated statements of operations, comprehensive income, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2013. 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, 2013 and 2012, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2013, 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, 2013, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 framework) and our report dated February 25, 2014 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

McLean, Virginia  
February 25, 2014

Table of Contents

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

The Board of Directors and Shareholders  
United Therapeutics Corporation

We have audited United Therapeutics Corporation's internal control over financial reporting as of December 31, 2013, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 framework) (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, 2013, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of United Therapeutics Corporation as of December 31, 2013 and 2012 and the related consolidated statements of operations, comprehensive income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2013 and our report dated February 25, 2014, expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

McLean, Virginia  
February 25, 2014

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

	<b>December 31,</b>	
	<b>2013</b>	<b>2012</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 278,889	\$ 154,030
Marketable investments	409,645	325,175
Accounts receivable, net of allowance of none for 2013 and 2012	126,297	116,626
Other current assets	46,424	35,385
Inventories, net	47,758	37,254
Total current assets	909,013	668,470
Marketable investments	448,134	305,726
Marketable investments and cash restricted	5,369	5,377
Goodwill and other intangible assets, net	14,115	16,408
Property, plant, and equipment, net	464,950	453,685
Deferred tax assets, net	192,718	150,147
Other assets	53,268	26,782
Total assets	\$ 2,087,567	\$ 1,626,595
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 92,244	\$ 83,188
Convertible notes	215,845	
Share Tracking Award Plans	287,956	75,412
Mortgages payable current	66,613	1,291
Other current liabilities	25,016	16,864
Total current liabilities	687,674	176,755
Non-current liabilities:		
Convertible notes		204,667
Mortgages payable	3,724	70,343
Other liabilities	91,858	79,967
Total liabilities	783,256	531,732
Commitments and contingencies:		
Temporary equity	45,037	10,882
Stockholders' equity:		

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-K

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, 63,013,192 and 62,082,007 shares issued, and 50,388,140 and 50,165,953 shares outstanding at December 31, 2013 and 2012, respectively	630	621
Additional paid-in capital	1,057,224	1,015,835
Accumulated other comprehensive loss	(13,183)	(14,957)
Treasury stock at cost, 12,625,052 and 11,916,054 shares at December 31, 2013 and 2012, respectively	(513,437)	(470,998)
Retained earnings	728,040	553,480
<b>Total stockholders' equity</b>	<b>1,259,274</b>	<b>1,083,981</b>
Total liabilities and stockholders' equity	\$ 2,087,567	\$ 1,626,595

See accompanying notes to consolidated financial statements.

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

	<b>Year Ended December 31,</b>		
	<b>2013</b>	<b>2012</b>	<b>2011</b>
<b>Revenues:</b>			
Net product sales	\$ 1,106,944	\$ 906,123	\$ 741,094
Other	10,040	9,953	2,089
Total revenues	1,116,984	916,076	743,183
<b>Operating expenses:</b>			
Research and development	299,348	173,387	180,015
Selling, general and administrative	394,010	201,746	156,482
Cost of product sales	131,127	119,297	88,904
Total operating expenses	824,485	494,430	425,401
Operating income	292,499	421,646	317,782
<b>Other (expense) income:</b>			
Interest income	3,827	3,941	3,450
Interest expense	(18,058)	(16,639)	(21,367)
Other, net	635	31,723	(748)
Total other (expense) income, net	(13,596)	19,025	(18,665)
Income from continuing operations before income taxes	278,903	440,671	299,117
Income tax expense	(104,343)	(136,229)	(81,874)
Income from continuing operations	174,560	304,442	217,243
<b>Discontinued operations</b>			
Income from discontinued operations, net of tax			7
Gain on disposal of discontinued operations, net of tax			618
Income from discontinued operations			625
Net income	\$ 174,560	\$ 304,442	\$ 217,868
<b>Net income per common share:</b>			
<b>Basic</b>			
Continuing operations	\$ 3.49	\$ 5.84	\$ 3.80
Discontinued operations	0.00	0.00	0.01

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-K

Net income per basic common share	\$	3.49	\$	5.84	\$	3.81
-----------------------------------	----	------	----	------	----	------

<b>Diluted</b>						
Continuing operations	\$	3.28	\$	5.71	\$	3.66
Discontinued operations		0.00		0.00		0.01

Net income per diluted common share	\$	3.28	\$	5.71	\$	3.67
-------------------------------------	----	------	----	------	----	------

<b>Weighted average number of common shares outstanding:</b>						
Basic		50,076		52,093		57,163

<b>Diluted</b>		53,231		53,280		59,395
----------------	--	--------	--	--------	--	--------

See accompanying notes to consolidated financial statements.

F-5

---

Table of Contents

**UNITED THERAPEUTICS CORPORATION**  
**CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME**  
(In thousands)

	Year Ended December 31,		
	2013	2012	2011
Net income	\$ 174,560	\$ 304,442	\$ 217,868
Other comprehensive gain (loss):			
Foreign currency translation (loss) gain	(1,193)	691	(1,709)
Defined benefit pension plan:			
Prior service cost arising during period, net of tax			(1,010)
Actuarial gain (loss) arising during period, net of tax	2,075	(5,352)	431
Less: amortization of actuarial gain and prior service cost included in net periodic pension cost	1,020	522	572
Defined benefit pension plan, net	3,095	(4,830)	(7)
Unrealized (loss) gain on available-for-sale securities, net of tax	(128)	67	6
Other comprehensive gain (loss), net of tax	1,774	(4,072)	(1,710)
Comprehensive income	\$ 176,334	\$ 300,370	\$ 216,158

See accompanying notes to consolidated financial statements.



Table of Contents

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

	Common Stock		Additional	Accumulated	Treasury	Retained	Stockholders'
	Shares	Amount	Paid-in	Other	Stock	Earnings	Equity
			Capital	Comprehensive			
				Income/(Loss)			
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
Defined benefit pension plan				(7)			(7)
Shares received upon sale of subsidiary					(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			56,192				56,192
2016 convertible note hedge and warrants, net of tax			(29,069)				(29,069)
Repurchase of shares			(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
Net income						304,442	304,442
Foreign currency translation adjustments				691			691
Unrealized gain on available-for-sale securities				67			67
Defined benefit pension plan				(4,830)			(4,830)
Repurchase of shares					(188,000)		(188,000)
Exercise of stock options	575,944	6	16,799				16,805
Tax benefit from exercises of non-qualified stock options			3,054				3,054
Share-based compensation			3,264				3,264
Balance, December 31, 2012	62,082,007	621	1,015,835	(14,957)	(470,998)	553,480	1,083,981
Net income						174,560	174,560
Foreign currency translation adjustments				(1,193)			(1,193)
Unrealized (loss) on available-for-sale securities				(128)			(128)
Defined benefit pension plan				3,095			3,095
Shares issued under employee stock purchase plan	55,070	1	2,734				2,735
Equity component 2016 convertible notes (Note 10)			(34,155)				(34,155)
Repurchase of shares					(42,439)		(42,439)
Exercise of stock options	876,115	8	26,611				26,619
Tax benefit from exercises of non-qualified stock options			9,299				9,299
Share-based compensation			36,900				36,900
Balance, December 31, 2013	63,013,192	\$ 630	\$ 1,057,224	\$ (13,183)	\$ (513,437)	\$ 728,040	\$ 1,259,274

See accompanying notes to consolidated financial statements.

F-7

---

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

	<b>Year Ended December 31,</b>		
	<b>2013</b>	<b>2012</b>	<b>2011</b>
<b>Cash flows from operating activities:</b>			
Net income	\$ 174,560	\$ 304,442	\$ 217,868
<b>Adjustments to reconcile net income to net cash provided by operating activities:</b>			
Depreciation and amortization	31,259	27,145	20,535
Provisions for inventory obsolescence	2,590	11,829	5,180
Share-based compensation expense (benefit)	320,786	30,115	(15,715)
Impairment write downs		6,804	
Expense associated with outstanding license fees			37,049
Amortization of debt discount and debt issue costs	12,601	11,064	19,359
Current and deferred tax expense	104,343	136,229	81,432
Amortization of discount or premium on investments	4,501	4,604	4,474
Excess tax benefits from share-based compensation	(9,299)	(3,054)	(11,347)
Other	592	2,642	2,614
<b>Changes in assets and liabilities:</b>			
Accounts receivable	(10,027)	(23,991)	(16,158)
Inventories	(12,394)	(5,933)	(16,055)
Other assets	(5,112)	(9,705)	(5,733)
Accounts payable and accrued expenses	7,507	(22,804)	20,251
Other liabilities	(196,640)	(145,759)	(93,559)
Net cash provided by operating activities	425,267	323,628	250,195
<b>Cash flows from investing activities:</b>			
Purchases of property, plant and equipment	(31,910)	(111,905)	(35,978)
Purchases of held-to-maturity investments	(762,198)	(579,316)	(815,684)
Maturities of held-to-maturity investments	529,900	527,858	733,876
Investments in privately-owned companies	(30,766)		
Acquisitions			(3,547)
Net cash used in investing activities	(294,974)	(163,363)	(121,333)
<b>Cash flows from financing activities:</b>			
Principal payments of debt	(1,320)	(999)	(251,039)
Proceeds received from issuance of debt			250,000
Payments of transaction costs related to issuance of debt			(7,535)
Payment for convertible note hedge and warrants, net			(33,250)
Payments to repurchase common stock	(42,439)	(188,000)	(212,000)
Proceeds from exercise of stock options	26,611	16,805	24,398
Proceeds from employee stock purchase plan	2,734		
Excess tax benefits from share-based compensation	9,299	3,054	11,347
Net cash used in financing activities	(5,115)	(169,140)	(218,079)

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

Effect of exchange rate changes on cash and cash equivalents	(319)	229	(269)
Net (decrease) increase in cash and cash equivalents	124,859	(8,646)	(89,486)
Cash and cash equivalents, beginning of year	154,030	162,676	252,162

Cash and cash equivalents, end of year	\$ 278,889	\$ 154,030	\$ 162,676
--	------------	------------	------------

**Supplemental cash flow information:**

Cash paid for interest	\$ 5,518	\$ 5,302	\$ 4,103
------------------------	----------	----------	----------

Cash paid for income taxes	\$ 142,140	\$ 101,505	\$ 46,510
----------------------------	------------	------------	-----------

**Non-cash investing and financing activities:**

Acquisitions non-cash consideration	\$	\$	\$ 5,873
-------------------------------------	----	----	----------

Non-cash additions to property, plant and equipment	\$ 9,018	\$ 1,820	\$ 23,063
---	----------	----------	-----------

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.

Table of Contents

**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.

We have approval from the United States Food and Drug Administration (FDA) to market the following therapies: Remodulin® (treprostini) Injection (Remodulin), Tyvaso® (treprostini) Inhalation Solution (Tyvaso), Adcirca® (tadalafil) tablets (Adcirca) and, since December 2013, Orenitram (treprostini) Extended-Release Tablets (Orenitram). We expect to launch Orenitram sales in the United States in mid-2014. Remodulin has also been approved in various countries outside 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. In March 2011, we sold our wholly-owned telemedicine subsidiary, Medicomp, Inc. (Medicomp). Accordingly, the operating results of Medicomp for the year ended December 31, 2011 have been presented within discontinued operations on our consolidated statement of operations. We did not recast our consolidated statement of cash flows for the year ended December 31, 2011 to reflect the classification of Medicomp as a discontinued operation as the impact was not significant to that statement (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 percent Convertible Senior Notes due September 15, 2016 (2016 Convertible Notes) are reported in Note 4 *Marketable Investments* and Note 5 *Fair Value Measurements*, respectively. The recorded value of our 2010 Wells Fargo Bank mortgage financing

Table of Contents

**UNITED THERAPEUTICS CORPORATION**

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

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

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 Bank*.

***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, fair value is measured using unobservable inputs i.e., inputs that a reporting entity believes market participants would use in pricing that are developed based on the best information available. Unobservable inputs are given the lowest priority within the hierarchy (Level 3). The level 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 assets on our consolidated balance sheets based on their contractual maturity dates and are 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

Table of Contents**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):

	<b>As of December 31,</b>	
	<b>2013</b>	<b>2012</b>
Raw materials	\$ 18,377	\$ 13,603
Work-in-progress	11,802	11,708
Finished goods	17,579	11,943
Total inventories(1)	\$ 47,758	\$ 37,254

---

(1)

During the year ended December 31, 2012, we increased our reserves for obsolescence by \$8.9 million, which represents the cost of the nebulizers incorporated into our Tyvaso Inhalation System expected to be rendered obsolete based on the then pending commercial release in 2013 of our improved nebulizer, the TD-100.

