# UNITED THERAPEUTICS CORP

# FORM 10-K (Annual Report)

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# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, D.C. 20549** 

### **FORM 10-K**

(Mark One)	(Ma	ırk	On	e)
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ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the fiscal year ended December 31, 2009

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

Name of each exchange on which registered
NASDAQ Global Select Market

Common Stock, par value \$.01 per share and associated preferred stock purchase rights

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  $\square$  No  $\boxtimes$ 

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 oursuant 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 $\square$ No $\square$
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 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   Non-accelerated filer   (Do not check if a smaller reporting company)  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 区
The aggregate market value of the Common Stock held by non-affiliates of the registrant, based on the closing price on June 30, 2009, as reported by the NASDAQ Global Select Market was approximately \$1,923,449,000.
The number of shares outstanding of the issuer's common stock, par value \$0.01 per share, as of February 19, 2010, was 54,608,343.
DOCUMENTS INCORPORATED BY REFERENCE
Portions of the registrant's definitive proxy statement for the registrant's 2010 annual meeting of shareholders scheduled to be held on June 28, 2010, are incorporated by reference in Part III of this Form 10-K.

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EXHIBITS		
EX-10.46**	Form of Amendment to Employment Agreement between the Registrant and each of Roger Jeffs, Paul Mahon and John Ferrari, each dated as of February 22, 2010.	
EX-10.47	Distribution Agreement, dated August 17, 2009, between the Registrant and Accredo Health Group, Inc.	
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<sup>\*\*</sup> Designates management contracts and compensation plans.

#### PART I

#### ITEM 1. BUSINESS

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

Our key therapeutic platforms are:

- Prostacyclin Analogues, which are stable synthetic forms of prostacyclin, an important molecule produced by the body that has powerful effects on blood vessel health and function. Our lead product is Remodulin® (treprostinil) Injection (Remodulin) to be administered subcutaneously or intravenously for the treatment of pulmonary arterial hypertension (PAH). The United States Food and Drug Administration (FDA) initially approved Remodulin in 2002 for subcutaneous (under the skin) administration. Subsequently, the FDA broadened its approval of Remodulin for intravenous (in the vein) use and for the treatment of patients who require transition from Flolan®, the first drug approved by the FDA for the treatment of PAH. In addition to the United States, Remodulin is approved in many other countries, primarily for subcutaneous use. In July 2009, the FDA approved Tyvaso® (treprostinil) Inhalation Solution (Tyvaso), an inhaled prostacyclin therapy for the treatment of PAH. We commenced commercial sales of Tyvaso in the third quarter of 2009. Our oral tablet of treprostinil diethanolamine is in the later stages of development. We are also developing modified release beraprost (beraprost-MR), another oral prostacyclin analogue, for the treatment of PAH;
- Phosphodiesterase Type 5 (PDE-5) Inhibitors, which act to inhibit the degradation of cyclic guanosine monophosphate (cGMP) in cells. cGMP is activated by nitric oxide (NO) to signal relaxation of vascular smooth muscle. Our PDE-5 inhibitor product is Adcirca® (tadalafil) tablets (Adcirca), a once-daily oral therapy for the treatment of PAH. We acquired certain exclusive commercialization rights to Adcirca from Eli Lilly and Company (Lilly) in 2008. In May 2009, the FDA approved Adcirca for the treatment of PAH. We commenced commercial sales of Adcirca in the third quarter of 2009;
- *Monoclonal Antibodies*, which act by targeting tumor-associated antigens on cancer cells. We are developing the antibodies 3F8 MAb and 8H9 MAb for the treatment of neuroblastoma and metastatic brain cancer, respectively. We began a Phase II clinical trial in the second quarter of 2009 with 3F8 in primary refractory neuroblastoma; and
- Glycobiology Antiviral Agents, which are a novel class of small, sugar-like molecules that have shown pre-clinical indications of efficacy against a broad range of viruses, such as hepatitis C, dengue fever and certain influenza viruses. We are currently conducting preclinical tests on potential compounds for further development.

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

We generate revenues from the sale of Remodulin, Tyvaso and Adcirca (which we refer to as our Commercial Products) and telemedicine products and services. Our sales and marketing staff for our Commercial Products, which is supplemented by our specialty pharmaceutical distributors, supports the commercial availability of our Commercial Products in the countries in which they are approved.

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 as of February 15, 2010:

Product	Mode of Delivery	Indication/Market	Current Status	Our Territory
Remodulin	Continuous subcutaneous	Pulmonary arterial hypertension	Commercial in the U.S., most of Europe*, Canada, Israel, Australia, Mexico, Argentina and Peru	Worldwide
Remodulin	Continuous intravenous	Pulmonary arterial hypertension	Commercial in the U.S., Canada, Israel, Mexico, Argentina and Peru	Worldwide
Tyvaso	Inhaled	Pulmonary arterial hypertension	Commercial in the U.S.	Worldwide
Adcirca (tadalafil) Tablets	Oral	Pulmonary hypertension	Commercial in the U.S. and Puerto Rico	United States/Puerto Rico
CardioPAL® SAVI and Decipher Cardiac Monitors	Telemedicine	Cardiac arrhythmias and ischemic heart disease	Commercial in the U.S.	Worldwide
CardioPAL SAVI Wireless Cardiac Event Monitors	Telemedicine	Cardiac arrhythmias and ischemic heart disease	Commercial in the U.S.	Worldwide
Oral Treprostinil	Oral	Pulmonary arterial hypertension	Phase III	Worldwide
Beraprost-MR	Oral	Pulmonary arterial hypertension	Phase II	North America/Europe
3F8 MAb	Intravenous	Neuroblastoma	Phase II	Worldwide
Oral Treprostinil	Oral	Peripheral vascular disease	Phase II	Worldwide
Aviptadil	Inhaled	Pulmonary hypertension and other pulmonary diseases	Phase II	Worldwide
8H9 MAb	Intravenous	Metastatic brain cancer	Phase I	Worldwide
IW001	Oral	Idiopathic Pulmonary Fibrosis and Primary Graft Dysfunction	Phase I	Worldwide
Glycobiology Antiviral Agents	Oral	Hepatitis C and other infectious diseases	Pre-Clinical	Worldwide

<sup>\*</sup> We have obtained approval in 23 member countries of the European Union (EU), as well as in certain European countries that are not members of the EU. We have received formal approval letters and pricing approval in most of these countries.

#### **Pulmonary Arterial Hypertension**

PAH is a life-threatening disease that affects the blood vessels in the lungs and is characterized by increased blood pressure 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, which eventually leads to right heart failure and, ultimately, death. PAH is characterized by structural changes in blood vessel walls, the aggregation of platelets and an alteration of smooth muscle cell function. It is estimated that PAH affects between 100,000 and 200,000 individuals worldwide. In recent years, as awareness of PAH has

grown, we have seen an increase in the number of people diagnosed with the disease. However, only a small fraction of patients with PAH are being treated due to the rarity of the disease and the complexity of diagnosing it. There is scientific interest in identifying easier, less invasive methods of diagnosing PAH. If this research is successful, more patients could be diagnosed at an earlier stage of the disease.

The complexity of diagnosing PAH reflects in part the current uncertainties surrounding the etiology and pathophysiology of the condition. Currently, treatment of PAH focuses on three distinct molecular pathways that have been implicated in the disease process: the endothelin (ET) pathway, the nitric oxide (NO) pathway, and the prostacyclin pathway.

- Endothelin Receptor Antagonists. PAH patients have been shown to have elevated levels of ET-1, a naturally occurring substance in the body that causes constriction and structural changes of the pulmonary blood vessels. Therefore, one established therapeutic approach has been to block the action of endothelin with drugs that are known as endothelin receptor antagonists (ETRAs).
- *PDE-5 Inhibitors.* Patients with PAH have also been shown to have reduced levels of the enzyme responsible for producing NO, a naturally occurring substance in the body that causes relaxation of the pulmonary blood vessels. NO produces this effect by increasing intracellular levels of an intermediary known as cyclic guanosine monophosphate (cGMP). Therefore, another established therapeutic approach has been to inhibit the degradation of cGMP, using drugs that are known as PDE-5 inhibitors.
- *Prostacyclin Analogues*. Finally, patients with PAH have been shown to have reduced levels of prostacyclin, a naturally occurring substance that has the effect of relaxing the pulmonary blood vessels, preventing platelet aggregation, and inhibiting the proliferation of smooth muscle cells in the pulmonary vessels. Therefore, drugs that mimic the action of prostacyclin, known as prostacyclin analogues, are also established PAH treatments.

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

#### Remodulin

Our lead product for treating PAH is Remodulin (treprostinil) Injection, the main ingredient of which is treprostinil, a prostacyclin analogue. We sell Remodulin to our specialty pharmaceutical distributors in the United States at a discount from an average wholesale price recommended by us, and to our international distributors at a transfer price set by us. We recognized approximately \$331.6 million, \$269.7 million and \$200.9 million in Remodulin revenues, representing 90%, 96% and 95% of our net revenues in 2009, 2008 and 2007, respectively. In May 2002, Remodulin was approved by the FDA as a continuous subcutaneous infusion for the treatment of PAH in patients with New York Heart Association (NYHA) Class II-IV (moderate to severe) symptoms. In November 2004, the FDA expanded its approval to permit continuous intravenous infusion of Remodulin for patients who cannot tolerate subcutaneous infusion. In March 2006, the FDA expanded its approval to include transition of patients to Remodulin from Flolan® (epoprostenol), the first FDA-approved prostacyclin therapy for PAH, to reduce the rate of clinical deterioration. Remodulin is also approved as a continuous subcutaneous infusion treatment for various forms of PAH in 33 countries throughout the world, and as a continuous intravenous infusion treatment for various forms of PAH in Canada, Israel, Mexico, Peru and Argentina. Applications for approval for both subcutaneous and intravenous Remodulin are under review in other countries. We continue to work on expanding Remodulin commercialization to other new territories, including Japan.

Flolan is delivered continuously through a surgically implanted intravenous catheter connected to an external pump. Flolan is approved for the treatment of patients with certain subsets of late-stage PAH. Generic formulations of Flolan are also available. We believe Remodulin provides patients with a less invasive alternative to Flolan and its equivalents. In contrast to Flolan, Remodulin is stable at room temperature and lasts significantly longer inside the human body. These attributes allow for safer and more convenient drug delivery to patients. Unlike Flolan, Remodulin can be delivered by subcutaneous infusion with a pager-sized miniature pump. Subcutaneous delivery of Remodulin also eliminates the risk of central venous catheter infection and the hospitalization required to begin intravenous infusion. Remodulin's extended presence in the body may also reduce the risk of rebound PAH, and possibly death, if treatment is abruptly interrupted. The stability of Remodulin also allows it to be packaged as an aqueous solution, so patients do not have to mix the drug, as they do with Flolan. Remodulin can be continuously infused for up to 48 hours before refilling the infusion pump, unlike Flolan, which must be mixed and refilled every 24 hours. Treprostinil, the active ingredient in Remodulin, is highly soluble in an aqueous solution, which enables us to manufacture Remodulin in highly concentrated solutions. This allows therapeutic concentrations of Remodulin to be delivered at low flow rates via miniaturized infusion pumps for both subcutaneous and intravenous infusion. Lastly, Remodulin does not require the patient to keep the drug cool during infusion. This eliminates the need for cooling packs or refrigeration to keep it stable, as is required with Flolan due to Flolan's chemical instability at room temperature.

In June 2008, the FDA approved a generic version of Flolan, developed by GeneraMedix, Inc. (GeneraMedix), that is stable at room temperature, but still shares all of Flolan's other attributes including, but not limited to, risk of central venous catheter infection, required hospitalization at the start of treatment, shorter half-life increasing risk of rebound PAH, mixing, greater frequency of pump refills and larger pump size. In February 2009, GeneraMedix licensed the commercial rights for its generic Flolan to Actelion Pharmaceuticals Ltd (Actelion). Actelion also markets Tracleer® and Ventavis® for the treatment of PAH.

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

In January 2007, the results of a prospective, open-label study demonstrated that stable patients with PAH can be safely transitioned from Flolan to intravenous Remodulin using a rapid switch protocol.

FDA Approval of Subcutaneous and Intravenous Remodulin

We filed a New Drug Application with the FDA for Remodulin in late 2000. In May 2002, the FDA approved Remodulin as a continuous subcutaneous infusion for the treatment of PAH in patients with NYHA class II-IV symptoms to diminish symptoms associated with exercise. Remodulin is approved for all types of PAH and is the only PAH prostacyclin analogue therapy approved for patients with NYHA class II-IV symptoms.

In July 2003, we opened an Investigational New Drug Application (IND) for the development of Remodulin by intravenous delivery for the treatment of PAH. A late 2003 study performed in healthy volunteers established that intravenous and subcutaneous Remodulin were bioequivalent (meaning that the two routes of infusion result in comparable levels of treprostinil in the blood).

In January 2004, we filed a Supplemental New Drug Application with the FDA to request approval for intravenous Remodulin for the treatment of PAH. In November 2004, based on data establishing intravenous Remodulin's bioequivalence with the previously approved subcutaneous Remodulin, the FDA approved intravenous Remodulin for those not able to tolerate subcutaneous infusion.

International Regulatory Review of Subcutaneous and Intravenous Remodulin

Remodulin for subcutaneous use is approved in countries throughout the world. We used the mutual recognition process, described more fully in *Governmental Regulation*, to obtain approval of subcutaneous Remodulin in most countries in the EU. The mutual recognition process for subcutaneous Remodulin was completed in August 2005, with positive decisions received from most EU member countries. We withdrew our applications in the Republic of Ireland (Ireland), Spain and the United Kingdom (UK) following a request for additional documentation from these countries. A license variation for intravenous Remodulin will be resubmitted once our compulsory five-year renewal application for subcutaneous Remodulin is approved, which we believe will occur in the first half of 2010. At that time, we will submit the intravenous Remodulin license variation to our host nation, France.

Under the named-patient system, we are permitted to import Remodulin into EU member countries for sale to hospitals for use in treating specifically identified patients. We will continue to sell (but not market) Remodulin under the named-patient system in certain EU member countries where Remodulin is not approved. In December 2009, we notified the hospitals and physicians in the UK and Ireland that we will not be providing Remodulin therapy for new PAH patients after March 31, 2010. We will continue to support and provide Remodulin to PAH patients who start Remodulin therapy prior to March 31, 2010, for as long as it is required for each patient. Antigen International Ltd. (part of Goldshield Group Ltd.), our Remodulin distributor in the UK and Ireland, is disputing our decision and has filed an arbitration request. We are currently in the preliminary stages of the arbitration process.

#### **Tyvaso**

We commenced commercial sales of Tyvaso in September 2009. We sell Tyvaso at a discount from an average wholesale price recommended by us to the same specialty pharmaceutical distributors in the United States that distribute Remodulin. In 2009, we recognized approximately \$20.3 million in Tyvaso revenues, representing 5% of our net revenues. We did not recognize any revenues from Tyvaso in 2008 and 2007.

Currently, the only other FDA approved inhaled prostacyclin analogue is Ventavis. Ventavis is marketed by Actelion in the United States and by Bayer Schering Pharma AG in Europe. The active ingredient in Ventavis, iloprost, has a half-life of approximately 20 to 30 minutes and can cause a decrease in systemic blood pressure if the drug is administered at too high a dose. As a result, Ventavis is inhaled via a nebulizer six to nine times per day at a low dose. Per its label, each Ventavis inhalation consists of 4 to 10 minutes of continuous inhalation via the nebulizer. Tyvaso has a longer half-life and greater selectivity to the lungs than Ventavis. Thus, patients only need to take Tyvaso four times a day, inhaling nine breaths during each two-to-three-minute treatment session. We are conducting an open-label study in the United States to investigate the clinical effects of switching patients from Ventavis to Tyvaso. Data is being prepared and has been accepted for presentation at the American Thoracic Society scientific symposia in May 2010.

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

Tyvaso Inhalation System

The Tyvaso Inhalation System, an ultra-sonic nebulizer and related accessories, was exclusively used for administration of Tyvaso in the TRIUMPH-1 trial. The Tyvaso Inhalation System is manufactured by NEBU-TEC International Med Products Eike Kern GmbH (NEBU-TEC), a German company. The Tyvaso Inhalation System is CE-marked in Europe, which means that the device conforms to EU health and safety requirements. In December 2008, we entered into an Agreement of Sale and Transfer with NEBU-TEC under which NEBU-TEC would sell to us its Tyvaso Inhalation System business and all associated assets and rights upon FDA approval of Tyvaso and the use of the Tyvaso Inhalation System with Tyvaso. As specified in the agreement, the closing and the transfer of all the associated assets and rights occurred in September 2009. Our agreement with NEBU-TEC also gives us the right to purchase their next generation nebulizer, the SIM-Neb. For additional details on the terms of our agreement with NEBU-TEC, see *NEBU-TEC Agreement of Sale and Transfer* below.

#### FDA Approval of Tyvaso

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

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

In accordance with the PMR, we will conduct a long-term observational study in the U.S. that will include 1,000 patient-years of follow-up in Tyvaso-treated patients, and 1,000 patient-years of follow-up in matched control patients receiving other PAH treatments to evaluate the potential association between Tyvaso and oropharyngeal and pulmonary toxicity. We have submitted a draft protocol of the PMR to the FDA for review, and have committed to submitting the results by December 15, 2013.

The PMC requires us to modify the Tyvaso Inhalation System and perform a usability analysis followed by a human factors study, and we will conduct a study in healthy volunteers to collect data to verify expected dosing with the modified device. We have submitted draft protocols for these PMCs to the FDA for review, and we have committed to submitting a supplement to our Tyvaso NDA describing the results no later than October 31, 2010. The human factors study will commence in March 2010; therefore, we believe we are on track to meet the timeline for final report submission.

International Regulatory Review of Tyvaso

In April 2004, the EMA designated Tyvaso an orphan medicinal product for the treatment of both PAH and chronic thromboembolic pulmonary hypertension. We filed an MAA in December 2008 for Tyvaso and the Tyvaso Inhalation System with the EMA using the centralized filing process. See *Governmental Regulation* below for further discussion on the centralized filing process for the EU. In February 2010, we withdrew our MAA from consideration by the EMA due to the EMA's major objection related to findings of non-compliance with good clinical practice (GCP) at two clinical sites. The EMA stated that these findings would preclude a recommendation for approval of Tyvaso in the

EU. The EMA had no major objections at the time of withdrawal related to the safety or efficacy of Tyvaso.

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

Pulmonary Arterial Hypertension

We are developing a novel salt form of treprostinil, treprostinil diethanolamine for oral administration. We use technology licensed from Supernus Pharmaceuticals, Inc. (Supernus), to provide for sustained release of treprostinil in tablets. The tablet coating technology allows for treprostinil to be released into the body through an extremely small hole that is laser-drilled into the coating of each tablet. This technology releases treprostinil at a relatively even rate in the gastrointestinal tract. In 2005, a Phase I study of healthy volunteers demonstrated that the formulation and coating provided sustained blood concentrations of treprostinil for 8 to 10 hours following a single oral dose. This duration may allow for twice daily dosing. In July 2005, the EMA announced that oral treprostinil had been designated an orphan medicinal product for the treatment of PAH.

In October 2006, we commenced two Phase III multi-national, placebo-controlled clinical trials of oral treprostinil in patients with PAH to study both safety and efficacy. The FREEDOM-C trial was a 16-week study of patients on approved background therapy using a PDE-5 inhibitor, such as Revatio, or an ERA, such as Tracleer, or a combination of both. The FREEDOM-M trial is a 12-week study of patients who are not on any background therapy. These trials have been conducted at a total of approximately 60 centers throughout the United States and the rest of the world.

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

In November 2008, we announced that the FREEDOM-C trial did not meet statistical significance for its primary endpoint.

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

Analysis of other secondary efficacy measures demonstrated statistically significant improvements compared to placebo.

Enrollment in FREEDOM-M was initially closed on October 31, 2008, with 171 patients enrolled in the trial. We believe that the results of the FREEDOM-C clinical trial, particularly as they relate to treatment effect and dosing, support our continued development of oral treprostinil. Accordingly, based on our observations from the FREEDOM-C clinical trial relating to patient tolerability and tablet strength, we submitted a protocol amendment to the FDA in February 2009 to add patients to the ongoing FREEDOM-M trial. These additional patients will be provided a lower-strength tablet (0.25 mg) when they begin the trial and their doses will be titrated in 0.25 mg increments, which we believe will improve tolerability. In addition, our amendment to the FREEDOM-M protocol specifies that the primary statistical analysis of the trial will include only those patients who started the trial using the 0.25 mg tablet. By amending the protocol for the FREEDOM-M trial we hope to achieve the following objectives: (1) to assess more accurately the effectiveness of oral treprostinil; (2) to improve patient tolerability of oral treprostinil so that an effective maintenance dose can be attained; and (3) to reduce the rate of premature discontinuation due to adverse events. We believe the results of the protocol amendment will reflect the benefits of a favorable dosing regimen for oral treprostinil. In April 2009, we began enrolling patients in FREEDOM-M under the amended protocol.

We commenced a second Phase III clinical trial, FREEDOM-C2, to continue studying dosage and efficacy of oral treprostinil in PAH patients on an approved background therapy. Enrollment in FREEDOM-C2 began in June 2009. Currently, we do not anticipate filing an NDA for oral treprostinil before 2012.

There are currently no approved oral prostacyclin therapies available to patients in the United States or Europe. If we are successful in developing oral treprostinil, then patients and physicians may use prostacyclin earlier in the PAH disease continuum.

Scleroderma

We also initiated a Phase II study to investigate the effectiveness of oral treprostinil in reducing the frequency and severity of ulcers located on the fingers and toes of scleroderma patients. Enrollment of this 150- patient Phase II trial remains ongoing.

#### Adcirca

We began commercial sales of Adcirca in July 2009. Adcirca is a PDE-5 inhibitor, the active pharmaceutical ingredient of which is tadalafil. Tadalafil is also the active pharmaceutical ingredient in Cialis®, which is marketed by Lilly for the treatment of erectile dysfunction. We acquired the commercial rights to Adcirca for the treatment of PAH in the U.S. from Lilly in November 2008. We sell Adcirca at a discount from an average wholesale price to pharmaceutical wholesalers. In 2009, we recognized approximately \$5.8 million in Adcirca revenues, representing 2% of our net revenues. We did not recognize any revenues from Adcirca in 2008 and 2007.

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

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

#### FDA Approval of Adcirca

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

#### Commercial Rights to Adcirca

In December 2008, we completed the transactions contemplated by several agreements we entered into with Lilly and one of its subsidiaries in November 2008, including a license agreement, a manufacturing and supply agreement and a stock purchase agreement. Pursuant to the license agreement, Lilly granted us an exclusive license for the right to develop, market, promote and commercialize Adcirca for the treatment of pulmonary hypertension in the United States and Puerto Rico. Pursuant to the manufacturing and supply agreement, Lilly agreed to manufacture Adcirca and distribute it on our behalf via its wholesaler network, in the same manner that it distributes its own pharmaceutical products. In December 2008, upon closing, we made a one-time, non-refundable, non-creditable payment of \$125.0 million under the manufacturing and supply agreement and a one-time payment of \$25.0 million under the license agreement. Pursuant to the stock purchase agreement, Lilly purchased 6,301,674 shares of our common stock (adjusted for our September 2009 two-for-one stock split) for an aggregate purchase price of \$150.0 million. We issued those shares from treasury. See *Strategic Licenses and Relationships* below for more details on these agreements.

#### Beraprost-MR

In June 2000, we entered into an agreement with Toray Industries, Inc. (Toray) for the exclusive right to develop and market a sustained release formulation of beraprost (beraprost-SR) in the United States and Canada for the treatment of cardiovascular indications. Beraprost is a chemically stable, orally bioavailable prostacyclin analogue. Like natural prostacyclin and Remodulin, beraprost is believed to dilate blood vessels, prevent platelet aggregation and prevent proliferation of smooth muscle cells surrounding blood vessels.

In March 2007, Lung Rx entered into an amended agreement with Toray to assume and amend the rights and obligations of our June 2000 agreement with Toray concerning the commercialization of a modified release formulation of beraprost (beraprost-MR). The amended agreement grants us additional exclusive rights to commercialize beraprost-MR in Europe and broadens the treatment indication to include vascular disease (excluding renal disease), among other revisions.

The drug substance beraprost consists of equal amounts of four optical isomers, one of which is primarily responsible for the pharmacologic activity of the drug. As we continue clinical development, we plan to proceed with a modified release drug product containing only the most pharmacologically active isomer. As a result, future clinical trials will use the single active isomer.

In October 2007, Toray announced that beraprost-MR received regulatory approval in Japan for use in the treatment of PAH. In July 2008, beraprost-MR was designated an orphan medicinal product by the EMA.

#### Aviptadil

In February 2010, Lung Rx entered into an agreement with Mondobiotech Holding AG (Mondobiotech) for the exclusive right to develop and market aviptadil, a synthetically produced version of the naturally occurring hormone Vasoactive Intestinal Peptide (VIP), a peptide produced in the digestive system, for the treatment of PAH and other pulmonary diseases. A Phase II study of

Aviptadil in PAH was recently completed by Mondobiotech and the EMA has designated aviptadil an orphan medicinal product for the treatment of acute lung injury and sarcoidosis.