***Goodwill and Other Intangible Assets***

The carrying amount of goodwill is not amortized but is subject to annual impairment testing. We conduct our impairment testing of goodwill annually during the fourth quarter, or more frequently, if impairment indicators exist. Initially, we evaluate various pertinent qualitative factors to assess whether it is more likely than not that the fair value of a reporting unit to which goodwill has been assigned is less than its carrying value. Such qualitative factors can include, among others: (1) industry and market conditions; (2) present and anticipated sales and cost factors; and (3) overall financial performance. If we conclude based on our qualitative assessment that it is more likely than not that the fair value of a reporting unit is less than its carrying value, we then measure the fair value of the reporting unit and compare its fair value to its carrying value (Step 1 of the goodwill impairment test). If the carrying amount of the reporting unit exceeds its fair value, then the amount of an impairment loss, if any, is measured as the excess of the recorded amount of goodwill over its implied fair value (Step 2 of the goodwill impairment test).

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 measured and recognized to the extent the carrying value of such assets exceeds their fair value.





Table of Contents

## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

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

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

	As of December 31, 2013			As of December 31, 2012		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Goodwill(1)	\$ 10,703	\$	\$ 10,703	\$ 10,530	\$	\$ 10,530
Other intangible assets(1):						
Technology, patents and trade names	5,049	(3,730)	1,319	4,859	(2,825)	2,034
Customer relationships and non-compete agreements	4,947	(2,886)	2,061	4,749	(2,232)	2,517
Contract-based	2,020	(1,988)	32	2,020	(693)	1,327
Total	\$ 22,719	\$ (8,604)	\$ 14,115	\$ 22,158	\$ (5,750)	\$ 16,408

(1) Includes foreign currency translation adjustments.

We are amortizing other intangible assets over an estimated weighted average life of 6.0 years. Related amortization expense for the years ended December 31, 2013, 2012 and 2011, was \$2.6 million, \$2.1 million and \$1.7 million, respectively. As of December 31, 2013, 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,	
2014	\$ 1,385
2015	1,090
2016	562
2017	375
2018	
Thereafter	
	\$ 3,412

***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:

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-K

Buildings	25-39 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

F-12

---

Table of Contents**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,	
	2013	2012
Land	\$ 47,677	\$ 38,104
Buildings, building improvements and leasehold improvements	381,577	393,174
Buildings under construction	32,609	4,302
Furniture, equipment and vehicles	109,295	96,096
	571,158	531,676
Less accumulated depreciation	(106,208)	(77,991)
Property, plant and equipment, net	\$ 464,950	\$ 453,685

Depreciation expense for the years ended December 31, 2013, 2012 and 2011 was \$28.6 million, \$25.0 million and \$18.2 million, respectively.

Buildings under construction consist of direct costs relating to our construction projects and include capitalized interest.

***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 paid to our distributors. Calculating these sales allowances involves the use of significant estimates and judgments and information obtained 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 our product pricing, if any, sales trends and government rebate programs, particularly as they relate to eligibility requirements and/or rebate pricing.

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.



Table of Contents

**UNITED THERAPEUTICS CORPORATION**

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

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

We pay our distributors for contractual services rendered and accrue for related fees based on contractual rates applied to the estimated units of service provided by distributors for a given financial reporting 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 notification 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 thirty- to sixty-day supply of our products at any given time. In addition, we closely track inventory levels held by our distributors. Except for contractual minimum inventory levels to prevent shortages of drug supply, 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 and Tyvaso have been immaterial and we expect the volume of exchanges to be consistent with historical levels. Specifically, exchanges of Remodulin and Tyvaso have comprised substantially less than one percent of the volume of the units that we sell. Because historical and anticipated future exchanges of Remodulin and Tyvaso have been and are expected to be immaterial, we do not record a reserve for estimated exchange rights in the period of sale. Lastly, we closely monitor product 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 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 government-based and commercial payer rebates; (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 and we consider the impact of sales trends, changes in government and commercial rebate programs and anticipated changes in Adcirca's pricing. We base our estimates for prompt pay discounts on observed customer payment behavior and expectations regarding the future utilization of such discounts. Prior to 2013, we derived estimates relating to our allowance for returns of Adcirca from published industry data specific to specialty pharmaceuticals. Beginning in 2013, we derive these estimates based on actual return data accumulated since the commercial launch

Table of Contents

**UNITED THERAPEUTICS CORPORATION**

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

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

of Adcirca in 2009. This change in the methodology for estimating returns resulted in a \$3.1 million reduction of our allowance for returns for the twelve-month period ending December 31, 2013. 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 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 financial 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. We issue new shares of our common stock upon the exercise of stock options.

We measure the fair value of stock to be purchased through our employee stock purchase plan at the beginning of an offering period, or grant date, and recognize related compensation expense ratably over the requisite service period (the offering period). We issue new shares of our common stock upon the end of each offering period, or exercise date.

Table of Contents

**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 judgment, 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 marketable debt securities have been issued by corporate entities and federally-sponsored enterprises with high credit ratings. We mitigate investment risks by investing in highly-rated securities with relatively short maturities that we believe do not subject us to undue investment or credit risk. In addition, our investment policy does not provide for investments in complex or structured financial instruments. 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 be equal to amounts reported on our consolidated balance sheets.

Table of Contents**UNITED THERAPEUTICS CORPORATION****Notes to Consolidated Financial Statements (Continued)****2. Summary of Significant Accounting Policies (Continued)***Concentration of products, revenues, and customers*

In the United States, through 2013 we sold Remodulin and Tyvaso to three specialty pharmaceutical distributors: Accredo Health Group Inc. (Accredo), CuraScript Inc. (CuraScript) and CVS Caremark (Caremark). Beginning in December 2013, the operations of CuraScript have been integrated into Accredo's operations as a result of the 2012 acquisition of Medco Health Solutions, Inc., the parent company of Accredo, by Express Scripts, Inc., the parent company of CuraScript, and we have consolidated our distribution agreements with CuraScript and Accredo into one contract. During the years ended December 31, 2013, 2012 and 2011, net sales of Remodulin and Tyvaso to these distributors accounted for 76 percent, 78 percent and 81 percent, respectively, of our total net revenues. During the years ended December 31, 2013, 2012 and 2011, net sales of Remodulin accounted for 44 percent, 50 percent and 58 percent, respectively, of our total net revenues, while net sales of Tyvaso during the years ended December 31, 2013, 2012 and 2011 comprised 39 percent, 36 percent and 32 percent, respectively of our total net revenues.

At December 31, 2013 and 2012, 59 percent and 60 percent, respectively, of our accounts receivable was due from U.S.-based specialty pharmaceutical distributors.

During the years ended December 31, 2013, 2012 and 2011, we derived 57 percent, 56 percent and 61 percent of our total net revenues from one customer. Estimated net revenues from that customer were as follows (in thousands):

	<b>Year Ended December 31,</b>		
	<b>2013</b>	<b>2012</b>	<b>2011</b>
Accredo Health Group, Inc.	\$ 632,599	\$ 514,095	\$ 455,504

**3. Recently Issued Accounting Standards**

We noted no recent accounting standards updates issued by the Financial Accounting Standards Board (FASB) that would have a material impact on our consolidated financial statements.



Table of Contents

## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## 4. Marketable Investments

*Held-to-Maturity Investments*

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

As of December 31, 2013	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Government-sponsored enterprises	\$ 445,939	\$ 257	\$ (77)	\$ 446,119
Corporate notes and bonds	411,455	300	(163)	411,592
<b>Total</b>	<b>\$ 857,394</b>	<b>\$ 557</b>	<b>\$ (240)</b>	<b>\$ 857,711</b>

Reported under the following captions on the consolidated balance sheet:

Current marketable investments	\$ 409,645
Noncurrent marketable investments	447,749
	<b>\$ 857,394</b>

As of December 31, 2012	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Government-sponsored enterprises	\$ 350,043	\$ 261	\$ (35)	\$ 350,269
Corporate notes and bonds	280,385	184	(140)	280,429
<b>Total</b>	<b>\$ 630,428</b>	<b>\$ 445</b>	<b>\$ (175)</b>	<b>\$ 630,698</b>

Reported under the following captions on the consolidated balance sheet:

Current marketable investments	\$ 325,175
Noncurrent marketable investments	305,253
	<b>\$ 630,428</b>



Table of Contents

## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## 4. Marketable Investments (Continued)

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

	As of December 31,			
	2013		2012	
	Fair Value	Gross Unrealized Loss	Fair Value	Gross Unrealized Loss
Government-sponsored enterprises:				
Continuous unrealized loss position less than one year	\$ 76,651	\$ (77)	\$ 72,727	\$ (35)
Continuous unrealized loss position greater than one year				
	76,651	(77)	72,727	(35)
Corporate notes and bonds:				
Continuous unrealized loss position less than one year	168,669	(163)	90,960	(140)
Continuous unrealized loss position greater than one year				
	168,669	(163)	90,960	(140)
<b>Total</b>	<b>\$ 245,320</b>	<b>\$ (240)</b>	<b>\$ 163,687</b>	<b>\$ (175)</b>

We attribute the unrealized losses on held-to-maturity securities as of December 31, 2013 and 2012, to the variability in related market interest rates. We do not intend to sell these securities, nor is it more likely than not that we will be required to sell them prior to the end of their contractual terms as we stagger our maturities to provide a reasonable level of liquidity and do not invest in securities with maturities in excess of three years. Furthermore, we believe these securities do not expose us to undue market risk or counterparty credit risk. As such, we do not consider these securities to be other than temporarily impaired.

The following table summarizes the contractual maturities of held-to-maturity marketable investments at December 31, 2013 (in thousands):

	As of December 31, 2013	
	Amortized Cost	Fair Value
Due in less than one year	\$ 409,645	\$ 409,751
Due in one to two years	325,818	325,960
Due in three to five years	121,931	122,000
Due after five years		
<b>Total</b>	<b>\$ 857,394</b>	<b>\$ 857,711</b>

**5. Fair Value Measurements**

Assets and liabilities subject to fair value measurements are required to be disclosed within a fair value hierarchy. The fair value hierarchy ranks the quality and reliability of inputs used to determine fair value. Accordingly, assets and liabilities carried at, or permitted to be carried at, fair value are

F-19

---

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

classified within the fair value hierarchy in one of the following categories based on the lowest level input that is significant in measuring fair value:

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

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

Level 3 Fair value is determined by using inputs that are unobservable and not corroborated by market data. Use of these inputs involves the use of judgment.

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

	As of December 31, 2013			
	Level 1	Level 2	Level 3	Balance
<b>Assets</b>				
Money market funds(1)	\$ 145,194	\$	\$	\$ 145,194
Federally-sponsored and corporate debt securities(2)		857,711		857,711
<b>Total assets</b>	<b>\$ 145,194</b>	<b>\$ 857,711</b>	<b>\$</b>	<b>\$ 1,002,905</b>
<b>Liabilities</b>				
Convertible notes due 2016(3)	\$ 593,750	\$	\$	\$ 593,750
Contingent consideration(4)			6,616	6,616
<b>Total liabilities</b>	<b>\$ 593,750</b>	<b>\$</b>	<b>\$ 6,616</b>	<b>\$ 600,366</b>

	As of December 31, 2012			
	Level 1	Level 2	Level 3	Balance
<b>Assets</b>				
Money market funds(1)	\$ 77,436	\$	\$	\$ 77,436
Federally-sponsored and corporate debt securities(2)		630,698		630,698

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-K

Total assets \$ 77,436 \$ 630,698 \$ 708,134

Liabilities

Convertible notes due 2016(3) \$ 316,250 \$ 316,250

Contingent consideration(4) 6,730 6,730

Total liabilities \$ 316,250 \$ 6,730 \$ 322,980

---

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

(2) Included in current and non-current marketable investments on the accompanying consolidated balance sheets. The fair value of these securities is principally measured or corroborated by trade

Table of Contents

**UNITED THERAPEUTICS CORPORATION**

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

**5. Fair Value Measurements (Continued)**

data for identical securities in which related trading activity is not sufficiently frequent to be considered a Level 1 input or comparable securities that are more actively traded. See also Note 4 *Marketable Investments Held-to-Maturity Investments* to these consolidated financial statements.

- (3) Included in convertible notes on the accompanying balance sheets. As of December 31, 2012, the fair value of our 1.0 percent Convertible Senior Notes due September 15, 2016 (2016 Convertible Notes) was estimated using other than Level 1 observable inputs (Level 2 inputs). However, during the year ended December 31, 2013, our 2016 Convertible Notes began trading with sufficient frequency such that we believe related pricing can be used as the principal basis for measuring their fair value. As a result, our 2016 Convertible Notes have been transferred from Level 2 to Level 1.
- (4) Included in other liabilities on the accompanying consolidated balance sheets. The fair value of contingent consideration has been estimated using probability weighted discounted cash flow models (DCF). The DCFs incorporate Level 3 inputs including estimated discount rates that we believe market participants would consider relevant in pricing and the projected timing and amount of cash flows, which are estimated and developed, in part, based on the requirements specific to each acquisition agreement. We analyze and evaluate these fair value measurements quarterly to determine whether valuation inputs continue to be relevant and appropriate or whether current period developments warrant adjustments to valuation inputs and related measurements. Any increases or decreases in discount rates would have an inverse impact on the corresponding fair value, while increases or decreases in expected cash flows would result in corresponding increases or decreases in fair value. As of December 31, 2013 and December 31, 2012, the cost of debt and weighted average cost of capital used to discount projected cash flows relating to our contingent consideration ranged from 8.7 percent to 16.5 percent and from 6.6 percent to 17.2 percent, respectively.