#### **Products to Treat Cancer**

#### 3F8 and 8H9 Antibodies

In December 2007, we entered into two agreements with Memorial Sloan-Kettering Cancer Center (MSKCC) to license certain exclusive rights to two investigational monoclonal antibodies, 3F8 and 8H9, for the treatment of neuroblastoma and metastatic brain cancer. The monoclonal antibody 3F8 is a mouse IgG3 MAb, which is currently used in an investigational setting for the treatment of neuroblastoma, a rare cancer of the sympathetic nervous system mainly affecting children. It is the most common extracranial solid cancer in children and the most common cancer in infants. More than 400 patients have been treated with the 3F8 antibody since 1986 under investigator-initiated Investigational New Drug Applications. There are fewer than 1,000 new cases of neuroblastoma diagnosed each year. In August 2009, we began enrolling patients in a Phase II clinical trial of 3F8 for primary refractory neuroblastoma.

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

#### **OvaRex**

In April 2002, we entered into a license agreement with AltaRex Corp., which later became AltaRex Medical Corp., a wholly-owned subsidiary of ViRexx Medical Corp. (AltaRex). Our license agreement with AltaRex provided us with certain exclusive rights to a platform of five investigational immunotherapeutic monoclonal antibodies. The lead product, OvaRex® MAb for the treatment of advanced ovarian cancer, had completed Phase II studies when we entered into the license agreement.

In December 2007, we announced the completion of our two pivotal trials of OvaRex. Analysis of the results demonstrated that the studies failed to reach statistical significance. Based on the trial results, we decided to terminate our license agreement with AltaRex and cease further development activities with the molecules licensed thereunder.

#### Products to Treat Infectious Diseases—Glycobiology Antiviral Agents

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

#### **Products to Treat Diseases in Other Platforms**

In February 2010, Lung Rx entered into a Development Agreement with ImmuneWorks, Inc. (ImmuneWorks) to develop ImmuneWorks' lead compound, IW001, a purified bovine (derived from cows) Type V Collagen oral solution for the treatment of Idiopathic Pulmonary Fibrosis (IPF), a progressive lung disease characterized by abnormal and excessive deposition of fibrotic tissue in the lung, and Primary Graft Dysfunction (PGD), a type of organ rejection in patients receiving lung transplant. We expect to commence human clinical testing of IW001 in 2010. In addition to funding the

development program, we have been granted an option to acquire all of the issued and outstanding capital stock of ImmuneWorks. In November 2009, the FDA granted IW001 orphan drug exclusivity.

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

#### CardioPAL SAVI and Decipher Recorders

We provide telemedicine monitoring services to detect cardiac arrhythmias and ischemic heart disease through our wholly-owned subsidiary Medicomp, Inc. (Medicomp), which we acquired in December 2000. Cardiac arrhythmias and ischemic heart disease affect an estimated 20 million Americans, and possibly ten times that number worldwide. If left undetected and untreated, these conditions can result in heart attacks and death. Medicomp provides cardiac Holter monitoring (a 24-hour continuous test of heart rhythms), event monitoring (a test that typically extends to 30 days and looks for more elusive, intermittent arrhythmias) and other cardiac monitoring services remotely via telephone and the internet for hospitals, clinicians and other providers. Medicomp's services are delivered through its proprietary, miniaturized, digital Decipher Holter recorder/analyzer and its CardioPAL family of event monitors.

In March 2005, Medicomp received FDA market clearance for a p-wave analysis in addition to its artificial intelligence algorithm that runs on all of its newly manufactured CardioPAL devices. The p-wave is a diminutive but important portion of the electrocardiograph, the analysis of which helps determine if an arrhythmia was generated from the top chambers of the heart, the atria, or from the bottom chambers of the heart, the ventricles. This level of analysis leads to more reliable, automatic detection of arrhythmias, like atrial fibrillation. In October 2009, we received FDA approval for a wireless version of our CardioPAL SAVI event monitor, which we launched in 2010.

Holter and event services and systems are marketed to physicians, hospitals, and managed care providers directly by Medicomp's sales force. We recognized revenues of approximately \$11.0 million, \$9.5 million and \$7.7 million from the sales of telemedicine products and services in 2009, 2008 and 2007, respectively.

#### Sales and Marketing

Our marketing strategy for our Commercial Products is to use our sales and marketing teams to reach out to the prescriber community to: (1) increase PAH awareness; (2) understand the progressive nature of PAH; and (3) increase awareness of our Commercial Products and how they fit into the various stages of disease progression and treatment. The sales and marketing team consisted of approximately 70 employees as of December 31, 2009. We anticipate growth in our sales force in the near-term as we position our business for further expansion. We divide our domestic sales force into two teams. One sales team is primarily responsible for medical practice accounts that are historically large Remodulin prescribers. The other sales team is primarily responsible for medical practice accounts that have not historically been large prescribers of Remodulin. The efforts of our sales and marketing teams are supplemented by our specialty pharmaceutical distributors. For additional information about our agreements with our distributors, see *Domestic Distribution of Commercial Products*. Our distributors are experienced in all aspects of using and administering chronic therapies, as well as patient care, the sale and distribution of these medicines and reimbursement from insurance companies and other payers. Outside of the United States, we have entered into exclusive distribution agreements covering most of Europe, South America, Israel, and parts of Asia. Sales in Canada are currently conducted under the management of our wholly-owned subsidiary, Unither Biotech Inc., through a national specialty pharmaceutical wholesaler. We are working with our current distributors to expand Remodulin sales into other countries in which they have distribution rights.

#### **Domestic Distribution of Commercial Products**

Remodulin and Tyvaso

We have entered into separate, non-exclusive distribution agreements with CuraScript, Inc. (CuraScript), Accredo Health Group, Inc. (Accredo), and CVS Caremark (Caremark), our specialty pharmaceutical distributors in the United States, to market, promote and distribute both Remodulin and Tyvaso. Our Remodulin distribution agreements with Accredo and Caremark include automatic term renewals for additional one-year periods subject to notice of termination. Our Remodulin distribution agreement with Curascript contains two-year term renewal periods. We entered into our distribution agreements for Tyvaso in August 2009. Our Tyvaso distribution agreements have one-year terms and renew automatically for additional one-year periods, unless terminated earlier. We update our distribution agreements from time to time to reflect changes in the regulatory environment. Such changes have not had a significant impact on our operations or our relationships with our distributors, and tend to occur in the ordinary course of business. We compensate our distributors on a fee-for-service basis as set forth in our distribution agreements. If any of our distribution agreements expire or terminate, we may, under certain circumstances, be required to repurchase any unsold Remodulin or Tyvaso inventory held by our distributors. None of our current agreements grants our distributors the distribution rights for oral treprostinil in the United States.

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

In January 2010, we notified Accredo, CuraScript and Caremark of our intention to increase the price of Remodulin for all concentrations by 9.6 percent effective March 25, 2010. This is only the second time since the launch of Remodulin that we have initiated an across-the-board increase in its price. The last such increase was in mid-2006 and we increased the price by 3.4 percent. Our Remodulin distribution agreements do not allow our distributors to preorder inventory prior to a price increase. We are currently analyzing the impact of this price increase on our business.

Adcirca

We sell Adcirca at a discount from an average wholesale price to pharmaceutical wholesalers. Under our manufacturing and supply agreement with Lilly, (see *Strategic Licenses and Relationships* below for more details), Lilly has agreed to manufacture Adcirca and distribute it via its wholesaler network, which includes our specialty pharmaceutical distributors, in the same manner that it distributes its own pharmaceutical products. Under the terms of this agreement, we take title to Adcirca upon completion of its manufacture by Lilly. Adcirca is shipped to customers, generally pharmaceutical wholesalers, in accordance with purchase orders received by Lilly. When customers take delivery of Adcirca, Lilly sends an invoice and collects the amount due from the customer subject to customary discounts and rebates, if any. Although Lilly provides these services on our behalf, we maintain the risk of loss as it pertains to inventory and non-payment of invoices. The manufacturing and supply agreement will continue in effect until expiration or termination of the license agreement.

#### International Distribution of Remodulin

We currently sell subcutaneous and intravenous Remodulin to six distributors who have exclusive distribution rights in certain EU member countries, and other non-EU countries, such as South America, Israel and parts of Asia. In some of the European markets where we are not licensed, we sell (but do not market) Remodulin under the named-patient system in which therapies are approved for

individual patients by a national medical review board on a case-by-case basis. We are working on expanding our sales of subcutaneous and intravenous Remodulin into new territories outside of the United States through our existing distributors and by creating relationships with new distributors. In March 2007, we entered into a distribution agreement with Mochida Pharmaceutical Co., Ltd. (Mochida) to obtain approval and exclusively distribute subcutaneous and intravenous Remodulin in Japan. In addition, Grupo Ferrer Internacional, S.A. (Grupo Ferrer) has been actively working toward commencing commercial sales of Remodulin in Taiwan and South Korea. However, certain countries, like Japan, may require that new clinical trials, called bridging studies, be conducted in order to demonstrate the efficacy and safety of a drug in their patient population prior to approval. Commercial sales in such countries could therefore be several years from realization.

During the first half of 2010, we expect to notify our international distributors of our intention to increase the transfer price of Remodulin for all concentrations, as we have already done for our U.S.-based specialty pharmaceutical distributors.

#### **Strategic Licenses and Relationships**

#### Lilly Agreements Related to Adcirca

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

License Agreement. Under the terms of the license agreement, which is more fully described in Lilly License, Lilly granted us an exclusive license for the right to develop, market, promote and commercialize Adcirca for the treatment of pulmonary hypertension in the United States and Puerto Rico.

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

The license agreement will continue in effect until the later of: (1) expiration, lapse, cancellation, abandonment or invalidation of the last claim to expire within a Lilly patent covering the commercialization of Adcirca for the treatment of pulmonary hypertension in the United States and Puerto Rico; or (2) expiration of any government-conferred exclusivity rights to use Adcirca for the treatment of pulmonary hypertension in the United States and Puerto Rico.

We have the right to terminate the license agreement upon six months written notice to Lilly. Either party may terminate the license agreement upon a material breach by the other party of it or the manufacturing and supply agreement, described below.

Manufacturing and Supply Agreement. Under the terms of the manufacturing and supply agreement, Lilly has 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 will take title to Adcirca upon its manufacture by Lilly. Adcirca will be shipped to customers, generally pharmaceutical wholesalers, in accordance with customers' purchase orders received by Lilly. Lilly invoices and collects the invoice amount due from the customer subject to customary discounts and rebates, if any, and remit the collections to us. Although Lilly is providing these services on our behalf, we maintain the risk of loss as it pertains to inventory and nonpayment of sales invoices. The manufacturing and supply agreement will continue in effect until expiration or termination of the license agreement.

As consideration for Lilly's agreement to manufacture and supply Adcirca, we made a one-time payment to Lilly of \$125.0 million in December 2008, which was expensed. We also agreed to purchase Adcirca at a fixed cost. The agreement provides a mechanism, generally related to the increase in the national cost of pharmaceutical manufacturing, in which Lilly may raise our acquisition cost of Adcirca.

Stock Purchase Agreement. Under the terms of the stock purchase agreement, on December 18, 2008, we issued 6,301,674 shares of our common stock to Lilly from treasury for an aggregate purchase price of \$150.0 million, representing approximately 13.6% of the then-current outstanding shares of our common stock. The shares were issued at a price of \$23.805 per share (adjusted for our September 2009 stock split), representing 90% of the average closing price of our common stock for the five trading days commencing on and including November 17, 2008. The weighted average acquisition price of the treasury stock issued was \$26.02 per share. The excess of the acquisition cost of the treasury stock above the price paid by Lilly for the shares was approximately \$14.2 million and has been included in our accumulated deficit.

#### Toray Amended License Agreement

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

In accordance with the terms of the amended agreement, in March 2007 we issued 400,000 shares of our common stock to Toray in exchange for the cancellation of Toray's existing right under the original agreement to receive an option grant to purchase 1,000,000 shares of our common stock (the Option Grant). Under the terms of the amended agreement, Toray has the right to request that we repurchase the 400,000 shares of our common stock upon 30 days prior written notice at the price of \$27.205 per share (share based numbers and prices are adjusted for our September 2009 two-for-one stock split), which was the average closing price of our common stock between January 11, 2007, and February 23, 2007. Based on the average closing price of our common stock for the two trading days prior to and the two trading days after the effective date of the amended agreement (March 16, 2007), we recognized a research and development expense of approximately \$11.0 million related to the issuance of these shares, because beraprost-MR had not yet obtained regulatory approval for commercial sales. In accordance with the provisions of FASB ASC 85, *Derivatives Hedging*, and Accounting Series Release No. 268, *Presentation in Financial Statements of Redeemable Preferred Stocks* these shares of our common stock are reflected in mezzanine equity as common stock subject to repurchase valued at the repurchase price. If Toray requests that we repurchase these shares, then an amount equal to the repurchase price will be transferred to a liability account until the repurchase is completed.

The amended agreement also specifies that we make certain milestone payments to Toray during the development period and upon U.S. or EU regulatory approval. Upon execution of the amended agreement, we made a \$3.0 million payment to Toray in addition to the issuance of the shares of our common stock discussed above. Additional annual milestone payments of \$2.0 million are specified in the amended agreement and commenced in the first quarter of 2008, increasing annually in \$1.0 million increments through 2011. These payments are expensed when incurred. These payments are contingent upon the receipt of clinical trial material and commercial drug from Toray that meet all regulatory standards and requirements, including those relating to chemistry, manufacturing and controls, and are documented to the satisfaction of U.S. and EU regulatory authorities. In addition, if Toray elects to

terminate production of beraprost-MR, no further payments would be due under the amended agreement. Conversely, if we elect to terminate development of beraprost-MR, then all remaining milestone payments would be due to Toray, unless certain regulatory standards and requirements have not been met, or if material problems have been identified with respect to manufacturing and regulatory compliance.

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

In December 2008, our wholly-owned German subsidiary, Unither Therapeutik GmbH, entered into an Agreement of Sale and Transfer with NEBU-TEC, under which NEBU-TEC agreed to sell us its line of business to manufacture the Tyvaso Inhalation System and all related assets and rights for €5.0 million plus future consideration of up to €10.0 million depending on the occurrence of specific events, generally €1.0 million for each 1,000 patients cumulatively using the Tyvaso Inhalation System. We have the right of first refusal to acquire NEBU-TEC's next generation inhalation device, the SIM-Neb, which is currently under development. Upon signing the agreement, we paid NEBU-TEC €2.5 million.

Prior to the closing of the Agreement of Sale and Transfer, we had in place a Clinical and Commercial Supply Agreement with NEBU-TEC, which provided for the availability of nebulizers and related supplies for use in our TRIUMPH-1 clinical trial of inhaled treprostinil. These non-exclusive agreements required NEBU-TEC to sell us devices and supplies for clinical and commercial use at specified prices and payment terms. These agreements also set forth each party's obligations with respect to regulatory approvals.

Closing and transfer of the related assets and rights occurred in September 2009 after we received FDA approval for Tyvaso. At closing, we paid NEBU-TEC an additional €2.5 million. During the interim period prior to the closing of the Agreement of Sale and Transfer, both NEBU-TEC and we remained subject to the existing Clinical and Commercial Supply Agreements, as amended. Under the terms of the Agreement of Sale and Transfer, we purchase the device components and manage the manufacturing process for the Tyvaso Inhalation System; however, NEBU-TEC supplies the labor to assemble the devices at cost plus 10 percent.

#### Mondobiotech License Agreement

In February 2010, Lung Rx entered into an agreement with Mondobiotech for the exclusive right to develop and market aviptadil, a synthetically produced version of the naturally occurring hormone VIP, a peptide produced in the digestive system, for the treatment of PAH and other pulmonary diseases. A Phase II study of Aviptadil in PAH was recently completed by Mondobiotech and the EMA has designated aviptadil an orphan medicinal product for the treatment of acute lung injury and sarcoidosis.

#### ImmuneWorks License Agreement

In February 2010, Lung Rx entered into a Development Agreement with ImmuneWorks to pursue development of ImmuneWorks' lead compound, IW001, a purified bovine (derived from cows) Type V Collagen oral solution for the treatment of IPF and PGD in patients receiving lung transplant. We expect to commence human clinical testing of IW001 in 2010. In addition to funding the development program, we have been granted an option to acquire all of the issued and outstanding capital stock of ImmuneWorks. In November 2009, the FDA granted IW001 orphan drug exclusivity.

#### **Patents and Proprietary Rights**

Our success depends in part on our ability to obtain and maintain patent protection for our products, preserve trade secrets, prevent third parties from infringing upon our proprietary rights and operate without infringing upon the proprietary rights of others in the United States and worldwide.

#### Glaxo Assignment

In January 1997, GlaxoSmithKline PLC (formerly Glaxo Wellcome, Inc) (Glaxo) assigned to us all rights to the use of the stable prostacyclin analogue now known as treprostinil, the active ingredient in Remodulin, Tyvaso and our oral treprostinil tablet. The patent covering the use of treprostinil for PAH expires in the United States in October 2014 (as extended—see *Patent Term Extensions* below) and on various dates from May 2011 to June 2014 in three other countries.

#### Pfizer, Inc. (Pfizer) License

In December 1996, Pharmacia & Upjohn Company (now Pfizer) exclusively licensed to us certain patents, a patent application and know-how for the composition and production of treprostinil. We filed our own United States patent application for a new synthesis and production method for treprostinil in October 1997, and the patent was granted in August 2002. Two additional patents covering this synthesis and production method were granted in March 2003 and August 2004. We believe that our method of synthesis is a substantial improvement over the Pharmacia method and we are using our unique synthesis method rather than the licensed Pharmacia method for the production of treprostinil. We have additional registered and pending patents relating to other methods of synthesizing treprostinil.

#### Lilly License

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

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

Lilly retained the exclusive rights to develop, manufacture and commercialize pharmaceutical products containing tadalafil, the active pharmaceutical ingredient in Adcirca, for the treatment of pulmonary hypertension outside of the United States and Puerto Rico and for the treatment of other diseases worldwide. Lilly will retain authority for all regulatory activities with respect to Adcirca, including retail pricing, which is expected to be a price parity with Cialis, Lilly's therapy for the treatment of erectile dysfuction, the active ingredient of which is also tadalafil.

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

The license agreement will continue in effect until the later of: (1) expiration, lapse, cancellation, abandonment or invalidation of the last claim to expire within a Lilly paten covering the commercialization of Adcirca for the treatment of pulmonary hypertension in the United States and Puerto Rico; or (2) expiration of any government-conferred exclusivity rights to use Adcirca for the treatment of pulmonary hypertension in the United States and Puerto Rico.

We have the right to terminate the license agreement upon six months written notice to Lilly. Either party may terminate the license agreement upon a material breach by the other party of it or the manufacturing and supply agreement, described above.

#### Supernus Pharmaceutical License

In June 2006, we entered into an exclusive license agreement with Supernus to use certain of its technologies in our sustained release oral treprostinil diethanolamine tablet. Under the agreement, in return for the license, we will pay Supernus certain amounts upon the achievement of specified milestones based on the development of oral treprostinil and its commercial launch. In addition, the agreement provides that we will pay a royalty to Supernus based on net worldwide sales of the initial product. Any such royalty will be paid for approximately twelve years commencing with the first product sale and is subject to adjustments as specified in the agreement. Additional milestone payments and royalty payments may be due for the development and commercialization of other products developed using the technology granted under this license.

#### Memorial Sloan Kettering License

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

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

#### **Patent Term Extensions**

In February 2005, we were granted a five-year patent term extension by the United States Patent and Trademark Office for a patent covering the method of treating PAH using Remodulin and Tyvaso. U.S. Patent Number 5,153,222, entitled "Method of Treating Pulmonary Hypertension with Benzidine Prostaglandins", was originally scheduled to expire on October 6, 2009. It will now expire on October 6, 2014. The five-year Hatch-Waxman Act extension is the maximum extension allowed under 35 U.S.C. §156. Additional patents covering other products to which we have rights may also be eligible for extensions of up to five years based upon patent term restoration procedures under the Hatch-Waxman Act in the United States, and under similar procedures in Europe.

#### Research & Development Expenditures

We are engaged in research and development and have incurred substantial expenses for these activities. These expenses generally include the cost of acquiring or inventing new technologies and products, as well as new product development. Research and development expenses during 2009, 2008 and 2007 totaled approximately \$122.2 million, \$239.2 million and \$83.4 million, respectively. See *Item 7—Management's Discussion and Analysis of Financial Condition and Results of Operations—Major Research and Development Projects* for additional information regarding expenditures related to major research and development projects.

#### **Manufacturing and Supply**

We make treprostinil, the active ingredient for Remodulin and Tyvaso, and treprostinil diethanolamine, the active ingredient for oral treprostinil, at our laboratory facility in Silver Spring, Maryland. Until March 2007, we made treprostinil at our Chicago, Illinois facility. In June 2009, the FDA approved our Silver Spring facility for commercial manufacturing of treprostinil. In November 2009, we also received European regulatory approval to manufacture treprostinil in our Silver Spring facility.

With the transfer of our manufacturing operations to our Silver Spring facility, we have also changed our internal manufacturing process. It is more cost effective for us to purchase the advanced intermediate compounds we use to manufacture treprostinil from several third-party vendors. Our planned manufacturing process has been designed to give us the flexibility to produce both treprostinil diethanolamine (the form of treprostinil used in our oral tablet) and treprostinil (used to produce Remodulin and Tyvaso) efficiently in proportion to forecasted demand.

Baxter Healthcare Corporation (Baxter) manufactures Remodulin for us. The initial term of our agreement with Baxter ended in October 2004, but the agreement automatically renews for successive eighteen-month terms unless earlier terminated by either party. In April 2009, we amended our agreement with Baxter to extend it through 2013. In addition, we agreed that Remodulin will be manufactured using a different set of equipment and in larger quantities than the current manufacturing process. Since Baxter will make Remodulin on different equipment and in a larger production batch than the current process, we are required to have the new equipment and process approved by the FDA. We are currently conducting the validation testing for the new equipment and process. If the validation testing is successful, we anticipate filing for FDA approval of the new equipment and process in the second half of 2010. Baxter continues to manufacture Remodulin for us according to the process currently approved by the FDA.

We eventually intend to primarily manufacture Remodulin and Tyvaso in our new combination office and laboratory facility in Silver Spring, Maryland. Also, although we maintain a three-year inventory of Remodulin and Tyvaso, based on expected demand, we believe that having third parties approved to manufacture these products will mitigate some of our manufacturing risks, including the risk that we might not be able to produce sufficient quantities to meet patient demand.

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

The nebulizer used in our Tyvaso Inhalation System is manufactured by us through Unither Therapeutik GmbH. While we purchase the components and manage the manufacturing process, NEBU-TEC supplies all the labor to manufacture the nebulizers.

In 2010, we anticipate commencing development of the 3F8 and 8H9 antibodies licensed from MSKCC at our Silver Spring facility. We expect that we will be able to utilize much of the equipment that we obtained for a previous project for 3F8 and 8H9 antibody development.

Our telemedicine products are currently manufactured by Winland Electronics, Inc.

Although we believe that other manufacturers and suppliers could provide similar products, services and materials, there are few companies that could replace these manufacturers and suppliers. A change in supplier or manufacturer could cause a delay in the manufacture, distribution and research efforts associated with our respective products or result in increased costs. See also *Item 1A—Risk Factors* included in this Annual Report on Form 10-K.

#### Competition

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

- Flolan. The first product approved by the FDA for treating PAH, Flolan, also known as epoprostenol, is a prostacyclin that is delivered by intravenous infusion. Glaxo began marketing Flolan in the United States in 1996. In 2006, Myogen, Inc. (Myogen) acquired the marketing rights from Glaxo for Flolan in the United States. In November 2006, Myogen was acquired by Gilead Sciences, Inc. (Gilead). In 2009, Gilead returned the rights to Flolan to Glaxo. The generic exclusivity period for Flolan expired in April 2007;
- Generic epoprostenol. In April 2008, Teva Pharmaceuticals Industries Ltd. (Teva) announced that the FDA approved its version of generic epoprostenol for the treatment of PAH. This is the first approved generic version of Flolan. In June 2008, GeneraMedix Inc. (GeneraMedix) received FDA approval for its version of epoprostenol, which is stable at room temperature. In February 2009, Actelion announced that it had entered into an agreement with GeneraMedix to acquire its epoprostenol product and expects to begin commercial sales of this product in the first half of 2010;
- Ventavis. Approved in December 2004 in the United States and in September 2003 in Europe, Ventavis is an inhaled prostacyclin analogue. Ventavis was initially marketed by CoTherix, Inc. (CoTherix) in the United States and is marketed by Bayer Schering Pharma AG in Europe as Iloprost. In January 2007, CoTherix was acquired by Actelion, the manufacturer and distributor of Tracleer and distributor of GeneraMedix's epoprostenol product;
- Tracleer. The first oral drug to be approved for PAH, Tracleer is also the first drug in its class, known as endothelin receptor antagonists (ETRAs). Tracleer was approved in December 2001 in the United States and in May 2002 in Europe. Tracleer is marketed worldwide by Actelion;
- Revatio. Approved in June 2005 in the United States, Revatio is also an oral therapy and is marketed by Pfizer Inc. Revatio contains sildenafil, the same active ingredient as Viagra, and is the first PDE-5 inhibitor to be approved for PAH;
- Letairis<sup>TM</sup>. Approved in June 2007 in the United States, Letairis is an oral therapy marketed by Gilead for the treatment of PAH. Like Tracleer, Letairis is an ETRA. In April 2008, Glaxo received marketing authorization from the EMA for Letairis in Europe where it is known as Volibris®; and
- Thelin®. Approved in August 2006 in the EU, Thelin is an oral therapy, which was developed and initially marketed in Europe by Encysive Pharmaceuticals Inc. (Encysive), for the treatment of PAH. Like Tracleer and Letairis, Thelin is an ETRA. In June 2008, Pfizer completed its acquisition of Encysive. Pfizer has stated that it plans to conduct a pivotal Phase III clinical trial to support registration of Thelin in the United States and eventually seek FDA approval.