Table of Contents

## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## 5. Fair Value Measurements (Continued)

The tables below provide a reconciliation of the beginning and ending balances of Level 3 assets and liabilities for the years ended December 31, 2013 and 2012 (in thousands):

	Contingent Consideration
Balance January 1, 2013 Asset (Liability)	\$ (6,730)
Transfers into Level 3	
Transfers out of Level 3	
Total gains/(losses) realized/unrealized:	
Included in earnings	210
Included in other comprehensive income	(96)
Purchases	
Sales	
Issuances	
Settlements	
Balance December 31, 2013 Asset (Liability)	\$ (6,616)

Amount of total gains/(losses) for the year ended December 31, 2013 included in earnings that are attributable to the change in unrealized gains or losses related to outstanding obligations	\$ 210
---	--------

	Contingent Consideration
Balance January 1, 2012 Asset (Liability)	\$ (7,973)
Transfers into Level 3	
Transfers out of Level 3	
Total gains/(losses) realized/unrealized:	
Included in earnings	663
Included in other comprehensive income	(34)
Purchases	
Sales	
Issuances	
Settlements	614
Balance December 31, 2012 Asset (Liability)	\$ (6,730)



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

Amount of total gains/(losses) for the year ended December 31, 2012 included in earnings that are attributable to the change in unrealized gains related to outstanding obligations \$ 663

### ***Fair Value of Financial Instruments***

The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable, and accrued expenses approximate fair value because of their short maturities. The fair values of our marketable investments and our 2016 Convertible Notes are reported above within the fair value hierarchy. The recorded value of our 2010 Wells Fargo Bank mortgage financing 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* for details.

F-22

---

Table of Contents

## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

**6. Accounts Payable and Accrued Expenses**

Accrued expenses consist of the following by major category (in thousands):

	As of December 31,	
	2013	
	2013	2012
Accounts payable	\$ 6,708	\$ 10,203
Accrued expenses:		
Royalties and rebates	48,213	37,264
Payroll related	26,930	26,013
Research related	5,780	5,057
Other	4,613	4,651
<b>Total accrued expenses</b>	<b>85,536</b>	<b>72,985</b>
Total accounts payable and accrued expenses	\$ 92,244	\$ 83,188

**7. Share Tracking Award Plans**

We maintain the United Therapeutics Corporation Share Tracking Awards Plan, adopted in June 2008 (2008 STAP) and the United Therapeutics Corporation 2011 Share Tracking Awards Plan, adopted in March 2011 (2011 STAP). In 2012, we amended the 2008 STAP to prohibit future grants from the plan. Since both plans otherwise contain similar terms and conditions, we refer to these plans collectively as the "STAP" and awards granted and/or outstanding under either of these plans as "STAP Awards." STAP Awards convey the right to receive in cash an amount equal to the appreciation of our common stock, which is calculated as the positive difference between the closing price of our common stock on the date of exercise and the date of grant. Awards generally vest in equal increments on each anniversary of the date of grant over a four-year period and expire ten years from the grant date. The aggregate balance of the STAP liability at December 31, 2013 was \$305.2 million, of which \$17.2 million has been classified as long term under the caption "Other Liabilities" as these STAP Awards will vest in excess of one year. At December 31, 2013, 1.0 million STAP awards remained available for grant under the 2011 STAP. On January 30, 2014 our Board of Directors approved an additional 3.0 million increase in the number of available STAP awards under the 2011 STAP.

We estimate the fair value of STAP awards using the Black-Scholes-Merton valuation model. In estimating the fair value of STAP awards, we are required to use inputs that can materially impact the determination of fair value and the amount of compensation expense (benefit) to be recognized. These inputs include the price of our common stock, the expected volatility of the price of our common stock, the risk-free interest rate, the expected term of STAP awards, the expected forfeiture rate and the expected dividend yield.

A description of the key inputs, requiring estimates, used in determining the fair value of the awards is provided below:

*Expected volatility* Volatility is a measure of the amount the price of our common stock has fluctuated (historical volatility) or is expected to fluctuate (expected volatility) during a period. We use historical volatility based on weekly price observations of our common stock during the period immediately preceding an award that is equal to its expected term up to a maximum period of five

Table of Contents

## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## 7. Share Tracking Award Plans (Continued)

years. We believe the volatility in the price of our common stock over the preceding five years generally provides a reliable projection of future long-term volatility.

*Risk-free interest rate* The risk-free interest rate is the average interest rate consistent with the yield available on a U.S. Treasury note with a term equal to the expected term of an award.

*Expected term of awards* An award's expected term reflects the estimated time period we expect an award to remain outstanding. We apply the simplified method to develop an estimate of the expected term.

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

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

The table below presents the assumptions used to measure the fair value of STAP Awards

	As of December 31, 2013		
	2013	2012	2011
Expected volatility	32.7%	32.8%	38.0%
Risk-free interest rate	1.1%	0.5%	0.5%
Expected term of awards (in years)	3.9	3.7	3.9
Expected forfeiture rate	10.1%	8.7%	7.0%
Expected dividend yield	0.0%	0.0%	0.0%

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

	Number of Awards	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in 000s)
Outstanding at January 1, 2013	7,962,375	\$ 49.00		
Granted	3,372,994	57.55		
Exercised	(2,049,136)	43.55		
Forfeited	(551,332)	62.16		
Outstanding at December 31, 2013	8,734,901	\$ 52.75	7.7	\$ 526,976
Exercisable at December 31, 2013	3,277,377	\$ 47.50	6.2	\$ 214,929

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-K

Expected to vest at December 31, 2013	4,895,737	\$	55.95	8.5	\$	279,704
---------------------------------------	-----------	----	-------	-----	----	---------

The weighted average grant date fair value of STAP awards granted during the years ended December 31, 2013, 2012 and 2011 was \$24.78, \$21.28 and \$27.80, respectively.

F-24

---

Table of Contents**UNITED THERAPEUTICS CORPORATION****Notes to Consolidated Financial Statements (Continued)****7. Share Tracking Award Plans (Continued)**

Share-based compensation expense (benefit) recognized in connection with the STAP is as follows (in thousands):

	Year Ended December 31,		
	2013	2012	2011
Research and development	\$ 134,355	\$ 11,130	\$ (8,190)
Selling, general and administrative	143,407	14,490	(8,023)
Cost of product sales	6,124	1,230	(174)
Share-based compensation expense (benefit) before taxes	283,886	26,850	(16,387)
Related income tax (benefit) expense	(106,693)	(9,902)	6,058
Share-based compensation expense (benefit), net of taxes	\$ 177,193	\$ 16,948	\$ (10,329)
Share-based compensation capitalized as part of inventory	\$ 1,593	\$ 275	\$ (203)

Cash paid to settle STAP exercises during the years ended December 31, 2013, 2012 and 2011 was \$55.9 million, \$31.8 million, and \$28.7 million, respectively.

**8. Debt***Line of Credit*

On September 26, 2013, we entered into a Credit Agreement with Wells Fargo Bank, National Association (Wells Fargo) providing us a \$75.0 million revolving loan facility, which may be increased by up to an additional \$75.0 million provided certain conditions are met (the 2013 Credit Agreement). At our option, amounts borrowed under the 2013 Credit Agreement bear interest at either the one-month LIBOR rate plus a 0.50 percent margin, or a fluctuating base rate excluding any margin. In addition, we are subject to a monthly commitment fee of 0.06 percent per annum on the average daily unused balance of the facility. Amounts borrowed under the 2013 Credit Agreement are secured by certain of our marketable investments. As of December 31, 2013, we have not drawn on the facility, which has a one-year term. The 2013 Credit Agreement does not subject us to any financial covenants.

*Convertible Notes Due 2016*

In October 2011, we issued \$250.0 million in aggregate principal value 1.0 percent Convertible Senior Notes due September 15, 2016 (2016 Convertible Notes). The 2016 Convertible Notes are unsecured, unsubordinated debt obligations that rank equally with all of our other unsecured and unsubordinated indebtedness. We pay interest semi-annually on March 15 and September 15 of each year. The initial conversion price is \$47.69 per share and the number of underlying shares used to determine the aggregate consideration upon conversion is approximately 5.2 million shares.

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

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 percent 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

F-25

---

Table of Contents

**UNITED THERAPEUTICS CORPORATION**

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

**8. Debt (Continued)**

consecutive trading-day period in which the trading price of the 2016 Convertible Notes is less than 95 percent 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.

The closing price of our common stock exceeded 130 percent of the conversion price of the 2016 Convertible Notes for more than 20 trading days during the 30 consecutive trading day period ended December 31, 2013. Consequently, the 2016 Convertible Notes are convertible at the election of their holders. As we do not control this conversion right, the 2016 Convertible Notes have been classified as a current liability on our consolidated balance sheet at December 31, 2013. We are required to calculate this contingent conversion provision at the end of each quarterly reporting period. Therefore, the convertibility and classification of our 2016 Convertible Notes may change depending on the price of our common stock.

At December 31, 2013, the aggregate conversion value of the 2016 Convertible Notes exceeded their par value by \$342.8 million using a conversion price of \$113.08, which was the closing price of our common stock on December 31, 2013.

Upon conversion, holders of our 2016 Convertible Notes are entitled to receive: (1) cash equal to the lesser of the par value 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 par value 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 notes' par value plus any accrued and unpaid interest.

The terms of the 2016 Convertible Notes provide for settlement wholly or partially in cash. Consequently, we are required to account for their liability and equity components separately so that the subsequent recognition of interest expense reflects our non-convertible borrowing rate. Accordingly, we estimated the fair value of the 2016 Convertible Notes without consideration of the conversion option as of the date of issuance (Liability Component). The excess of the proceeds received over the estimated fair value of the Liability Component totaling \$57.9 million has been recorded as the conversion option (Equity Component) and a corresponding offset has been recognized as a discount to the 2016 Convertible Notes to reduce their net carrying value. A portion of the Equity Component equal to the unamortized discount as of December 31, 2013 has been reclassified to temporary equity because one of the contingent conversion criteria had been met at December 31, 2013, as disclosed above. Refer to Note 10 *Temporary Equity*. We are amortizing the discount over the five-year period ending September 15, 2016 (the expected life of the Liability Component) using the interest method and an effective rate of interest of 6.7 percent, which corresponded to our estimated non-convertible borrowing rate at the date of issuance.

Table of Contents**UNITED THERAPEUTICS CORPORATION****Notes to Consolidated Financial Statements (Continued)****8. Debt (Continued)**

Interest expense incurred in connection with our convertible notes consisted of the following (in thousands):

	Year Ended December 31,		
	2013	2012	2011
Contractual coupon rate of interest	\$ 2,500	\$ 2,500	\$ 1,510
Discount amortization	11,178	10,487	16,118
Interest expense convertible notes(1)	\$ 13,678	\$ 12,987	\$ 17,628

(1)

Interest expense recognized in connection with our convertible notes for the year ended December 31, 2011 includes the effective interest relating to a prior issue of convertible notes that matured in October 2011 (2011 Convertible Notes). We accounted for the 2011 Convertible Notes in a manner similar to that of the 2016 Convertible Notes using an effective interest rate of 7.5 percent over the five-year term of the notes.

The carrying value of our convertible notes consisted of the following (in thousands):

	As of December 31,	
	2013	2012
Principal balance	\$ 250,000	\$ 250,000
Discount, net of accumulated amortization of \$23,783 and \$12,605	(34,155)	(45,333)
Carrying amount	\$ 215,845	\$ 204,667

***Convertible Note Hedge and Warrant Transactions***

In connection with the issuance of our 2016 Convertible Notes, we entered into separate convertible note hedge and warrant transactions with Deutsche Bank AG London (DB London) to reduce the potentially dilutive impact of the conversion of our convertible notes. Pursuant to the convertible note hedge, we purchased call options to acquire up to approximately 5.2 million shares of our common stock with a strike price of \$47.69. The call options become exercisable upon conversion of the 2016 Convertible Notes, and will terminate upon the maturity of the 2016 Convertible Notes or the first day the 2016 Convertible Notes are no longer outstanding, whichever occurs first. We also sold DB London warrants to acquire up to approximately 5.2 million shares of our common stock with a strike price of \$67.56. The warrants will expire incrementally on a series of expiration dates subsequent to the maturity date of our 2016 Convertible Notes. Both the convertible note hedge and warrant transactions will be settled on a net-share basis. If the conversion price of our 2016 Convertible Notes remains between the strike prices of the call options and warrants, our shareholders will not experience any dilution in connection with the conversion of our 2016 Convertible Notes; however, to the extent that the price of our common stock exceeds the strike price of the warrants on any or all of the series of related



incremental expiration dates, we will be required to issue shares of our common stock to DB London.

F-27

---

Table of Contents

**UNITED THERAPEUTICS CORPORATION**

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

**8. Debt (Continued)**

*Mortgage Financing Wells Fargo Bank*

In December 2010, we entered into a Credit Agreement with Wells Fargo and Bank of America, N.A., pursuant to which we obtained a \$70.0 million mortgage loan (the 2010 Credit Agreement). The 2010 Credit Agreement matures in December 2014 and is secured by certain of our facilities in Research Triangle Park, North Carolina and Silver Spring, Maryland. Annual principal payments were based on a twenty-five year amortization schedule using a fixed rate of interest of 7.0 percent and the outstanding debt bears a floating rate of interest per annum based on the one-month LIBOR, plus a credit spread of 3.75 percent, or approximately 3.9 percent as of December 31, 2013. 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. We can prepay the loan balance without being subject to a prepayment premium or penalty. As of December 31, 2013, the principal balance under the 2010 Credit Agreement was \$66.5 million and included with other current liabilities on our consolidated balance sheet at December 31, 2013 as the remaining balance will become due within one year.

The 2010 Credit Agreement subjects us to the following financial covenants: (1) a maximum consolidated leverage ratio of 2.5:1.0, calculated as the ratio of our consolidated indebtedness to "Consolidated EBITDA" which is defined as consolidated net income, adjusted for the following, as applicable: (i) interest expense; (ii) income taxes; (iii) non-cash license fees; (iv) depreciation and amortization; (v) impairment charges; and (vi) share-based compensation (stock option and share tracking awards 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 2010 Credit Agreement, minimum liquidity is defined as the sum of our cash and cash equivalents, plus the fair value of our marketable investments as of the last day of a fiscal quarter less the sum of indebtedness that matures within the next twelve months and the liability related to vested STAP awards in excess of \$50.0 million. As of December 31, 2013, we were in compliance with these covenants.

*Mortgage Financing Midland Loan Services (PNC Bank N.A.)*

In November 2011, we assumed a mortgage loan in connection with the acquisition of an office building that is located adjacent to our corporate headquarters. The mortgage loan is secured by the acquired office building. The outstanding principal balance on the mortgage loan of \$3.6 million as of December 31, 2013 bears interest at 6.35 percent per annum. The loan is payable in monthly installments which are based on a thirty-year amortization schedule. The loan matures on June 1, 2016, at which time the remaining principal balance of approximately \$3.4 million will be due in full.

Table of Contents**UNITED THERAPEUTICS CORPORATION****Notes to Consolidated Financial Statements (Continued)****8. Debt (Continued)**

As of December 31, 2013, future maturities relating to our mortgage financings are as follows (in thousands):

<b>Year Ended December 31,</b>	
2014	\$ 66,636
2015	97
2016	3,490
2017	114
2018	
<b>Total</b>	<b>\$ 70,337</b>

***Interest Expense***

Details of interest expense presented on our consolidated statements of operations are as follows (in thousands):

	<b>Year Ended December 31,</b>		
	<b>2013</b>	<b>2012</b>	<b>2011</b>
Interest expense	\$ 18,117	\$ 17,544	\$ 22,209
Less: interest capitalized	(59)	(905)	(842)
<b>Total interest expense</b>	<b>\$ 18,058</b>	<b>\$ 16,639</b>	<b>\$ 21,367</b>

**9. Commitments and Contingencies*****Operating Leases***

We lease facilities space and equipment under operating lease arrangements that have terms expiring at various dates through 2020. Certain lease arrangements include renewal options and escalation clauses. In addition, various lease agreements to which we are party require that we comply with certain customary covenants throughout the term of these leases. If we are unable to comply with these covenants and cannot reach a satisfactory resolution in the event of noncompliance, these agreements could terminate.

Future minimum lease payments under non-cancelable operating leases are as follows (in thousands):

<b>Year Ending December 31,</b>	
2014	\$ 3,285
2015	3,195
2016	3,043
2017	2,998

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-K

2018	2,343
Thereafter	365

\$ 15,229

F-29

---

Table of Contents

## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

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

Total rent expense was \$3.5 million, \$3.6 million and \$4.6 million for the years ended December 31, 2013, 2012 and 2011, respectively.

***Milestone Payments***

We are party to certain license agreements as described in Note 15 *Assignment and License Agreements* and acquisition agreements. Generally, these agreements require that we make milestone payments in cash upon the achievement of certain product development and commercialization goals and payments of royalties upon commercial sales.

Future milestone payments based on our estimates of the timing and probability of achieving milestones specified under these arrangements are as follows (in thousands):

Year Ending December 31,	(1)
2014	\$ 4,300
2015	1,450
2016	2,247
2017	6,668
2018	1,075
Thereafter	6,170
<b>Total</b>	<b>\$ 21,910</b>

---

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

***Research Agreement***

We maintain a research agreement with the University of Oxford (Oxford) to develop antiviral compounds. Research under this agreement is performed by Oxford Glycobiology Institute, which is headed by a member of our Board of Directors and our scientific advisory board. Under the terms of the agreement, we are required to fund related research activities and make milestone payments for the successful completion of clinical trials. We are also obligated to pay royalties to Oxford equal to a percentage of our net sales from any discoveries and products developed by Oxford. Milestone payments and royalties are subject to reduction depending upon third-party contributions to discoveries and/or third-party licenses necessary to develop products. In August 2010, the term of the research agreement was extended through September 2016. In connection with the extension of the term, we agreed to pay Oxford a total of \$2.9 million (using the then-prevailing exchange rate) in sixty equal installments. As of December 31, 2013, approximately \$1.7 million remains outstanding under this 2010 agreement. In addition, in December 2012, we amended our agreement with Oxford, under which we agreed to pay Oxford an additional \$871,000 in the aggregate (using the exchange rate as of the amendment date) in thirty-six equal installments for additional work supporting the development of our virology platform which began in January 2013. As of December 31, 2013, approximately \$594,000 remains outstanding under this 2012 amendment. During the years ended December 31, 2013, 2012 and 2011, we incurred approximately \$890,000, \$577,000 and \$658,000, respectively, in expenses under the terms of the agreement.

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

From time to time, we may enter into other service agreements with Oxford relating to specific development activities that are outside the scope of our research agreement described above. We incurred expenses of approximately \$55,000, \$336,000 and \$550,000 relating to these additional services during the years ended December 31, 2013, 2012 and 2011, respectively.

**10. Temporary Equity**

Temporary equity includes securities that: (1) have redemption features that are outside our control; (2) are not classified as an asset or liability; (3) are excluded from permanent stockholders' equity; and (4) are not mandatorily redeemable. Amounts included in temporary equity relate to securities that are redeemable at a fixed or determinable price.

Components comprising the carrying value of temporary equity include the following (in thousands):

	As of December 31, 2013	As of December 31, 2012
Reclassification of Equity Component(1)	\$ 34,155	\$
Common stock subject to repurchase(2)	10,882	10,882
<b>Total</b>	<b>\$ 45,037</b>	<b>\$ 10,882</b>

---

(1) Represents the reclassification of the Equity Component equal to the unamortized discount of our 2016 Convertible Notes as of December 31, 2013 from additional paid-in capital to temporary equity. As of December 31, 2013, our 2016 Convertible Notes were convertible at the election of their holders as disclosed above in Note 8 *Debt Convertible Notes Due 2016*.

(2) In connection with our amended 2007 agreement with Toray Industries Inc. (Toray), we issued 400,000 shares of our common stock and provided Toray the right to request that we repurchase the shares at a price of \$27.21 per share.

**11. Stockholders' Equity*****Equity Incentive Plan***

We maintain an equity incentive plan (EIP) under which we may grant stock options to employees and non-employees. The EIP provides for the issuance of up to 29.9 million shares of our common stock. As of December 31, 2013, there were 10.0 million shares remaining for issuance under the EIP, of which approximately 9.9 million were reserved for issuance in connection with options granted to our Chief Executive Officer (CEO). If granted, options awarded under the EIP are nontransferable, carry a maximum contractual term of ten years and typically vest in equal annual increments over a maximum period of three years, except for options granted to our CEO, which vest immediately upon grant in accordance with the terms of her employment agreement. The exercise price of stock option awards granted under the EIP can be no less than the fair market value of our common stock on the date of grant. Historically, we have issued new shares of our common stock upon the exercise of options.



Table of Contents

## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## 11. Stockholders' Equity (Continued)

*Employee Stock Options*

We estimate the fair value of stock options using the Black-Scholes-Merton valuation model. Option-pricing models, including the Black-Scholes-Merton model, require the use of judgment and subjective assumptions that can materially impact the estimation of fair value and share-based compensation.

Inputs included in estimating the fair value of a stock option include the price of our common stock, the expected volatility of our common stock, risk-free interest rate, the expected term of stock option awards, expected forfeiture rate and the expected dividend yield.

A description of the key inputs, requiring estimates, used in determining the fair value of stock options is provided below:

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

*Risk-free interest rate* The risk-free interest rate is the average interest rate consistent with the yield available on a U.S. Treasury note with a term equal to the expected term of a given stock option grant.

*Expected term* The expected term reflects the estimated time period we expect an option grant to remain outstanding. We use historical data to develop this input.

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

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

The following weighted-average assumptions were used in estimating the fair value of stock options granted to employees (we did not grant any stock options during the year ended December 31, 2011):

	Year Ended December 31,	
	2013	2012
Expected volatility	33.0%	41.6%
Risk-free interest rate	1.8%	0.7%
Expected term of options (in years)	5.0	5.0
Expected forfeiture rate	0.0%	0.0%
Expected dividend yield	0.0%	0.0%

F-32



Table of Contents

## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## 11. Stockholders' Equity (Continued)

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

	Options	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in 000s)
Outstanding at January 1, 2013	4,551,050	\$ 38.95		
Granted	1,000,000	113.08		
Exercised	(797,613)	30.12		
Forfeited	(3,988)	10.48		
Outstanding and exercisable at December 31, 2013	4,749,449	\$ 56.06	5.7	\$ 270,801

The weighted average fair value of an employee stock option granted during each of the years in the three-year period ended December 31, 2013, was \$36.10, \$19.74 and none, respectively. The total fair value of vested employee stock options for each of the years in the three-year period ended December 31, 2013 was \$36.1 million, \$3.0 million and \$1.6 million, respectively.

Total share-based compensation expense relating to employee stock options is as follows (in thousands):

	Year Ended December 31,		
	2013	2012	2011
Research and development	\$	\$	\$ 196
Selling, general and administrative	36,097	3,024	315
Share-based compensation expense before taxes	36,097	3,024	511
Related income tax benefit	(13,566)	(1,115)	(189)
Share-based compensation expense, net of taxes	\$ 22,531	\$ 1,909	\$ 322
Share-based compensation capitalized as part of inventory	\$	\$	\$ 15

As of December 31, 2013, all employee stock options were fully vested; consequently, there were no amounts of unrecognized compensation cost remaining.

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

Employee and non-employee stock option exercise data is summarized below (dollars in thousands):

	Year Ended December 31,		
	2013	2012	2011
Number of options exercised	876,115	575,944	837,690
Cash received from options exercised	\$ 26,620	\$ 14,290	\$ 24,398
Total intrinsic value of options exercised	\$ 37,530	\$ 15,508	\$ 30,644
Tax benefits realized from options exercised	\$ 9,299	\$ 3,054	\$ 11,347

F-33

---

Table of Contents

**UNITED THERAPEUTICS CORPORATION**

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

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

***Employee Stock Purchase Plan***

In June 2012, our shareholders approved the United Therapeutics Corporation Employee Stock Purchase Plan (ESPP), which has been structured to comply with Section 423 of the Internal Revenue Code. The ESPP provides eligible employees the right to purchase shares of our common stock at a discount through elective accumulated payroll deductions at the end of each offering period. Offering periods, which began in September 2012, occur in consecutive six-month periods commencing on September 5th and March 5th of each year. During the year ended December 31, 2013, we issued 55,070 shares of our common stock in exchange for \$2.7 million in employee contributions. Eligible employees may contribute up to 15 percent of their base salary, subject to certain annual limitations as defined in the ESPP. The purchase price of the shares is equal to the lower of 85 percent of the closing price of our common stock on either the first or last trading day of a given offering period. In addition, the ESPP provides that no eligible employee may purchase more than 4,000 shares during any offering period. The ESPP has a 20-year term and limits the aggregate number of shares that can be issued to 3.0 million.

Related share-based compensation expense for years ended December 31, 2013, 2012 and 2011 was \$802,800, \$240,100 and none, respectively. We estimate the fair value of the option to purchase shares of our common stock under the ESPP using the same methodology that we employ in valuing our stock options and STAP awards.