Due to their ease of use, oral therapies, such as Adcirca, Revatio and Tracleer, are generally considered first-line therapies for newly diagnosed NYHA Class II PAH patients. Inhaled therapies like Tyvaso and Ventavis are generally used in NYHA Class III patients during the middle stages of the PAH disease treatment cycle. Flolan and Remodulin, more complex infusion therapies, are generally considered later-stage therapies for NYHA Class IV patients. The use of the available oral therapies and Tyvaso, either alone or in combination, will delay the need for infusion therapy for many patients. As a result, the success of other therapies in preventing disease progression affects our commercial operations. Furthermore, the commercialization of generic forms of other approved PAH therapies may exert downward pressure on the pricing of our products. For further discussion on this risk, see

Item 1A—Risk Factors—We may not compete successfully with established and newly developed drugs or products, or the companies that develop and market them.

Holter and event monitoring analysis services and systems are provided by many local and regional competitors and a few national competitors.

We compete with all of these products for customers, funding, access to licenses, personnel, third-party collaborators, product development and commercialization. Almost all of these companies have substantially greater financial, marketing, sales, distribution and technical resources, and more experience in research and development, product development and marketing, clinical trials and regulatory matters, than we have.

#### **Governmental Regulation**

The research, development, testing, manufacture, promotion, marketing and distribution of pharmaceutical products are extensively regulated by governmental agencies in the United States and in other countries. Drugs are subject to rigorous regulation by the FDA in the United States, the 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 IND for a new drug;
- Clinical studies in healthy volunteers;
- Adequate and well-controlled clinical trials to establish the safety and efficacy of the drug for each indication;
- Clinical studies in patients to explore safety, efficacy and dose-response characteristics;
- The submission of an NDA to the FDA; and
- FDA review and approval of the NDA prior to any commercial sale or shipment of the drug.

Preclinical tests include laboratory evaluation of product chemistry and formulation, as well as animal studies to explore toxicity and for proof-of-concept. The results of preclinical testing are submitted to the FDA as part of an IND. A 30-day review period after the filing of each IND is generally required prior to the commencement of clinical testing in humans. At any time during this 30-day period or at any time thereafter, the FDA may halt proposed or ongoing clinical trials until it authorizes trials under specified terms. The IND process may be extremely costly and may substantially delay development of our products. Moreover, positive results of preclinical tests will not necessarily indicate positive results in clinical trials.

Clinical trials in support of an NDA are typically conducted in three sequential phases, but the phases may overlap. During Phase I, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess its effects on bodily functions and safety, including side effects associated with increasing doses. Phase II usually involves studies in a limited patient population to:

- assess the efficacy of the drug in specific, targeted indications;
- assess tolerance and optimal dosage; and
- identify possible adverse effects and safety risks.

If a compound is found to be potentially effective and to have an acceptable safety profile in Phase II evaluations, then Phase III trials, also called pivotal studies, major studies or advanced clinical trials, are undertaken to further demonstrate clinical efficacy and to further test for safety within an expanded patient population at geographically diverse clinical study sites.

After successful completion of the required clinical testing, an NDA or a Biologics License Application is typically submitted to the FDA in the United States, and an MAA is typically submitted to the EMA in the EU. The regulatory authorities may request additional information before accepting an application, in which case the application must be resubmitted with the additional information. Once the application has been accepted, the regulatory authority reviews the application and responds to the applicant. The review process is often significantly extended by requests from regulatory authorities for additional information or clarification. In the United States, the FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether it should be approved. The FDA is not bound by the recommendation of an advisory committee. The regulatory authorities may also inspect the manufacturing facility before approving an application.

In the United States, if FDA evaluations of the application and the manufacturing facilities are favorable, the FDA may issue either an approval letter or a complete response letter. A complete response letter will usually contain a number of conditions that must be met in order to secure final approval of the application and authorization of commercial marketing of the drug for certain indications.

At the request of an applicant, the FDA may designate a product as an "orphan drug" in the United States if the drug is intended to treat an orphan, or rare, disease or condition. A disease or condition is considered orphan if it affects fewer than 200,000 people in the United States. If an applicant obtains the first FDA marketing approval for a certain orphan drug, the applicant will have a seven-year exclusive right against generic versions to market the drug for the orphan indication. The FDA granted orphan designation for the active ingredient treprostinil for the treatment of PAH as a continuous infusion. However, this designation does not preclude us from seeking orphan drug designation for other formulations or routes of administration, such as oral or inhaled, of treprostinil to treat PAH, or for treprostinil used to treat other orphan diseases. In order for the FDA to grant orphan drug designation for other formulations or routes of administration of treprostinil to treat PAH, we must demonstrate that such new formulation or route of administration is clinically superior to the formulation or route of administration previously granted orphan designation.

The Hatch-Waxman Act provides that patent terms may be extended to compensate for some of the patent life that is lost during the FDA regulatory review period for a product. This extension period would generally be one-half the time between the effective date of an IND and the submission date of an NDA, plus all of the time between the submission date of an NDA and its approval, subject to a maximum extension of five years. Similar patent term extensions are available under European laws. Following FDA approval, we filed a patent term extension application with the United States Patent and Trademark Office for our patent covering the method of treating PAH using Remodulin. The application was approved in February 2005 with the maximum patent term extension of five years, and the patent will expire on October 6, 2014.

Outside of the United States, our ability to market our products will also be contingent upon receiving marketing authorizations from regulatory authorities. The foreign regulatory approval process may include some or all of the risks associated with FDA approval set forth above. The requirements governing the conduct of clinical trials and marketing authorization vary widely from country to country. At present, foreign marketing authorizations are applied for at a national level, although, within Europe, procedures are available to companies wishing to market a product in more than one EU member state.

In the EU, marketing authorizations may be submitted through a centralized body or through a decentralized or a national level process. The centralized procedure is mandatory for the approval of biotechnology products, high technology products and orphan products and is available at the applicant's option for other products. The centralized procedure provides for the grant of a single marketing authorization that is valid in all EU member countries. The decentralized procedure is available for all medicinal products that are not subject to the centralized procedure. The decentralized procedure provides for mutual recognition of national approval decisions, changes existing procedures for national approvals and establishes procedures for coordinated EU actions on products, suspensions and withdrawals. Under this procedure, the holder of a national marketing authorization for which mutual recognition is sought may submit an application to one or more EU member countries, certify that the dossier is identical to that on which the first approval was based, or explain any differences and certify that identical dossiers are being submitted to all EU member countries for which recognition is sought. Within 90 days of receiving the application and assessment report, each EU member country must decide whether to recognize approval. The procedure encourages member states to work with applicants and other regulatory authorities to resolve disputes concerning mutual recognition. Lack of objection of a given country within 90 days automatically results in approval in that country. Following receipt of marketing authorization in an EU member country, the applicant is then required to engage in pricing discussions and negotiations with a separate prescription pricing authority in that country. Commercial sales are only able to commence in a country once pricing approval has been received.

To secure European regulatory approvals for subcutaneous Remodulin for PAH, we used the mutual recognition process. Under the rules then applicable, centralized filing was not required and we perceived the decentralized procedure to be the most effective means for approval. We filed our first MAA in France in February 2001. Review of our application was completed in 2005. As a result, Remodulin was approved in 23 member countries of the EU under the mutual recognition process described above. We withdrew applications in Spain, the United Kingdom and Ireland with the intent of resubmitting some or all of the applications when we filed for approval for intravenous Remodulin since these countries required additional information not required by the other European countries.

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

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

To continue marketing our products after approval, applicable regulations require us to maintain a positive risk-benefit profile, maintaining regulatory applications through periodic reports to regulatory authorities, fulfilling pharmacovigilance requirements, maintaining manufacturing facilities according to the FDA's current Good Manufacturing Practices requirements, and successfully completing regulatory

agency inspections, among other requirements. Our manufacturing facilities are subject to continual review and periodic inspections.

Our telemedicine products are manufactured at contract facilities that are regulated by the FDA under different laws and regulations that apply to medical devices. The telemedicine devices designed and sold by Medicomp have received marketing clearance from the FDA under Section 510(k) of the Food, Drug and Cosmetic Act. Medical devices are required to be manufactured in conformance with the FDA's Quality System Regulations.

In the United States, many independent third-party payers, as well as the Medicare and State Medicaid programs, reimburse our Commercial Products. Medicare is the federal program that provides health care benefits to senior citizens and certain disabled and chronically ill persons. Medicaid is the federal program administered by the states to provide health care benefits to certain indigent persons. The Medicare contractors who administer the program provide reimbursement for our pharmaceutical Commercial Products at a rate generally equal to 95% of the published average wholesale price as of October 1, 2003 (the Medicare Part B payment formula for drugs infused through durable medical equipment) or 106% of Average Sales Price (the Medicare Part B payment formula for drugs inhaled through durable medical equipment). The State Medicaid programs also generally provide reimbursement for our Commercial Products, at reimbursement rates that are below the published average wholesale price and that vary from state to state. In return for including our pharmaceutical Commercial Products in the Medicare and Medicaid programs, we have agreed to pay a rebate to State Medicaid agencies that provide reimbursement for those products. We have also agreed to sell our Commercial Products under contracts with the Veterans Administration, Department of Defense, Public Health Service and numerous other federal agencies as well as certain hospitals that are designated as 340B entities (entities designated by federal programs to receive drugs at discounted prices) at prices that are significantly below the price we charge to our specialty pharmaceutical distributors. These programs and contracts are highly regulated and impose restrictions on our business. Failure to comply with these regulations and restrictions could result in a loss of our ability to continue receiving reimbursement for Remodulin. We estimate that between 35-50% of Remodulin and Tyvaso sales in the United States are reimbursed under the Medicare and Medicaid prog

#### **Employees**

We had 410 employees as of January 5, 2010. We also maintain active independent contractor relationships with various individuals, most of whom have month-to-month or annual consulting agreements. We believe our employee relations are excellent.

#### **Industry Segments and Geographic Areas**

We operate two business segments: pharmaceuticals and telemedicine. We sell our products in the United States and throughout the rest of the world. The information required by Item 101(b) and 101(d) of Regulation S-K relating to financial information about industry segments and geographical areas, respectively, is contained in Note 19 of the consolidated financial statements included in this Annual Report on Form 10-K.

#### **Corporate Website**

Our Internet website address is <a href="http://www.unither.com">http://www.unither.com</a>. Our filings on Form 10-K, Form 10-Q, Form 3, Form 4, Form 5, Form 8-K and any and all amendments thereto are available free of charge through this internet website as soon as reasonably practicable after they are filed or furnished to the Securities and Exchange Commission (SEC). They are also available through the SEC at <a href="http://www.sec.gov/edgar/searchedgar/companysearch.html">http://www.sec.gov/edgar/searchedgar/companysearch.html</a>.

#### **EXECUTIVE OFFICERS OF THE REGISTRANT**

The following is a list, as of February 1, 2010, 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.	55	Chairman, Chief Executive Officer and
		Director
Roger Jeffs, Ph.D.	48	President, Chief Operating Officer and Director
II ME		CI. CE. 110CC 1T
John M. Ferrari	55	Chief Financial Officer and Treasurer
Paul A. Mahon, J.D.	46	Executive Vice President for Strategic Planning, General Counsel and Corporate Secretary

Martine A. Rothblatt, Ph.D., J.D., M.B.A., started United Therapeutics in 1996 and has served as Chairman and Chief Executive Officer since its inception. Prior to United Therapeutics, she created and served as Chairman and CEO of Sirius Satellite Radio. She also led the International Bar Association's efforts to present the United Nations with a draft Human Genome Treaty. Her book, Y OUR L IFE OR M INE: H OW G EOETHICS C AN R ESOLVE THE C ONFLICT B ETWEEN P UBLIC AND P RIVATE I NTERESTS I NX ENOTRANSPLANTATION, was published by Ashgate in 2004. She is a co-inventor on three of our patents pertaining to treprostinil.

Roger Jeffs, Ph.D., joined United Therapeutics in September 1998 as Director of Research, Development and Medical. Dr. Jeffs was promoted to Vice President of Research, Development and Medical in July 2000 and to President and Chief Operating Officer in January 2001. Prior to 1998, Dr. Jeffs worked at Amgen, Inc. as Manager of Clinical Affairs and Associate Director of Clinical Research from 1995 to 1998, where he served as the worldwide clinical leader of the Infectious Disease Program.

John M. Ferrari joined United Therapeutics in May 2001 as Controller. Mr. Ferrari was promoted to Vice President of Finance in December 2003 and to Vice President of Finance and Treasurer in June 2004. In August 2006, Mr. Ferrari was promoted to Chief Financial Officer and Treasurer. Prior to joining United Therapeutics, Mr. Ferrari served as Controller for Blackboard, Inc., from 1998 to 2001. Prior to his employment with Blackboard, Inc., Mr. Ferrari served in various senior financial management positions since beginning his accounting career in 1984.

Paul A. Mahon, J.D., has served as General Counsel and Corporate Secretary of United Therapeutics since its inception in 1996. In June 2001, Mr. Mahon joined United Therapeutics full-time as Senior Vice President, General Counsel and Corporate Secretary. In November 2003, Mr. Mahon was promoted to Executive Vice President for Strategic Planning, General Counsel and Corporate Secretary. Prior to June 2001, he served United Therapeutics, beginning with its formation in 1996, in his capacity as principal and managing partner of a law firm specializing in technology and media law.

#### ITEM 1A. RISK FACTORS

#### **Forward-Looking Statements**

This Annual Report on Form 10-K contains forward-looking statements made pursuant to the safe harbor provisions of Section 21E of the Securities Exchange Act of 1934 (the Exchange Act) and the Private Securities Litigation Reform Act of 1995 which are based on our beliefs and expectations as to future outcomes. These statements include, among others, statements relating to the following:

- Expectations of revenues, profitability, and cash flows;
- The sufficiency of current and future working capital;
- The expectation that our 0.50% Convertible Senior Notes due October 2011 (Convertible Senior Notes) will be held to maturity;
- The ability to obtain financing or raise capital in the future;
- The expectation of liquidating our investment holdings without significant losses;
- The value of our common stock;
- The timing and outcome of clinical studies and regulatory filings;
- The pace and timing of enrollment in our clinical trials;
- The expectation and timing of regulatory approvals for drug candidates under development and the timing of related sales;
- The achievement and/or maintenance of both domestic and international regulatory approvals;
- The outcome of potential future regulatory actions, including audits and inspections, from the United States Food and Drug Administration (FDA) and international regulatory agencies;
- The existence and activities of competitors;
- The pricing of Remodulin® (treprostinil) Injection (Remodulin), Adcirca® (tadalafil) tablets (Adcirca) and Tyvaso® (treprostinil) Inhalation Solution (Tyvaso) (which we refer to as our Commercial Products);
- The expected volume and timing of sales of our commercial therapies;
- The dosing and rate of patient use of our Commercial Products;
- The impact of competing therapies, including generic products, on sales of our Commercial Products;
- The expectation that we will be able to maintain adequate inventories of our Commercial Products;
- The adequacy of our intellectual property protections and expiration dates on our patents and licensed patents and products;
- The ability of third parties to market, distribute and sell our products;
- The projected timing and costs relating to our construction projects;
- The potential effects of the Auction-Rate Securities Rights Offer and our expectations regarding the right to borrow thereunder;
- The expected timing of payments to third parties under license agreements;

- The outcome of any litigation or arbitration proceedings in which we are or may become involved;
- The expected impact of new accounting standards;
- The expectation that our business tax credit carryforwards will be fully utilized;
- Any statements preceded by, followed by or that include any form of the words "believe," "seek," "expect," "predict,"
   "anticipate," "forecast," "project," "intend," "estimate," "should," "could," "may," "will," or similar expressions; and
- Other statements contained or incorporated by reference in this Annual Report on Form 10-K that are not historical facts.

The statements identified as forward-looking statements may exist in *Item7—Management's Discussion and Analysis of Financial Condition and Results of Operations* or in this Annual Report on Form 10-K. These statements are subject to risks and uncertainties and our actual results may differ materially from anticipated results. Factors that may cause such differences include, but are not limited to, those discussed below. We undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise.

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

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

We have experienced financial reporting periods in which we incurred net losses. For example, for the year ended December 31, 2008, we recognized a net loss of approximately \$49.3 million as we incurred a fourth quarter charge to research and development of \$150.0 million in connection with our license of certain rights to commercialize Adcirca from Eli Lilly and Company (Lilly). We also incurred a net loss of \$3.3 million in the quarter ended December 31, 2009. While we believe we formulate our annual cash-based operating budgets with reasonable assumptions and targets, there may be factors that could affect our profitability and cause uneven quarterly and/or annual operating results.

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

During the twelve months ended December 31, 2009, net Remodulin sales accounted for approximately 90 percent of our total revenues and Tyvaso, which we commercially launched in September 2009, accounted for approximately five percent of our revenues. A wide variety of events, many of which are described in other risk factors below, could cause net Remodulin and/or Tyvaso sales to decline. For example, if regulatory approvals for Remodulin were withdrawn, we would be unable to sell Remodulin and our business could be jeopardized. In the event that GlaxoSmithKline PLC (Glaxo) terminates its assignment agreement or Pfizer, Inc. (Pfizer) terminates its license agreement, we would have no further rights to utilize assigned patents or trade secrets to develop and commercialize Remodulin and Tyvaso. Any substantial change in the dosing pattern of patients using Remodulin, due to combination therapy, side effects, deaths or any other reason, could decrease related revenues. In addition, we rely on third parties to produce, market, distribute and sell Remodulin and Tyvaso. The inability of any one of these third parties to perform these functions, or the failure of these parties to perform successfully, could negatively affect our revenues. Because we are very dependent on sales of Remodulin and Tyvaso, any reduction in sales of either or both of these products would cause our results of operations to suffer.

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

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

There are existing treatments that compete with our products, especially in the field of PAH. For the treatment of PAH, we compete with several approved products in the United States and worldwide, including the following: Flolan®, Ventavis®, Tracleer®, Revatio®, Letairis™, Thelin® and two generic epoprostenol formulations. Patients and doctors may perceive these competing products as safer, more effective, more convenient and/or less expensive than our therapies. Alternatively, doctors may reduce the prescribed doses of our products if they prescribe them as combination therapy with our competitors' products. In addition, certain competing products are less invasive than Remodulin and the use of these products may delay or prevent initiation of Remodulin therapy. Any of these circumstances may dampen our sales growth, or cause our revenues to decline.

As a result of merger activity, Actelion Ltd (Actelion), Gilead Sciences, Inc. and Pfizer presently control the majority of the approved therapies for PAH in the United States. In addition to reducing the number of competitors through merger activity, each of these companies has achieved considerable influence over prescribers through the sales and marketing of their respective therapies and through market dominance in this therapeutic area. The future commercialization of additional forms of PAH therapies could exert downward pressure on the pricing of our products and reduce our market share.

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

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

## If third-party payers do not reimburse our products, or if third-party payers reduce or limit reimbursements for our products, our sales will suffer.

Third-party payers such as Medicare, Medicaid and private insurance companies agree to reimburse the costs of our pharmaceutical products. Accordingly, our commercial success is tied to such third-party payers. These third-party payers frequently challenge the pricing of new and expensive drugs. Consequently, it may be difficult for our specialty pharmaceutical distributors or wholesalers to obtain reimbursement of our products from third-party payers. Alternatively, third-party payers may reduce the amount of reimbursement for our products based on changes in pricing of other therapies for PAH, including generic formulations of other approved therapies. If third-party payers do not approve our products for reimbursement, or limit their amount of reimbursement, patients could opt for a competing product that is approved for reimbursement. Presently, most third-party payers, including Medicare and Medicaid, reimburse the cost of our Commercial Products. Our prostacyclin analogue products, Remodulin and Tyvaso, are expensive therapies. The Medicare Modernization Act (MMA) requires that we negotiate a new price for our commercial products with the Centers for

Medicare and Medicaid Services. As a result of the staggered implementation of the MMA, our products have not yet been subject to its pricing provisions; however, future reimbursements could be subject to reduction. Furthermore, to the extent that private insurers or managed care programs follow any reduced Medicaid and Medicare coverage and payment developments, the negative impact on our business would be compounded. Further legislative developments related to health-care reform at the federal and state level appear likely and such legislation could adversely impact our business.

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

Frequently, we involve third parties to assist us in conducting clinical studies, obtaining regulatory approvals, and marketing and distributing our products, as we do not possess the internal capacity to perform all of these functions. Accordingly, the success of these third parties in performing their contractual obligations is critical to our operations. Furthermore, we may not locate acceptable contractors or enter into favorable agreements with them.

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

We rely on Baxter International Inc. (Baxter) to manufacture Remodulin for us. We are also evaluating alternative supply arrangements, including other third-party production arrangements and the production of Remodulin in our combination office and laboratory facility that we recently completed in Silver Spring, Maryland. In addition, we have increased our supply of Remodulin to cover three years of expected demand. If we are unable to implement these alternatives satisfactorily, we may not have sufficient inventory levels of Remodulin to meet future demand.

Catalent Pharma Solutions, LLC (Catalent) manufactures Tyvaso for commercial use. In addition, Catalent conducts stability studies on Remodulin and Tyvaso for us and analyzes other products that we are developing. We are producing oral treprostinil at our new manufacturing facility in Research Triangle Park, North Carolina. Our process to manufacture oral treprostinil has not been approved by the FDA; therefore, we may encounter unforeseen obstacles in getting the process approved. Catalent also maintains the ability to manufacture oral treprostinil for us.

NEBU-TEC International Med Products Eike Kern GmbH (NEBU-TEC) retains many responsibilities related to the manufacture of the Tyvaso Inhalation System, which includes a nebulizer and related accessories. Although we manage the manufacturing process, we rely on NEBU-TEC to provide the labor to manufacture the Tyvaso Inhalation System. We rely on NEBU-TEC to adhere to and maintain the manufacturing process in accordance with all applicable regulatory requirements. Any regulatory compliance problems encountered by NEBU-TEC relative to the manufacture of the Tyvaso Inhalation System could adversely affect the sale of Tyvaso. The NEBU-TEC facility is the only facility currently approved for the manufacturing of the Tyvaso Inhalation System. If we are unable to manufacture or supply the Tyvaso Inhalation System in the quantities we require or if our suppliers are unable to supply sufficient parts to manufacture the Tyvaso Inhalation System, it could delay, disrupt or prevent us from selling Tyvaso, which could impede our business and the projected growth in our business.

We rely on Accredo Therapeutics, Inc. (Accredo), CuraScript, Inc. (CuraScript), and CVS Caremark (Caremark) to market, distribute and sell Remodulin and Tyvaso in the United States. These distributors are also partially responsible for negotiating reimbursements from third-party payers for the cost of our therapies. In January 2010, we notified Accredo, CuraScript and Caremark of our intention to increase the price of Remodulin for all concentrations by 9.6 percent effective March 25, 2010. We

also intend on increasing the price of Remodulin to our international distributors in 2010. If our distributors do not recognize acceptable profit margins, they may discontinue the sale of our products. Furthermore, if our domestic and international distributors devote fewer resources to selling our products or are unsuccessful in their sales efforts, our revenues will suffer.

Pursuant to certain rights we licensed from Lilly in 2008 to commercialize Adcirca, Lilly manufactures and supplies Adcirca to 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 impede the projected growth of our business.

Although most of our current suppliers and service providers could be replaced, a change in suppliers and/or 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.