Table of Contents

## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## 11. Stockholders' Equity (Continued)

*Earnings per Share*

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

	Year Ended December 31,		
	2013	2012	2011
<b>Numerator:</b>			
Income from continuing operations	\$ 174,560	\$ 304,442	\$ 217,243
Income from discontinued operations			625
Net income	\$ 174,560	\$ 304,442	\$ 217,868
<b>Denominator:</b>			
Weighted average outstanding shares basic	50,076	52,093	57,163
<b>Effect of dilutive securities(1):</b>			
Convertible notes	1,736	218	569
Warrants	276		263
Stock options and employee stock purchase plan	1,143	969	1,400
Weighted average shares diluted	53,231	53,280	59,395
<b>Earnings per common share:</b>			
<b>Basic</b>			
Continuing operations	\$ 3.49	\$ 5.84	\$ 3.80
Discontinued operations	0.00	0.00	0.01
Net income per basic common share	\$ 3.49	\$ 5.84	\$ 3.81
<b>Diluted</b>			
Continuing operations	\$ 3.28	\$ 5.71	\$ 3.66
Discontinued operations	0.00	0.00	0.01
Net income per diluted common share	\$ 3.28	\$ 5.71	\$ 3.67

Stock options and warrants excluded from calculation(2)	11,210	11,862	16,299
---	--------	--------	--------

---

(1) Calculated using the treasury stock method.

(2) Certain stock options and warrants have been excluded from the computation of diluted earnings per share because their impact would be anti-dilutive.

***Share Repurchases***

In October 2011, our Board of Directors approved a share repurchase program authorizing up to \$300.0 million in aggregate repurchases of our common stock at our discretion, over a two-year period ending in October 2013 (Repurchase Program). In connection with the Repurchase Program, we paid \$212.0 million for an accelerated share repurchase agreement (ASR) entered into with DB London in October 2011, under which we repurchased approximately 4.7 million shares of our common stock in October 2011. In May 2012, we completed the Repurchase Program by acquiring approximately 2.0 million shares of our common stock at an aggregate cost of \$88.0 million.

Table of Contents

## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

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

In June 2012, our Board of Directors authorized the repurchase of up to an additional \$100.0 million of our common stock (2012 Repurchase Program). The 2012 Repurchase Program became effective for a one-year period beginning in July 2012. We acquired an aggregate of approximately 2.0 million shares of our common stock under the 2012 Repurchase Program, which was completed in November 2012.

In February 2013, our Board of Directors authorized a share repurchase program for up to \$420.0 million in aggregate repurchases of our common stock in open market or privately negotiated transactions, at our discretion over a one-year period which began March 4, 2013 (the 2013 Repurchase Program). As of December 31, 2013, we have acquired 708,998 shares of our common stock at an aggregate cost of \$42.4 million. On January 30, 2014, our Board of Directors authorized the extension of the 2013 Repurchase Program through March 3, 2015.

***Shareholder Rights Plan***

In June 2008, we entered into an Amended and Restated Rights Agreement with The Bank of New York as Rights Agent (the Plan), which amended and restated our original Rights Agreement dated December 17, 2000. The Plan, as amended and restated, extended the expiration date of the Preferred Share Purchase Rights (Rights) from December 29, 2010 to June 26, 2018, and increased the purchase price of each Right from \$64.75 to \$400.00, respectively. Each Right entitles holders to purchase one one-thousandth of a share of our Series A Junior Participating Preferred Stock. Rights are exercisable only upon our acquisition by another company, or commencement of a tender offer that would result in ownership of 15 percent or more of the outstanding shares of our voting stock by a person or group (as defined under the Plan) without our prior express written consent. As of December 31, 2013, we have not issued any shares of our Series A Preferred Stock.

**12. Accumulated Other Comprehensive Loss**

The following table includes changes in accumulated other comprehensive income (loss) by component, net of tax (in thousands):

	Defined Benefit Pension Plan(1)	Foreign Currency Translation Losses	Unrealized Gains and (Losses) on Available-for-Sale Securities	Total
Balance, January 1, 2013	\$ (11,540)	\$ (3,876)	\$ 459	\$ (14,957)
Other comprehensive income (loss) before reclassifications	2,075	(1,193)	(128)	754
Amounts reclassified from accumulated other comprehensive income	1,020			1,020
Net current-period other comprehensive income (loss)	3,095	(1,193)	(128)	1,774
Balance, December 31, 2013	\$ (8,445)	\$ (5,069)	\$ 331	\$ (13,183)

Refer to Note 14 *Employee Benefit Plans Supplemental Executive Retirement Plan* which identifies the captions within our consolidated statement of operations where reclassification adjustments were recognized and their associated tax impact.

Table of Contents

## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## 13. Income Taxes

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

	Year Ended December 31,		
	2013	2012	2011
<b>Current:</b>			
Federal	\$ 120,030	\$ 83,905	\$ 54,132
State	20,099	13,949	8,948
Foreign	2,164	659	544
<b>Total current</b>	<b>142,293</b>	<b>98,513</b>	<b>63,624</b>
<b>Deferred</b>			
Federal	(37,713)	37,259	11,228
State	(9,059)	(415)	(2,428)
Foreign	(1,055)	182	641
<b>Total deferred</b>	<b>(47,827)</b>	<b>37,026</b>	<b>9,441</b>
<b>Other non-current</b>			
Federal	7,797	573	7,605
State	1,907	114	1,621
Foreign	173	3	(417)
<b>Total other</b>	<b>9,877</b>	<b>690</b>	<b>8,809</b>
<b>Total income tax expense</b>	<b>\$ 104,343</b>	<b>\$ 136,229</b>	<b>\$ 81,874</b>

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

	Year Ended December 31,		
	2013	2012	2011
Federal tax provision computed at 35%	\$ 97,616	\$ 154,235	\$ 105,018
State tax provision, net of federal tax provision	8,320	9,149	5,549
General business credits	(13,346)	(10,980)	(15,776)
Incentive stock option expense	(304)	(479)	(290)
Section 199 deduction	(10,861)	(15,629)	(8,091)
Nondeductible compensation expense	22,813	2,609	(2,607)
Nondeductible expenses	105	(2,676)	(1,929)

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-K

Total income tax expense	\$	104,343	\$	136,229	\$	81,874
--------------------------	----	---------	----	---------	----	--------

F-37

---



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

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

	<b>As of December 31,</b>	
	<b>2013</b>	<b>2012</b>
<b>Deferred tax assets:</b>		
General business credits	\$ 277	\$ 25,834
Impairment losses on investments	318	2,884
Realized losses on marketable investments		2,095
License fees capitalized for tax purposes	75,181	74,964
Nonqualified stock options	40,808	30,872
SERP	14,059	14,594
STAP awards	84,274	20,238
Other	28,118	31,534
Total deferred tax assets	243,035	203,015
<b>Deferred tax liabilities:</b>		
Plant and equipment principally due to differences in depreciation	(32,725)	(31,428)
Other	(1,351)	(1,221)
Net deferred tax asset before valuation allowance	208,959	170,366
Valuation allowance	(2,507)	(5,665)
Net deferred tax assets	\$ 206,452	\$ 164,701

Deferred tax assets are reduced by a valuation allowance when, in our judgment, it is more likely than not that a portion or all of the deferred tax assets will not be realized. In evaluating our ability to realize deferred tax assets, we consider all available positive and negative evidence. Accordingly, we consider past operating results, forecasts of earnings and taxable income, the reversal of temporary differences and any prudent and feasible tax planning strategies. Future increases in the valuation allowance would result in a corresponding charge to earnings in the period such a determination is made. Conversely, future reductions to the valuation allowance would result in the recognition of a tax benefit in the period we conclude a reduction is warranted.

We expect to utilize all of our federal general business tax credits for tax-year 2013.

Table of Contents

## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

**13. Income Taxes (Continued)**

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

Unrecognized tax benefits at January 1, 2013	\$ 1,511
Gross increases tax positions in prior period	1,325
Gross decreases tax positions in prior period	
Gross increases tax positions in the current period	
Gross decreases tax positions in current period	
Settlements	
Lapse of statute of limitations	

Unrecognized tax benefits at December 31, 2013	\$ 2,836
--	----------

Unrecognized tax benefits at January 1, 2012	\$ 1,733
Gross increases tax positions in prior period	146
Gross decreases tax positions in prior period	(368)
Gross increases tax positions in the current period	
Gross decreases tax positions in the current period	
Settlements	
Lapse of statute of limitations	

Unrecognized tax benefits at December 31, 2012	\$ 1,511
--	----------

Unrecognized tax benefits at January 1 2011	\$ 7,406
Gross increases tax positions in prior period	500
Gross decreases tax positions in prior period	(7,406)
Gross increases tax positions in the current period	1,233
Gross decreases tax positions in the current period	
Settlements	
Lapse of statute of limitations	

Unrecognized tax benefits at December 31, 2011	\$ 1,733
--	----------

During the year ended December 31, 2011, the Internal Revenue Service (IRS) completed its audits of our 2009 and 2008 tax years and based on the results of these audits, we decreased our reserves for uncertain tax positions by \$7.4 million. Included in unrecognized tax benefits at December 31, 2013, 2012 and 2011, is \$2.4 million, \$1.0 million, and \$1.3 million, respectively, of tax benefits that, if recognized, would impact the effective tax rate. As of December 31, 2013 and 2012, we accrued \$249,000 and \$35,000, respectively, in interest expense relating to

uncertain state tax positions.

We are subject to federal and state taxation in the United States and various foreign jurisdictions. Currently, our 2012, 2011 and 2010 tax years are subject to examination by the IRS and by state taxing authorities. We are unaware of any positions for which it is reasonably possible that the total amounts of unrecognized tax benefits will significantly increase or decrease within the next twelve months.

F-39

---

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

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

Participants who retire at age 60 or older are eligible to receive either monthly payments or a lump sum payment based on an average of their total gross base salary over the last 36 months of active employment, subject to certain adjustments. Related benefit payments commence on the first day of the sixth month after retirement. Participants who elect to receive monthly payments will continue payments through the remainder of their life. Alternatively, participants who elected to receive a lump sum distribution will receive a payment equal to the present value of the estimated monthly payments that would have been received upon retirement. As of December 31, 2013 and 2012, all SERP participants had elected to receive a lump sum distribution. Participants who terminate employment for any reason other than death, disability, or change in control prior to age 60 will not be entitled to receive any benefits under the SERP.

To help fund our obligations under the SERP, we maintain the United Therapeutics Corporation Supplemental Executive Retirement Plan Rabbi Trust Document (Rabbi Trust). Participants of the SERP will have no preferred claim on, nor any beneficial ownership interest in, any assets of the Rabbi Trust. The balance in the Rabbi Trust was \$5.1 million as of December 31, 2013 and 2012. Investments held in the Rabbi Trust are included under restricted marketable investments and cash on our consolidated balance sheets.

We recognize the unfunded balance of the SERP as a liability on our consolidated balance sheets. Since we do not fund the SERP, the liability is equal to the projected benefit obligation as measured at the end of each fiscal year. Expenses related to the SERP are reported under the captions, "selling, general and administrative expense" and "research and development expense" in the accompanying consolidated statements of operations.

A reconciliation of the beginning and ending balances of the projected benefit obligation is presented below (in thousands):

	<b>Year Ended December 31,</b>	
	<b>2013</b>	<b>2012</b>
Projected benefit obligation at the beginning of the year	\$ 47,206	\$ 32,952
Service cost	5,406	4,315
Interest cost	1,584	1,475
Actuarial (gain) loss	(3,162)	8,464
Projected benefit obligation at the end of the year	\$ 51,034	\$ 47,206

Fair value of plan assets at the end of the year

Unfunded at end of the year(1)	\$ 51,034	\$ 47,206
--------------------------------	-----------	-----------

(1)

Included within other liabilities on our consolidated balance sheets.

The accumulated benefit obligation, a measure that does not consider future increases in participants' salaries, was \$37.2 million and \$33.2 million at December 31, 2013 and 2012, respectively.

F-40

---

Table of Contents

## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

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

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

Year Ended December 31,	
2014	\$
2015	23,502
2016	
2017	
2018	
2019-2023	29,330
	\$ 52,832

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

	Year Ended December 31,	
	2013	2012
Discount Rate	4.34%	3.36%
Salary Increases	5.00%	5.00%

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

	Year Ended December 31,		
	2013	2012	2011
Service cost	\$ 5,406	\$ 4,315	\$ 4,255
Interest cost	1,584	1,475	1,356
Amortization of prior service cost	827	827	773
Amortization of net actuarial loss	794		91
Total	\$ 8,611	\$ 6,617	\$ 6,475



Table of Contents

## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

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

Reclassification adjustments related to the SERP from accumulated other comprehensive loss to the statement of operations by line item and the tax impact of these reclassifications is presented below (in thousands):

Components Reclassified from Accumulated Other Comprehensive Loss(1)	As of December 31, 2013
Prior service cost:	
Research and development	\$ 312
Selling, general and administrative	515
 Total	 827
Amortization of net actuarial loss:	
Research and development	300
Selling, general and administrative	494
 Total	 794
Total prior service cost and amortization of net actuarial loss	1,621
Tax benefit	(601)
 Total, net of tax	 \$ 1,020

(1)

Refer to Note 12 *Accumulated Other Comprehensive Loss*.