Our manufacturing strategy presents the following risks:

- We and our third-party manufacturers are subject to the FDA's current Good Manufacturing Practices in the United States and similar stringent regulatory standards internationally. Although we can control compliance issues with respect to our internal synthesis and manufacturing processes, we do not have control over regulatory compliance by our third-party manufacturers;
- Even if we and our third-party manufacturers were to comply with domestic and international drug manufacturing regulations, the sterility and quality of the products being manufactured could be substandard. If this were to occur, such products would not be available for sale or use;
- If we have to replace a third-party manufacturer or our own manufacturing operations, the FDA and its international counterparts would require new testing and compliance inspections. Furthermore, a new manufacturer would have to be educated in the processes necessary to manufacture and commercially validate our products, as manufacturing our treprostinil-based products is complex;
- We may be unable to contract with needed manufacturers on satisfactory terms or at all; and
- The supply of materials and components necessary to manufacture and package our Commercial Products and our other products may become scarce or interrupted. Disruptions to the supply of these materials could delay the manufacture and subsequent sale of such products. Any products manufactured with substituted materials or components would be subject to approval from the FDA and international regulatory agencies before they could be sold. The timing of any such regulatory approval is difficult to predict.

Any of these factors could delay clinical trials or commercialization of our products, entail higher costs, and result in the inability to sell our products effectively.

Our operations must comply with extensive FDA and comparable international 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 by such agencies. The process of obtaining and maintaining regulatory approvals for new drugs is lengthy, expensive and uncertain. The manufacture, distribution, advertising and marketing of these products are also subject to extensive regulation. Any future product approvals we receive could be accompanied by significant restrictions on the use or marketing of the product. Potential products 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—e.g., a failure to comply with the FDA's post-marketing requirement and post-marketing conditions for Tyvaso could result in its withdrawal from the market—or upon the occurrence of adverse events subsequent to commercial introduction. We are subject to similar oversight and regulation governing how we manufacture and sell our approved products.

Discovery of previously unknown problems with our marketed products or problems with our manufacturing, regulatory, compliance, promotional or sales activities could result in regulatory restrictions on our products, including withdrawal of our products from the market. If we fail to comply with applicable regulatory requirements, we could be subject to penalties that may consist of fines, suspension of regulatory approvals, product recalls, seizure of our products and/or criminal prosecution.

Reports of side effects, such as sepsis, associated with intravenous Remodulin could cause physicians and patients to avoid or discontinue use of Remodulin in favor of alternative treatments.

Sepsis is a serious and potentially life-threatening infection of the bloodstream caused by a wide variety of bacteria. Intravenous prostacyclins are infused continuously through a catheter placed in a large vein in the patient's chest. Sepsis is an expected consequence of this type of delivery. As a result, sepsis is included as a risk in both the Remodulin and Flolan package inserts. Although a discussion of the risk of sepsis is currently included on the Remodulin label, and the occurrence of sepsis is familiar to physicians who prescribe intravenously administered therapies, concerns about bloodstream infections may adversely affect a physician's prescribing practice of Remodulin.

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

To obtain regulatory approvals from the FDA and international regulatory agencies such as the European Medicines Agency (EMA), we must conduct clinical trials demonstrating that our products, including any devices used to deliver them, are safe and effective. In the past, several of our product candidates failed or were discontinued at various stages in the development process. In addition, we may need to amend ongoing trials or the FDA and/or international regulatory agencies may require us to perform additional trials beyond those we planned. Such occurrences could result in significant delays and additional costs and related clinical trials may be unsuccessful. In November 2008, we reported that our FREEDOM-C Phase III clinical trial of oral treprostinil did not achieve statistical significance for its primary endpoint. Because we have decided to amend the protocol for our current FREEDOM-M Phase III clinical trial and conduct a new Phase III clinical trial, FREEDOM-C <sup>2</sup>, we expect delays in completing our clinical trials for oral treprostinil and do not anticipate filing a New Drug Application (NDA) prior to 2012.

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

Our clinical trials may be discontinued, delayed, or disqualified for various reasons. These reasons include:

- The drug is ineffective, or physicians believe that the drug is ineffective;
- Patients do not enroll in our studies at the rate we expect;
- Ongoing or new clinical trials conducted by drug companies in addition to our own clinical trials may reduce the number of
  patients available for our trials;
- Patients experience severe side effects during treatment;

- Other investigational or approved therapies are viewed as more effective or convenient by physicians or patients;
- Our clinical trial sites or our contracted clinical trial administrators do not adhere to the trial's protocol;
- Our trials do not comply with applicable regulations or guidelines;
- We do not pass inspections by regulatory agencies;
- Patients die during our trials because of an adverse event related to the trial drug, their disease is too advanced, or they experience medical problems unrelated to the drug being studied;
- Drug supplies are unavailable or unsuitable for use in our studies; and
- The results of preclinical testing cause delays in our trials.

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

# Our corporate compliance program cannot guarantee that we comply with all potentially applicable federal, state and international regulations.

The development, manufacture, distribution, pricing, sales, marketing, and reimbursement of our products, together with our general operations, are subject to extensive federal, state, local and international regulations. These regulations are subject to frequent revisions that often introduce more stringent requirements. While we believe we have developed and instituted adequate corporate compliance programs, we cannot ensure that we will always be in compliance with these regulations. If we fail to comply with any of these regulations, we could be subject to a range of penalties including, but not limited to: the termination of clinical trials, the failure to approve a product candidate, restrictions on our products or manufacturing processes, withdrawal of our products from the market, significant fines, exclusion from government healthcare programs, and other sanctions or litigation.

# If the licenses, assignments and alliance agreements we depend on are breached or terminated, we could lose our right to develop and sell products covered by such agreements.

Our business depends upon the acquisition, assignment and license of drugs and other products that have been discovered and initially developed by others. Under our product license agreements, we receive certain rights to existing intellectual property owned by third parties subject to the terms of each license agreement. Our assignment agreements transfer all right, title and interest in and to the intellectual property to us, subject to the terms of each agreement. In addition, we may be required to obtain licenses to other third-party technologies to commercialize our early-stage products. This dependence on technology developed by others involves the following risks:

- We may be unable to obtain future licenses or assignment agreements at a reasonable cost or at all;
- If any of our licenses or assignment agreements are terminated, we will lose our rights to develop and market related products;
- Our license and assignment agreements generally provide the licensor or assignor the right to terminate these arrangements in the event we breach such agreements—e.g., we fail to pay royalties and other fees timely; and
- If a licensor or assignor fails to maintain the intellectual property licensed or assigned to us as required by most of our license and assignment agreements, we may lose our rights to develop

and market some or all of our products. In addition, we may be forced to incur substantial costs to maintain the intellectual property ourselves or force the licensor or assignor to do so.

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

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

Provisions in our license and assignment agreements may impose other restrictions that affect our ability to develop and market related products. For example, Glaxo retained an exclusive option and right of first refusal to negotiate a license agreement with us if we decide to license any aspect of the commercialization of Remodulin and Tyvaso anywhere in the world. Similarly, our amended license agreement with Toray Industries, Inc. (Toray) includes a conditional non-compete clause that grants Toray the right to be our exclusive provider of beraprost-MR. Moreover, we must also meet certain minimum annual sales to maintain our exclusive rights to beraprost-MR.

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

The period under which our commercial and developmental therapies are protected by our patent rights is limited. Our U.S. patent for the method of treating PAH with Remodulin will expire in October 2014 (it has already received the maximum five-year extension). Patents covering methods of making Remodulin and Tyvaso in the U.S. and the EU expire between October 2017 and October 2018. The patent for Adcirca for the treatment of pulmonary hypertension will expire in 2017 and our patents for Tyvaso will expire in the United States and in various countries throughout the EU in 2018 and 2020, respectively.

Upon the expiration of our patents, competitors may develop generic versions of our products and market those generic versions to compete with our products. Competitors may also seek to design around our patents prior to their expiration to develop competing products.

The scope of any patent may be insufficient to deter competitors and patent laws of international jurisdictions may not protect our rights to the same extent as the patent laws of the U.S. Furthermore, our suppliers' intellectual property protection may not be adequate. Consequently, competitors may attempt to invalidate our existing patents before they expire. In addition to patent protection, we also rely on trade secrets, proprietary know-how and technological advances. We enter into confidentiality agreements with our employees and others, but these agreements may be ineffective in protecting our proprietary information.

To the extent third-party patents cover our products or services, we, or our strategic collaborators would be required to seek licenses from the holders of these patents in order to manufacture, use, or sell our products and services. Payments under these licenses would reduce our profits from the sale of related products and services. Moreover, we may be unable to obtain these licenses on acceptable terms or at all. If we fail to obtain a required license or are unable to alter the design of our technology to avoid infringing a third-party patent, we would be unable to market related products and services.

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

In July 2005, Vanderbilt University filed a lawsuit in the U.S. District Court for the District of Delaware against ICOS Corporation (ICOS) seeking to add three of its scientists as co-inventors of the tadalafil compound and method-of-use-patents. Lilly has since acquired ICOS. The patents that were the subject of this lawsuit are the same patents licensed to us by Lilly. In January 2009, the district court judge ruled in favor of ICOS/Lilly, declining to add any of these scientists as an inventor on either patent. The plaintiff has appealed this ruling. Lilly believes these claims are without legal merit and expects to prevail in the appeal; however, it is not possible to determine the outcome. An unfavorable final outcome could have a material adverse effect on our license for Adcirca.

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

The testing, manufacturing, marketing, and sale of drugs and diagnostics involve product liability risks. Although we currently maintain product liability insurance, we may not be able to maintain this insurance at an acceptable cost, if at all. In addition, our insurance coverage may not be adequate for all potential claims. If claims or losses significantly exceed our liability insurance coverage, we may be forced out of business.

## Our marketable investments may be subject to a loss in value and liquidity.

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

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

We may be required to seek additional sources of financing to meet unplanned 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.

Furthermore, we may require additional financing to meet significant future obligations. Our Convertible Senior Notes require partial cash settlement. Specifically, upon conversion we will be required to pay in cash the principal balance of approximately \$250.0 million or the conversion value at the settlement date, whichever is less. The Convertible Senior Notes will mature in October 2011, but may be convertible prior to maturity at the election of their holders if certain criteria are met. In addition, awards granted under our non-dilutive Share Tracking Awards Plan (STAP) entitle

participants to receive in cash an amount equal to the appreciation in the price of our common stock, which is calculated as the positive difference between the closing price of our common stock on the date of exercise and the date of grant. Consequently, the STAP may require significant future cash payments to the extent the price of our common stock continues to appreciate and the number of vested STAP awards increases over time. While we believe that our operating budgets incorporate the anticipated outlays of cash required by the STAP, if we do not have sufficient funds to meet our contractual obligations under the Convertible Senior Notes and the STAP or are unable to secure alternative sources of financing, we could be in default, face litigation and/or lose key employees.

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

Our research and development and manufacturing activities involve the controlled use of chemical and hazardous substances and we are expanding these activities both in their scale and in new locations. In addition, patients may dispose of our products using means we do not control. Such activities subject us to numerous federal, state, and local environmental and safety laws and regulations that govern the management, storage and disposal of hazardous materials. Compliance with current or future environmental laws and regulations can require significant costs; furthermore, we can be subject to substantial fines and penalties in the event of noncompliance. While we believe we comply with laws and regulations governing these materials, the risk of accidental contamination or injury from these materials cannot be completely eliminated. Furthermore, once chemical and hazardous materials leave our site, we cannot control what our hazardous waste removal contractors choose to do with these materials. In the event of an accident, we could be liable for substantial civil damages or costs associated with the cleanup of the release of hazardous materials. Any related liability could exceed our resources and could have a materially adverse effect on our business.

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

Several risks are inherent in our business development plans. Achieving our goals will require continued and substantial investment in research and development, sales and marketing, and facilities. For example, we have spent considerable resources building and seeking regulatory approvals for our laboratories and manufacturing facilities. These facilities may be insufficient to meet future demand for our products or we may have excess capacity at these facilities if future demand falls short of our expectations, or if we do not receive regulatory approvals for the products we intend to produce at these facilities. In addition, constructing our facilities is expensive, and our ability to recover our investment will depend on sales of the products manufactured at these facilities in sufficient volume to increase our revenues substantially. If we experience sales growth, we may have difficulty managing inventory levels as marketing new therapies is complicated, and gauging future demand is often difficult and uncertain.

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

As of December 31, 2009, we had approximately \$80.9 million in business tax credit carryforwards. These tax credit carryforwards expire on various dates through 2028. The Internal Revenue Service (IRS) has not yet audited or reviewed these business tax credit carryforwards since we began utilizing them for the 2008 tax year. We have conducted reviews of these tax credit carryforwards and have recognized reserves for those tax credits that we believe may be disallowed upon examination by the IRS. However, it is possible that, upon examination, the IRS could reduce our business tax credit carryforwards further. Any reduction in business tax credit carryforwards will increase our tax expense and shorten the period before we are required to pay federal income taxes.