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

	Year Ended December 31,		
	2013	2012	2011
Net unrecognized actuarial gain (loss)	\$ 3,956	\$ (8,464)	\$ 773
Net unrecognized prior service cost	827	827	(824)
 Total	 4,783	 (7,637)	 (51)
Tax	(1,688)	2,807	44
 Total, net of tax	 \$ 3,095	 \$ (4,830)	 \$ (7)



Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-K

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

	<b>Year Ended December 31,</b>		
	<b>2013</b>	<b>2012</b>	<b>2011</b>
Net unrecognized actuarial loss	\$ 7,803	\$ 11,758	\$ 3,295
Net unrecognized prior service cost	5,698	6,525	7,352
<b>Total</b>	<b>13,501</b>	<b>18,283</b>	<b>10,647</b>
Tax	(5,074)	(6,743)	(3,936)
<b>Total, net of tax</b>	<b>\$ 8,427</b>	<b>\$ 11,540</b>	<b>\$ 6,711</b>

F-42

---

Table of Contents

## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

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

Estimated amounts included in accumulated other comprehensive income as of December 31, 2013 that are expected to be recognized as components of net periodic pension expense on our statement of operations for the year ended December 31, 2014 comprise the following (in thousands):

Amortization of prior service cost	\$ 827
Amortization of net actuarial loss	333
<b>Total</b>	<b>\$ 1,160</b>

***Employee Retirement Plan***

We maintain a Section 401(k) Salary Reduction Plan which is open to all eligible full-time employees. Under the 401(k) Plan, eligible employees can make pre-tax contributions up to statutory limits. Currently, we make discretionary matching contributions to the 401(k) Plan equal to 40 percent of a participant's elected salary deferral. Matching contributions vest immediately for participants who have been employed for three years; otherwise, matching contributions vest annually, in one-third increments over a three-year period until the three-year employment requirement has been met. Expenses related to the 401(k) Plan were \$2.5 million, \$2.1 million and \$1.7 million for the years ended December 31, 2013, 2012 and 2011, respectively.

**15. Assignment and License Agreements*****GlaxoSmithKline PLC***

In 1997, GlaxoSmithKline PLC (Glaxo) assigned to us patents and patent applications for use of the stable prostacyclin analogue UT-15 (now known as treprostinil) for the treatment of PAH and congestive heart failure. Under the agreement, Glaxo is entitled to receive royalties 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 initial product containing treprostinil. Pursuant to these terms, our royalty obligation will end in October 2014.

***Supernus Pharmaceuticals, Inc.***

In June 2006, we entered into an exclusive license agreement with Supernus Pharmaceuticals, Inc. (Supernus) for the use of certain technologies developed by Supernus in our Orenitram tablet. The agreement requires us to make milestone payments to Supernus in connection with the development of Orenitram and \$2.0 million upon its commercial launch, which we anticipate in mid-2014. Additionally, we will pay a royalty to Supernus based on net sales of Orenitram. Royalties will be paid for approximately twelve years commencing with the first commercial sale subject to adjustments.

***Eli Lilly and Company***

In November 2008, we acquired from Lilly exclusive rights to develop, market, promote and commercialize Adcirca for the treatment of pulmonary hypertension in the United States and Puerto Rico. In exchange for these license rights, we agreed to pay Lilly, among other fees, royalties of five percent of our net sales of Adcirca as a pass through of Lilly's third-party royalty obligations for as long as Lilly is required to make such royalty payments. Pursuant to the terms of our license arrangement, Lilly manufactures Adcirca for us and distributes Adcirca via its wholesaler network in



Table of Contents

**UNITED THERAPEUTICS CORPORATION**

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

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

the same manner that it distributes its own pharmaceutical products. We purchase Adcirca from Lilly at a fixed manufacturing cost, which is adjusted by Lilly from time to time. The terms of this licensing arrangement will continue generally until the later of: (1) the expiration or lapse of the last to expire claim within a Lilly patent covering commercialization of Adcirca; or (2) the expiration of any government conferred exclusivity rights to Adcirca. In addition, at Lilly's discretion the license agreement may be terminated in the event that we undergo a change in control.

*National Cancer Institute*

In July 2010, we entered into a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI) of the United States National Institutes for Health (NIH) to collaborate on the late-stage development and regulatory approval process for 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 neuroblastoma by targeting GD2, a glycolipid on the surface of tumor cells. Under the terms of the CRADA, we have developed the capability to commercially produce the antibody and the NCI has completed necessary studies to support the filing of a marketing authorization application which was accepted by the European Medicines Agency in December 2013. In addition, we expect to file a biologics license application seeking FDA approval during the first quarter of 2014.

*Toray Industries, Inc.*

In 2000, we entered into an agreement with Toray to obtain exclusive rights to develop and market beraprost, a chemically stable oral prostacyclin analogue, in a sustained release formulation in the United States and Canada for the treatment of all cardiovascular indications. In 2007, we amended the agreement to expand our rights to commercialize a modified release formulation of beraprost (beraprost-MR). As part of the 2007 amendment, we issued 400,000 shares of our common stock to Toray with certain put rights. These put rights provide Toray the ability to request at its discretion that we repurchase these shares at a price of \$27.21 per share upon 30 days' prior written notice. Accordingly, we classified the value of the shares within temporary equity on our consolidated balance sheets. In the event that Toray requests that we repurchase these shares, we will reclassify the repurchase value of the stock as a liability until settlement. The 2007 amendment also provided for certain milestone payments during the development period and upon receipt of regulatory approval in the United States or the European Union.

In July 2011, we amended our license agreement with Toray. The amendment did not materially change the terms of our license agreement, 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, during the year ended December 31, 2011, we recognized an obligation and a corresponding charge to research and development expense of \$46.3 million, which represents the present value of the related payments discounted by our estimated current cost of debt at the date the contract was amended. As of December 31, 2013, our remaining obligation to Toray under this agreement is \$20.0 million.

Table of Contents

**UNITED THERAPEUTICS CORPORATION**

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

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

*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 PAH 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 year ended December 31, 2011. The agreement provides for additional milestone payments to Pluristem at various stages, as well as royalties on commercial sales.

*Ascendis Pharma A/S*

In September 2012, we signed a worldwide, exclusive agreement with Ascendis Pharma A/S (Ascendis Pharma) to apply Ascendis Pharma's proprietary TransCon technology platform to our treprostinil molecule. The TransCon technology platform may significantly enhance the delivery of treprostinil by establishing a once-daily, self-injectable alternative for patients who currently administer Remodulin through a continuous infusion pump for the treatment of PAH. We also intend to pursue the development of a TransCon technology-enabled sustained release formulation of beraprost. Pursuant to this agreement, we may be required to make future development-related milestone payments and royalty payments based on commercial sales.

*Other*

We are party to various other license agreements relating to therapies under development. These license agreements require us to make payments based on a percentage of sales, if we are successful in commercially developing these therapies, and may require other payments upon the achievement of certain milestones.

**16. Related Party Transaction**

In 2002, we entered into a technical services agreement for certain telemedicine technology development services for Medicomp, Inc. with Kurzweil Technologies, Inc. (KTI), a company controlled by Raymond Kurzweil, a non-independent member of our Board of Directors. Pursuant to this agreement, we agreed to pay KTI a five percent royalty on certain sales of products reasonably attributed to and dependent upon the technology developed by KTI. Upon closing of the sale of Medicomp in March 2011 (see Note 18 *Sale of Medicomp, Inc.*), further royalty obligations under this agreement were terminated. For the year ended December 31, 2011 we incurred royalties to KTI of \$80,000.

In 2007, we entered into another technical services agreement with KTI. Pursuant to this agreement, we paid KTI monthly consulting fees of up to \$12,000 plus all necessary, reasonable and direct out-of-pocket expenses incurred in connection with the performance of related services. In addition, we agreed to pay KTI up to a five percent royalty on sales of certain products reasonably attributed to and dependent upon certain technology developed by KTI. In 2011, we amended the 2007 technical services agreement such that, effective January 2012, we reduced the monthly consulting fees to KTI to \$6,000 plus all necessary, reasonable and direct out-of-pocket expenses. We terminated the 2007 technical services agreement effective December 31, 2013.

Table of Contents

**UNITED THERAPEUTICS CORPORATION**

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

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

We incurred expenses of approximately \$72,000, \$60,000 and \$156,000, for the years ended December 31, 2013, 2012 and 2011, respectively, under these agreements. As of December 31, 2013 and 2012, we owed KTI none and none, respectively.

**17. Distribution Agreements**

*U.S.-Based Specialty Pharmaceutical Distributors*

We are party to separate distribution agreements for Remodulin and Tyvaso with two U.S.-based specialty pharmaceutical distributors. The distribution agreements are similar to one another, and generally have one-year terms that renew automatically for additional one-year periods, unless terminated earlier. The agreements contain contractual responsibilities relating to ordering specifications, inventory requirements and exchange rights. We also have agreements with these distributors to perform certain services for us on a fee-for-service basis. If any of our distribution agreements expire or terminate, we may be required under certain circumstances to repurchase any unsold inventory held by our distributors.

*International Distributors*

We currently sell Remodulin internationally through various distributors. The financial terms and conditions relating to these distributor arrangements are structured in a manner substantially similar to those of our U.S. distribution agreements described above.

**18. Sale of Medicomp, Inc.**

In March 2011, we sold all of the outstanding stock of Medicomp, our former wholly-owned telemedicine subsidiary, to a group of private investors. Immediately after closing the sale, we purchased a 19.9 percent ownership interest in Medicomp and we carry the related investment at cost. Medicomp's revenues and pre-tax income for the year ended December 31, 2011 were \$3.1 million and \$935,000, respectively. In 2011, we met the criteria for reporting Medicomp as a discontinued operation. Accordingly, we have included the operating results of Medicomp, including the gain recognized on its disposal, within discontinued operations on our consolidated statement of operations for the year ended December 31, 2011.

**19. Segment Information**

Prior to June 2011, we operated in two business segments: pharmaceutical and telemedicine. Following the sale of our telemedicine subsidiary, Medicomp, and the discontinuation of further telemedicine-related activities in 2011, we began managing our business as one operating segment. However, our chief operating decision makers regularly review revenues, cost of revenues and gross profit data as a primary measure of performance for each of our three commercial products. Note that we expect to commence sales of our most recently approved commercial product, Orenitram, in mid-2014.

Table of Contents

## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

## 19. Segment Information (Continued)

Revenues, cost of revenues and gross profit for each of our commercial products are as follows (in thousands):

	Remodulin	Tyvaso	Adcirca	Total
<b><u>Year Ended December 31, 2013</u></b>				
Revenues	\$ 491,179	\$ 438,793	\$ 176,972	\$ 1,106,944
Cost of revenues	59,314	60,831	10,982	131,127

Gross profit	\$ 431,865	\$ 377,962	\$ 165,990	\$ 975,817
--------------	------------	------------	------------	------------

<b><u>Year Ended December 31, 2012</u></b>				
Revenues	\$ 457,969	\$ 325,614	\$ 122,540	\$ 906,123
Cost of revenues	57,618	53,825	7,854	119,297

Gross profit	\$ 400,351	\$ 271,789	\$ 114,686	\$ 786,826
--------------	------------	------------	------------	------------

<b><u>Year Ended December 31, 2011</u></b>				
Revenues	\$ 430,132	\$ 240,382	\$ 70,580	\$ 741,094
Cost of revenues	52,329	31,934	4,641	88,904

Gross profit	\$ 377,803	\$ 208,448	\$ 65,939	\$ 652,190
--------------	------------	------------	-----------	------------

Geographic revenues are determined based on the country in which our customers (distributors) are located. Net revenues from external customers by geographic area are as follows (in thousands):

Year Ended December 31,	2013	2012	2011
United States	\$ 1,032,435	\$ 846,611	\$ 676,967
Rest-of-World(1)	84,549	69,465	66,216
<b>Total</b>	<b>\$ 1,116,984</b>	<b>\$ 916,076</b>	<b>\$ 743,183</b>

---

(1) Primarily Europe.

For the years ended December 31, 2013, 2012 and 2011, sales to Accredo Health Group, Inc. comprised 57 percent, 56 percent and 61 percent, respectively, of total consolidated net revenues.

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

Year Ended December 31,	2013	2012	2011
United States	\$ 442,673	\$ 425,585	\$ 345,153
Rest-of-World(1)	22,277	28,100	20,893
<b>Total</b>	<b>\$ 464,950</b>	<b>\$ 453,685</b>	<b>\$ 366,046</b>

---

(1) Facilities principally located in the United Kingdom.



Table of Contents

## UNITED THERAPEUTICS CORPORATION

## Notes to Consolidated Financial Statements (Continued)

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

Summarized quarterly financial information for each of the years ended December 31, 2013 and 2012 are as follows (in thousands, except per share amounts):

	Quarter Ended			
	December 31, 2013	September 30, 2013	June 30, 2013	March 31, 2013
Net sales	\$ 289,017	\$ 302,225	\$ 280,606	\$ 245,136
Gross profit	247,519	269,290	245,175	213,833
Net (loss) income(1)	(30,314)	62,685	79,864	62,325
Net (loss) income per share basic	\$ (0.60)	\$ 1.25	\$ 1.60	\$ 1.24
Net (loss) income per share diluted	\$ (0.60)	\$ 1.17	\$ 1.52	\$ 1.19

	Quarter Ended			
	December 31, 2012	September 30, 2012	June 30, 2012	March 31, 2012
Net sales	\$ 243,817	\$ 242,468	\$ 225,577	\$ 204,214
Gross profit	202,766	212,949	192,199	178,912
Net income	83,255	78,111	72,316	70,760
Net income per share basic	\$ 1.65	\$ 1.52	\$ 1.37	\$ 1.32
Net income per share diluted	\$ 1.60	\$ 1.46	\$ 1.34	\$ 1.29

- (1) Operating results for the quarter ended December 31, 2013 include a \$111.2 million, net of tax charge to operating expenses related to share-based compensation expense.

**21. Litigation***Department of Health and Human Services Subpoena*

In December 2013, we received a subpoena from the Office of the Inspector General (OIG) of the Department of Health and Human Services reflecting a civil investigation by the United States Department of Justice, principally represented by the United States Attorney's Office for the District of Maryland. The subpoena requests documents regarding Remodulin, Tyvaso and Adcirca, including our marketing practices relating to these products. We are cooperating with the investigation. We are not aware that a claim, litigation or assessment has been asserted in connection with the subpoena. However, we cannot predict what actions, if any, may be taken by the OIG, the Department of Justice, other governmental entities, or any third parties in connection with such investigation.

*Sandoz Inc.*

In February 2012, we received a Paragraph IV Certification Notice Letter (the Original Notice Letter) from Sandoz Inc. (Sandoz) advising that Sandoz had submitted an abbreviated new drug application (ANDA) to the FDA requesting approval to market a generic version of the 10 mg/mL strength of Remodulin. In December 2012, we received notice (the Second Notice Letter) that Sandoz had amended its previously filed ANDA to request additional approval to market generic versions of the 1 mg/mL, 2.5 mg/mL, and 5 mg/mL strengths of Remodulin. In the Original Notice Letter and the Second Notice Letter, Sandoz stated that it intends to market a generic version of Remodulin before the expiration of the following patents we hold relating to Remodulin: U.S. Patent No. 5,153,222, which

Table of Contents

**UNITED THERAPEUTICS CORPORATION**

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

**21. Litigation (Continued)**

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. Each of these patents is listed in the FDA's Orange Book.

We responded to the Original Notice Letter by filing a lawsuit in March 2012 against Sandoz in the U.S. District Court for the District of New Jersey alleging patent infringement (the First Lawsuit). We responded to the Second Notice Letter by filing an additional lawsuit in January 2013 for patent infringement in the U.S. District Court for the District of New Jersey (the Second Lawsuit). Sandoz has filed its answer to our complaint in the First Lawsuit, and has also filed counterclaims alleging that the patents at issue in the litigation are invalid or will not be infringed by the commercial manufacture, use or sale of the proposed product described in Sandoz's ANDA submission.

Under the Hatch-Waxman Act, the FDA is automatically precluded from approving Sandoz's ANDA with respect to each concentration of Remodulin for up to 30 months from receipt of the Notice Letter corresponding to such concentration or until the issuance of a district court decision that is adverse to us, whichever occurs first. We intend to vigorously enforce our intellectual property rights relating to Remodulin.

*Lexington Insurance Company*

During the third quarter of 2011, we reported a claim to our insurance provider regarding damage to certain Remodulin inventory that occurred as the result of a warehouse accident. The estimated net commercial value of the damaged inventory was approximately \$65.0 million. Because we did not reach a satisfactory agreement on the amount to settle the claim, we filed a lawsuit against Lexington Insurance Company (Lexington) in April 2012 in the North Carolina Business Court, a specialized division of North Carolina's Superior Court, seeking to recover the full net commercial value of the damaged inventory.

In September 2012, we entered into a final and binding settlement agreement and release with Lexington, under which Lexington agreed to pay us \$31.0 million within thirty days. We received payment in early October 2012. The settlement agreement provided that the parties would release and forever discharge each other from any future claims, demands, or causes of action of any kind in connection with the matter. As all contingencies related to this matter were resolved, we recognized a corresponding gain during the third quarter ended September 30, 2012. The gain has been recognized under the caption "other, net" on our consolidated statement of operations for the year ended December 31, 2012.

Table of Contents

**United Therapeutics Corporation**  
**Schedule II Valuation and Qualifying Accounts**  
**Years Ended December 31, 2013, 2012, and 2011**  
**(In thousands)**

**Valuation Allowance on Deferred Tax Assets**

	<b>Balance at Beginning of Year</b>	<b>Additions Charged to Expense</b>	<b>Deductions</b>	<b>Balance at End of Year</b>
Year Ended December 31, 2013	\$ 5,665	\$ 169	\$ (3,327)	\$ 2,507
Year Ended December 31, 2012	\$ 5,458	\$ 207	\$	\$ 5,665
Year Ended December 31, 2011	\$ 6,021	\$	\$ (563)	\$ 5,458

**Reserve for Inventory Obsolescence**

	<b>Balance at Beginning of Year</b>	<b>Additions Charged to Expense</b>	<b>Deductions</b>	<b>Balance at End of Year</b>
Year Ended December 31, 2013	\$ 16,679	\$ 3,341	\$ (1,719)	\$ 18,301
Year Ended December 31, 2012	\$ 8,801	\$ 12,136	\$ (4,258)	\$ 16,679
Year Ended December 31, 2011	\$ 2,862	\$ 5,939	\$	\$ 8,801

Table of Contents

**ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

**ITEM 9A. CONTROLS AND PROCEDURES**

*Evaluation of Disclosure Controls and Procedures*

Our management, with participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as of December 31, 2013. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2013.

*Management's Report on Internal Control Over Financial Reporting*

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended). Our internal control over financial reporting was designed to provide reasonable assurance to our management and Board of Directors regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. All internal controls over financial reporting, no matter how well designed, have inherent limitations. As a result of these inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those internal controls determined to be effective can provide only reasonable assurance with respect to the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2013, based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control - Integrated Framework (1992)*. Management's assessment included an evaluation of the design of our internal control over financial reporting and testing of the operational effectiveness of our internal control over financial reporting. Based on this assessment, our management concluded that, as of December 31, 2013, our internal control over financial reporting was effective.

Ernst & Young LLP, an independent registered public accounting firm, has issued an attestation report on our internal control over financial reporting. The report of Ernst & Young LLP is contained in Item 8 of this Annual Report on Form 10-K.

*Attestation of Independent Registered Public Accounting Firm*

The attestation report of our independent registered public accounting firm regarding internal control over financial reporting is set forth in Item 8 of this Annual Report on Form 10-K under the caption "Report of Independent Registered Public Accounting Firm" and incorporated herein by reference.

*Changes in Internal Control over Financial Reporting*

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2013 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

**ITEM 9B. OTHER INFORMATION**

None.

Table of Contents

**PART III**

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

Information as to the individuals serving on our board of directors is set forth below under the heading *Board of Directors*. Additional information required by Item 10 regarding nominees and directors appearing under Proposal No. 1: *Election of Directors* in our definitive proxy statement for our 2014 annual meeting of shareholders scheduled for June 26, 2014 (the 2014 Proxy Statement) is hereby incorporated herein by this reference. Information regarding our executive officers appears in Part I, Item I of this Annual Report on Form 10-K under the heading *Executive Officers of the Registrant*. Information regarding the Audit Committee and the Audit Committee's financial expert appearing under the heading *Committees of our Board of Directors Audit Committee* in our 2014 Proxy Statement is hereby incorporated herein by this reference.

Information appearing under the heading *Section 16(a) Beneficial Ownership Reporting Compliance* in our 2014 Proxy Statement is hereby incorporated herein by this reference.

We have a written Code of Conduct and Ethics that applies to our principal executive officer, principal financial officer and our principal accounting officer and every other director, officer and employee of United Therapeutics. The Code of Conduct and Ethics is available on our Internet website at <http://www.unither.com>. A copy of the Code of Conduct and Ethics will be provided free of charge by making a written request and mailing it to our corporate headquarters offices to the attention of the Investor Relations Department. If any amendment to, or a waiver from, a provision of the Code of Conduct and Ethics that applies to the principal executive officer, principal financial officer and principal accounting officer is made, such information will be posted on our Internet website within four business days at [www.unither.com](http://www.unither.com).

**Board of Directors**

**Christopher Causey, M.B.A.**

Principal, Causey Consortium

**Raymond Dwek, F.R.S.**

Director of the Glycobiology Institute and Professor of Glycobiology, University of Oxford

**Richard Giltner**

Private Investor

**R. Paul Gray**

Managing Member, Potomac Management Group, LLC

**Roger Jeffs, Ph.D.**

President and Chief Operating Officer of United Therapeutics

**Ray Kurzweil**

Director of Engineering, Google Inc.

**Christopher Patusky, J.D., M.G.A.**

Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-K

Founding Principal, Patusky Associates, LLC

**Martine Rothblatt, Ph.D., J.D., M.B.A.**

Chairman and Chief Executive Officer of United Therapeutics

Table of Contents

**Louis Sullivan, M.D.**

Former Secretary, U.S. Department of Health and Human Services

**Tommy Thompson, J.D.**

Former Secretary, U.S. Department of Health and Human Services

**ITEM 11. EXECUTIVE COMPENSATION**

Information concerning executive compensation required by Item 11 will appear under the headings *Director Compensation, Compensation Discussion and Analysis, Summary Compensation Table and Grants of Plan-Based Awards in 2013, Narratives to Summary Compensation Table and Grants of Plan-Based Awards Table, Summary of Terms of Plan-Based Awards, Supplemental Executive Retirement Plan, Rabbi Trust, Potential Payments Upon Termination or Change in Control, and Director Compensation* in our 2014 Proxy Statement and is incorporated herein by reference.

Information concerning the Compensation Committee required by Item 11 will appear under the heading *Compensation Committee Report* in our 2014 Proxy Statement and is incorporated herein by reference.

Table of Contents**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

The information regarding beneficial ownership of our common stock required by Item 12 will appear under *Beneficial Ownership of Common Stock* in our 2014 Proxy Statement and is incorporated herein by reference.

**Securities Authorized for Issuance Under Equity Compensation Plans**

The following table presents information as of December 31, 2013, regarding our securities authorized for issuance under equity compensation plans:

Plan category	Number of securities to be issued upon exercise of outstanding options (a)	Weighted average exercise price of outstanding options (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a) (c)
Equity compensation plan approved by security holders	4,803,449	\$ 55.87	9,975,707
Equity compensation plans not approved by security holders		0.00	N/A
<b>Total</b>	<b>4,803,449</b>	<b>\$ 55.87</b>	<b>9,975,707</b>

All outstanding stock options were issued under our equity incentive plan approved by security holders in 1997 (the EIP). Information regarding this plan is contained in Note 11 *Stockholders' Equity* to the consolidated financial statements included in this Annual Report on Form 10-K. Aside from stock options issued under the EIP, we do not have any outstanding stock options, warrants or rights that are outstanding or available for issuance as described in Regulation S-K Item 201(d).

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

Information concerning related party transactions and director independence required by Item 13 will appear under the headings *Other Matters*, *Certain Relationships and Related Party Transactions*, *Board of Directors*, *Committees*, *Corporate Governance*, *Director Independence* and *Committees of our Board of Directors* in our 2014 Proxy Statement and is incorporated herein by reference.

**ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

Information required by Item 14 concerning the principal accounting fees paid by the Registrant and the Audit Committee's pre-approval policies and procedures, will appear under the heading *Report of the Audit Committee and Information on our Independent Auditors* in our 2014 Proxy Statement and is incorporated herein by reference.



Table of Contents

**PART IV**

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

In reviewing the agreements included or incorporated by reference as exhibits to this Annual Report on Form 10-K, it is important to note that they are included to provide investors with information regarding their terms, and are not intended to provide any other factual or disclosure information about United Therapeutics or the other parties to the agreements. The agreements contain representations and warranties made by each of the parties to the applicable agreement. These representations and warranties have been made solely for the benefit of the other parties to the applicable agreement, and: (1) should not be treated as categorical statements of fact, but rather as a way of allocating risk between the parties; (2) have in some cases been qualified by disclosures that were made to the other party in connection with the negotiation of the applicable agreement, which disclosures are not necessarily reflected in the agreement; (3) may apply standards of materiality in a way that is different from what may be material to investors; and (4) were made only as of the date of the applicable agreement or such other date or dates as may be specified in the agreement and are subject to more recent developments.

Accordingly, these representations and warranties may not describe the actual state of affairs as of the date they were made or at any other time. Additional information about United Therapeutics may be found elsewhere in this Annual Report on Form 10-K and our other public filings, which are available without charge through the SEC's website at <http://www.sec.gov>.

(a)(1) Our financial statements filed as part of this report on Form 10-K are set forth in the Index to Consolidated Financial Statements under Part II, Item 8 of this Form 10-K.

(a)(2) The Schedule II Valuation and Qualifying Accounts is filed as part of this Form 10-K. All other schedules are omitted because they are not applicable or not required, or because the required information is included in the consolidated statements or notes thereto.

(a)(3) Exhibits filed as a part of this Form 10-K are listed on the Exhibit Index, which is incorporated by reference herein.

**Certain exhibits to this report have been included only with the copies of this report filed with the Securities and Exchange Commission. Copies of individual exhibits will be furnished to shareholders upon written request to United Therapeutics and payment of a reasonable fee (covering the expense of furnishing copies). Shareholders may request exhibit copies by contacting: United Therapeutics Corporation, Attn: Investor Relations, 1040 Spring Street, Silver Spring, Maryland 20910.**



Edgar Filing: UNITED THERAPEUTICS Corp - Form 10-K

Table of Contents

<b>Signatures</b>	<b>Title</b>	<b>Date</b>
<u>/s/ CHRISTOPHER PATUSKY</u> Christopher Patusky	Director	February 25, 2014
<u>/s/ LOUIS W. SULLIVAN</u> Louis W. Sullivan	Director	February 25, 2014
<u>/s/ TOMMY G. THOMPSON</u> Tommy Thompson	Director	February 25, 2014

Table of Contents

**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
3.1	Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K, filed on June 28, 2010.
3.3	Second Amended and Restated By-laws of the Registrant, incorporated by reference to Exhibit 3.2 of the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2008.
3.4	Form of Certificate of Designation, Preferences and Rights of Series A Junior Participating Preferred Stock of the Registrant, incorporated by reference to Exhibit A to Exhibit 4 to the Registrant's Current Report on Form 8-K, filed December 18, 2000.
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3 and 3.4.
4.2	First Amended and Restated Rights Agreement, incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K filed on July 3, 2008.
4.3	Indenture, dated as of October 17, 2011, between the Registrant and The Bank of New York Mellon Trust Company, N.A., as trustee (including form of 1.0% Convertible Senior Note due September 15, 2016), incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K filed October 17, 2011.
10.1**	United Therapeutics Corporation Amended and Restated Equity Incentive Plan, as amended effective as of September 24, 2004, incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2004.
10.2**	Amended and Restated Executive Employment Agreement dated as of January 1, 2009, between the Registrant and Martine A. Rothblatt, incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2009.
10.3**	Employment Agreement dated as of June 16, 2001 between the Registrant and Paul A. Mahon, incorporated by reference to Exhibit 10.4 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2002.
10.4*	Exclusive License Agreement dated as of December 3, 1996, between the Registrant and Pharmacia and Upjohn Company, incorporated by reference to Exhibit 10.8 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
10.5*	Assignment Agreement dated as of January 31, 1997, between the Registrant, Glaxo Wellcome Inc. and The Wellcome Foundation Ltd., incorporated by reference to Exhibit 10.9 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
10.6**	Employment Agreement dated November 29, 2000 between the Registrant and Roger Jeffs, incorporated by reference to Exhibit 10.9 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2002.
10.7	Form of Indemnification Agreement between the Registrant and each of its Directors and Executive Officers, incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2009.
10.8	Amendment No. 1 to Exclusive License Agreement, effective as of December 3, 1996, made as of October 1, 2002 by and between Pharmacia & Upjohn Company and the Registrant, incorporated by reference to Exhibit 10.25 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.
10.9**	Amendment dated December 11, 2002 to Employment Agreement between the Registrant and Roger Jeffs, incorporated by reference to Exhibit 10.40 of the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2002.

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

### Table of Contents

<b>Exhibit No.</b>	<b>Description</b>
10.10**	Amendment dated December 11, 2002 to Employment Agreement between the Registrant and Paul Mahon, incorporated by reference to Exhibit 10.43 of the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2002.
10.11**	Amendment dated December 29, 2004 to Employment Agreement between Roger Jeffs and the Registrant dated November 29, 2000, as previously amended, incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on December 29, 2004.
10.12**	Amendment dated December 29, 2004 to Employment Agreement between Paul A. Mahon and the Registrant dated June 16, 2001, as previously amended, incorporated by reference to Exhibit 10.4 of the Registrant's Current Report on Form 8-K filed on December 29, 2004.
10.13**	Form of terms and conditions for awards granted to Employees by the Registrant under the Amended and Restated Equity Incentive Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on December 17, 2004.
10.14**	Form of Terms and Conditions for Awards granted to Non-Employees by the Registrant under the Amended and Restated Equity Incentive Plan, incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on December 17, 2004.
10.15**	United Therapeutics Corporation Supplemental Executive Retirement Plan, effective as of July 1, 2006, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on May 4, 2006.
10.16**	Employment Agreement, dated as of August 2, 2006, between John Ferrari and the Registrant, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on August 4, 2006.
10.17**	Amendment, dated as of July 31, 2006, to amended Employment Agreement, dated November 29, 2000, between Roger Jeffs and the Registrant, incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on August 4, 2006.
10.18**	Amendment, dated as of July 31, 2006, to amended Employment Agreement, dated June 16, 2001, between Paul A. Mahon and the Registrant, incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed on August 4, 2006.
10.19**	Amendment, dated as of December 28, 2006, to Employment Agreement, dated August 2, 2006, between John Ferrari and the Registrant, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on December 29, 2006.
10.20	United Therapeutics Corporation Supplemental Executive Retirement Plan Rabbi Trust Document entered into on December 28, 2007, by and between the Registrant and Wilmington Trust Company, as trustee, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on December 28, 2007.
10.21**	United Therapeutics Corporation Share Tracking Awards Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008.
10.22**	First Amendment to the United Therapeutics Corporation Share Tracking Awards Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on September 18, 2009.
10.23**	Second Amendment to the United Therapeutics Corporation Share Tracking Awards Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on February 6, 2012.
10.24**	Form of terms and conditions for awards granted to non-employees by the Registrant under the United Therapeutics Corporation Share Tracking Awards Plan, incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008.

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

### Table of Contents

<b>Exhibit No.</b>	<b>Description</b>
10.25**	Form of terms and conditions for awards granted to employees by the Registrant prior to January 1, 2010, under the United Therapeutics Corporation Share Tracking Awards Plan, incorporated by reference to Exhibit 10.3 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008.
10.26**	Form of terms and conditions for awards granted to employees by the Registrant on or after January 1, 2010, under the United Therapeutics Corporation Share Tracking Awards Plan, incorporated by reference to Exhibit 10.48 of the Registrant's Annual Report on Form 10-K for the year ended December 31, 2009.
10.27**	Form of terms and conditions for awards granted to employees on or after March 15, 2011 under the United Therapeutics Corporation 2011 Share Tracking Awards Plan and the United Therapeutics Corporation 2008 Share Tracking Awards Plan, incorporated by reference to Exhibit 10.2 of Registrant's Registration Statement on Form S-8 (Registration No. 333-173858) filed on May 2, 2011.
10.28**	Form of grant letter used by Registrant under the United Therapeutics Corporation Share Tracking Awards Plan, incorporated by reference to Exhibit 10.4 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008.
10.29**	United Therapeutics Corporation 2011 Share Tracking Awards Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on March 18, 2011.
10.30**	First Amendment to the United Therapeutics Corporation 2011 Share Tracking Awards Plan, incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on February 6, 2012.
10.31**	Second Amendment to the United Therapeutics Corporation 2011 Share Tracking Awards Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2012.
10.32**	Third Amendment to the United Therapeutics Corporation 2011 Share Tracking Awards Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on February 4, 2013.
10.33**	Fourth Amendment to the United Therapeutics Corporation 2011 Share Tracking Awards Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on January 31, 2014.
10.34**	Form of terms and conditions for awards granted to employees by the Registrant on or after March 15, 2011 under the United Therapeutics Corporation Share Tracking Awards Plan or the United Therapeutics Corporation 2011 Share Tracking Awards Plan, incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on March 18, 2011.
10.35**	Form of terms and conditions for awards granted to non-employees by the Registrant on or after March 15, 2011 under the United Therapeutics Corporation Share Tracking Awards Plan or the United Therapeutics Corporation 2011 Share Tracking Awards Plan, incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed on March 18, 2011.
10.36**	Form of grant letter used by Registrant under the United Therapeutics Corporation 2011 Share Tracking Awards Plan, incorporated by reference to Exhibit 10.4 of the Registrant's Current Report on Form 8-K filed on March 18, 2011.
10.37**	United Therapeutics Corporation Employee Stock Purchase Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2012.
10.39*	License Agreement, dated as of November 14, 2008, by and between Eli Lilly and Company and the Registrant, incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on December 24, 2008.

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

### Table of Contents

<b>Exhibit No.</b>	<b>Description</b>
10.40*	Manufacturing and Supply Agreement, dated as of November 14, 2008, by and between Eli Lilly and Company, Lilly del Caribe, Inc. and the Registrant incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed on December 24, 2008.
10.41**	Form of Amendment to Employment Agreement between the Registrant and each of Roger Jeffs, Paul Mahon and John Ferrari, each dated as of January 1, 2009, incorporated by reference to Exhibit 10.3 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2009.
10.42**	Form of Amendment to Employment Agreements between the Registrant and each of Roger Jeffs, Paul Mahon and John Ferrari, each dated as of February 22, 2010, incorporated by reference to Exhibit 10.46 of the Registrant's Annual Report on Form 10-K for the year ended December 31, 2009.
10.43	Distribution Agreement relating to Tyvaso, dated as of August 17, 2009 between the Registrant and Accredo Health Group, Inc., incorporated by reference to Exhibit 10.47 of the Registrant's Annual Report on Form 10-K for the year ended December 31, 2009.
10.44	First Amendment to Distribution Agreement relating to Tyvaso, dated as of September 1, 2011, between the Registrant and Accredo Health Group, Inc.
10.45	Second Amendment to Distribution Agreement relating to Tyvaso, dated as of December 18, 2013, between the Registrant, Accredo Health Group, Inc., CuraScript, Inc. and Priority Healthcare Distribution, Inc.
10.46	Stipulation of Settlement, dated October 25, 2010, among the parties to a derivative lawsuit against the directors and officers of the Registrant identified therein, incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2010.
10.47*	Credit Agreement, dated as of December 27, 2010, among the Registrant, the lenders party thereto from time to time, Wells Fargo Bank, National Association, as the Administrative Agent, and certain subsidiaries of the Registrant, as guarantors, incorporated by reference to Exhibit 10.37 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2010.
10.48*	Amended and Restated Distribution Agreement relating to Remodulin, dated as of February 21, 2011, between the Registrant and Accredo Health Group, Inc., incorporated by reference to Exhibit 10.38 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2010.
10.49	First Amendment to Amended and Restated Distribution Agreement relating to Remodulin, dated as of December 18, 2013, between the Registrant, Accredo Health Group, Inc., CuraScript, Inc. and Priority Healthcare Distribution, Inc.
10.50*	Confirmation, dated October 11, 2011, of a note hedging transaction between the Registrant and Deutsche Bank AG, London Branch, incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2011.
10.51*	Confirmation, dated October 11, 2011, of a warrant transaction between the Registrant and Deutsche Bank AG, London Branch, incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2011.
10.52*	Confirmation, dated October 11, 2011, of an accelerated share repurchase transaction between the Registrant and Deutsche Bank AG, London Branch, incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2011.

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

### Table of Contents

<b>Exhibit No.</b>	<b>Description</b>
10.53	Credit Agreement dated as of September 26, 2013, by and among the Registrant, the lenders party thereto from time to time, Wells Fargo Bank, National Association, as the Administrative Agent, and a subsidiary of the Registrant, as guarantor, incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed September 27, 2013.
21	Subsidiaries of the Registrant.
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following financial information from our Annual Report on Form 10-K for the year ended December 31, 2013, filed with the SEC on February 25 2014, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets as of December 31, 2013 and 2012, (ii) Consolidated Statements of Operations for each of three years in the period ended December 31, 2013, (iii) Consolidated Statements of Comprehensive Income for each of the three years in the period ended December 31, 2013, (iv) Consolidated Statements of Stockholders' Equity for each of the three years in the period ended December 31, 2013, (v) Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2013, and (vi) Notes to Consolidated Financial Statements.

---

\*  
Confidential treatment has been granted with respect to certain portions of this exhibit pursuant to Rule 406 of the Securities Act of 1933, as amended or Rule 246-2 of the Securities Act of 1934, as amended. The omitted portions of this document have been filed with the Securities and Exchange Commission.

\*\*  
Designates management contracts and compensation plans.