In addition, certain business tax credit carryforwards that were generated at various dates prior to December 2008 may be subject to limitations on their use pursuant to Internal Revenue Code Section 382 (Section 382) as a result of ownership changes as defined therein. Presently, we do not expect that these business tax credit carryforwards will expire unused. If Section 382 ownership changes occur in the future, the utilization of related carryforwards may be deferred and may expire unused.

Furthermore, our future operations may not generate sufficient taxable income in order to utilize our business tax credit carryforwards. Consequently, all or a portion of our business tax credit carryforwards might expire unused.

## We have been named as a party to derivative lawsuits. Litigation proceedings are inherently uncertain and could result in an unfavorable outcome.

Derivative lawsuits have been filed against certain of our directors and named executive officers relating to the modification of awards granted under our STAP and the exchange of certain stock options granted under our Amended and Restated Equity Incentive Plan. We have been named as nominal defendant in these lawsuits. See *Part I*, *Item III* — *Legal Proceedings* for a more detailed description of these proceedings. The defense of these lawsuits and any future actions could result in significant legal fees, divert our management's attention from the operation of our business, and result in an outcome that could be costly and have an adverse effect on the structure of our compensation plans and our ability to attract and retain employees.

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

#### Risks Related to Our Common Stock

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

The price of common stock can be highly volatile within the pharmaceutical and biotechnology sector. Consequently, there can be significant price and volume fluctuations in the market that may not always relate to operating performance. The table below sets forth the high and low closing prices for our common stock for the periods indicated, as adjusted for the two-for-one split of our common stock:

	High	Low
January 1, 2007—December 31, 2007	\$ 54.31	\$ 23.94
January 1, 2008—December 31, 2008	\$ 57.99	\$ 24.51
January 1, 2009—December 31, 2009	\$ 52.88	\$ 27.86

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

- Quarterly and annual financial and operating results;
- Failure to meet estimates or expectations of securities analysts;
- The 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 or Medicaid and changes in reimbursement policies of private health insurance companies;

- Announcements by us or others of technological innovations or new products or announcements regarding our existing products;
- Interference in patent or other proprietary rights;
- Substantial sales of our common stock by us or our existing shareholders;
- Future issuances of common stock by us or any other activity which could be viewed as being dilutive to our shareholders;
- Rumors among or incorrect statements by investors and/or analysts concerning our company, our products, or operations;
- Failure to maintain, or changes to, our approvals to sell our products;
- Discovery of previously unknown problems with our marketed products or problems with our manufacturing, regulatory, compliance, promotional, marketing or sales activities that result in regulatory restrictions on our products, including withdrawal of our products from the market;
- Failure to obtain or maintain regulatory approvals from the FDA and international regulatory agencies;
- Accumulation of significant short positions in our common stock by hedge funds or other investors or the significant
  accumulation of our common stock by hedge funds or other institutional investors with investment strategies that may lead to
  short-term holdings;
- Timing and outcome of additional regulatory submissions and approvals; and
- General market conditions.

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

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

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

The price of our common stock could decline if: (1) we issue common stock to raise capital or to acquire a license or business; (2) our shareholders transfer ownership of our common stock, or sell substantial amounts in the public market; or (3) our investors become concerned that substantial sales of our common stock may occur. A decrease in the price of our common stock could make it difficult for us to raise capital or fund acquisitions through the use of our stock.

The conversion of some or all of the Convertible Senior Notes when the price of our common stock exceeds \$52.85 per share would dilute the ownership interests of our existing shareholders. Any sales of our common stock issued upon such conversion could adversely affect the prevailing market price of our common stock. Furthermore, the existence of the Convertible Senior Notes may encourage short selling by market participants because the conversion of the Convertible Senior Notes could depress the price of our common stock.

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

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

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

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

- a merger, tender offer or proxy contest;
- the assumption of control by a holder of a large block of our securities; and/or
- the replacement or removal of current management by our shareholders.

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

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

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

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

Our directors and executive officers beneficially owned approximately 9.7 percent of our outstanding common stock as of December 31, 2009. Shares beneficially owned include stock options that could be exercised by those directors and executive officers within 60 days of December 31, 2009. Accordingly, these shareholders as a group may be able to influence the outcome of matters requiring shareholder approval, including the election of our directors. Such shareholder influence could delay or prevent a change in control that could benefit our shareholders.

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

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

## ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

## ITEM 2. PROPERTIES

Maryland—In December 2009, we completed construction of our new combination office and laboratory facility, which is connected to our leased Phase I laboratory in Silver Spring, Maryland. The Phase I laboratory is used for the synthesis of treprostinil-based compounds and monoclonal antibodies. We expect to use our newly constructed office and laboratory facility to manufacture Remodulin, Tyvaso and monoclonal antibodies for commercial use. It is also our corporate headquarters. Our old corporate headquarters and the buildings adjacent to it will be demolished for the construction of a new office building beginning in 2010, which we expect to be complete in 2012. We also own two other buildings in Silver Spring across the street from our existing buildings, which are used to support our operations. We also lease space at a warehouse near Silver Spring to maintain some of our raw material inventory used in our treprostinil manufacturing and synthesis processes.

Florida—We own our Remodulin Therapy Assistance office building in Satellite Beach, Florida. Lung Rx, LLC (Lung Rx), also occupies a portion of this building. Our subsidiaries, Lung Rx and Medicomp Inc., lease manufacturing and office space, respectively, in Melbourne, Florida.

North Carolina—We own a 200,000 square foot combination manufacturing facility and office building in Research Triangle Park, North Carolina, which is occupied by our clinical research and development and commercialization staffs. We warehouse and distribute Tyvaso and manufacture oral treprostinil at this location.

Other locations— Our legal department occupies leased space in Washington, D.C. We own a building adjacent to this office to house our virology-related government contracting operations. Our subsidiary, Unither Neurosciences, Inc., leases office space in Burlington, Vermont. Our subsidiary, United Therapeutics Europe, Ltd. (UTEL), owns a 24,000 square foot building and land near London, which is their headquarters. UTEL also purchased a building in Oxford, England, which will serve as laboratory space for our glycobiology projects. In addition, United Therapeutics Europe, Ltd., and LungRx Limited lease office space near London, England. Our Canadian subsidiary, Unither Biotech Inc., leases office space in Magog, Quebec, Canada. Our German subsidiary, Unither Therapeutik GmbH, leases office and production space from NEBU-TEC in Elsenfeld, Germany.

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

The office space in Melbourne, Florida, is used in our telemedicine segment. All other properties and leased facilities are used in our pharmaceutical segment.

#### ITEM 3. LEGAL PROCEEDINGS

As previously disclosed in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2009, on May 7, 2009, purported shareholder Jeffrey Benison IRA filed a derivative complaint in the Court of Chancery for the State of Delaware against those of our directors who were members of our Board of Directors as of December 31, 2008, and us as a nominal defendant. An amended complaint, which the plaintiff filed on August 27, 2009 (purportedly on our behalf), alleged, among other things, that the named director defendants breached their fiduciary duties of loyalty in connection with the 2008 modification of awards granted under the United Therapeutics Corporation Share Tracking Awards Plan (STAP) and the exchange of certain stock options granted under our Amended and Restated Equity Incentive Plan. The amended complaint also alleged that our Chief Executive Officer should not have been able to exchange certain of the stock options she exchanged pursuant to the same 2008 exchange. On October 2, 2009, a second plaintiff, the Retirement Board of

Allegheny County, filed a derivative complaint asserting similar challenges as the *Benison* complaint described above, also in the Court of Chancery for the State of Delaware. On November 9, 2009, the Court of Chancery entered an order consolidating these two derivative actions. The order authorizes the plaintiffs to file a consolidated amended complaint and provides that the defendants are not required to respond further to the previously filed complaints. As of February 26, 2010, a consolidated amended complaint has not yet been filed.

We disclosed the amendment of awards granted under the STAP and exchange of options (including by our Chief Executive Officer) in our filings with the Securities and Exchange Commission, including our Current Reports on Form 8-K filed on June 6, 2008, November 26, 2008, and December 31, 2008, our tender offer statement on Schedule TO, filed on November 26, 2008, and amendments thereto filed on December 5 and 31, 2008, our Annual Report on Form 10-K, filed on February 26, 2009, our Definitive Proxy Statement on Schedule 14A, filed on April 29, 2009, and our Quarterly Reports on Form 10-Q, filed on May 1, 2009, and July 31, 2009. The plaintiffs are seeking unspecified monetary damages, purportedly for United Therapeutics Corporation, as well as attorneys' fees and costs and injunctive relief. We believe the plaintiffs' allegations are without merit and have defended and intend to continue to defend against these claims vigorously. Furthermore, we have been advised that the individual director and officer defendants also intend to defend against these claims vigorously.

On July 28, 2009, the Retirement Board of Allegheny County also filed a complaint against us in the Court of Chancery for the State of Delaware seeking an order allowing the plaintiff to inspect our records relating principally to the same issues addressed in its derivative lawsuit summarized above, as well as attorneys' fees and costs. We have reached an agreement-in-principle with the plaintiff to resolve this matter, with each party to bear its own fees and costs, and pursuant to which we produced certain corporate books and records in November 2009.

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

## ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matters were submitted to a vote of security holders during the fourth quarter of the fiscal year covered by this report.

## **PART II**

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

## **Market for Common Equity**

Our common stock (and associated preferred stock purchase rights) trades on the NASDAQ Global Select Market under the symbol "UTHR". The table below sets forth the high and low closing prices for our common stock for the periods indicated, as adjusted for the two-forone split of our common stock on September 22, 2009:

	20	09	20	08
	High	Low	High	Low
January 1—March 31	\$ 36.64	\$ 29.60	\$ 51.58	\$ 37.40
April 1—June 30	\$ 42.93	\$ 27.86	\$ 48.88	\$ 41.08
July 1—September 30	\$ 50.30	\$ 39.32	\$ 57.99	\$ 49.69
October 1—December 31	\$ 52.88	\$ 40.63	\$ 53.02	\$ 24.51

As of February 19, 2010, there were 46 holders of record of our common stock. We estimate that there are approximately 13,000 beneficial owners of our common stock. As of February 22, 2010, the closing price of our common stock was \$55.06 per share.

## **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.

## 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,							
2009	2008(3)	2007(3)	2006(3)	2005			
\$ 369,848	\$ 281,497	\$ 210,943	\$ 159,632	\$ 115,915			
,		,		36,052			
,	- ,	,		24,655			
45,321	30,066	22,261	17,028	12,315			
343,847	363,553	204,640	130,650	73,022			
26,001	(82,056)	6,303	28,982	42,893			
5,146	11,025	13,602	10,700	5,359			
(12,875)	(11,439)	(14,281)	(2,417)	(29)			
(141)	(226)	(321)	(491)	(754)			
636	(1,025)	(826)	1,199	53			
(7,234)	(1,665)	(1,826)	8,991	4,629			
18,767	(83,721)	4,477	37,973	47,522			
695	34,394	7,876	34,623	17,494			
\$ 19,462	\$ (49,327)	\$ 12,353	\$ 72,596	\$ 65,016			
				<del></del>			
\$ 0.37	\$ (1.08)	\$ 0.29	\$ 1.58	\$ 1.42			
\$ 0.35	\$ (1.08)	\$ 0.28	\$ 1.50	\$ 1.29			
53,314	45,802	42,448	46,020	45,650			
56,133	45,802	44,902	48,276	50,412			
	\$ 369,848 122,188 176,338 45,321 343,847 26,001 5,146 (12,875) (141) 636 (7,234) 18,767 695 \$ 19,462 \$ 0.37 \$ 0.35	2009     2008(3)       \$ 369,848     \$ 281,497       122,188     239,181       176,338     94,306       45,321     30,066       343,847     363,553       26,001     (82,056)       5,146     11,025       (12,875)     (11,439)       (141)     (226)       636     (1,025)       (7,234)     (1,665)       18,767     (83,721)       695     34,394       \$ 19,462     \$ (49,327)       \$ 0.37     \$ (1.08)       \$ 0.35     \$ (1.08)       \$ 53,314     45,802	2009         2008(3)         2007(3)           \$ 369,848         \$ 281,497         \$ 210,943           122,188         239,181         83,352           176,338         94,306         99,027           45,321         30,066         22,261           343,847         363,553         204,640           26,001         (82,056)         6,303           5,146         11,025         13,602           (12,875)         (11,439)         (14,281)           (141)         (226)         (321)           636         (1,025)         (826)           (7,234)         (1,665)         (1,826)           18,767         (83,721)         4,477           695         34,394         7,876           \$ 19,462         \$ (49,327)         \$ 12,353           \$ 0.37         \$ (1.08)         \$ 0.29           \$ 0.35         \$ (1.08)         \$ 0.28	2009         2008(3)         2007(3)         2006(3)           \$ 369,848         \$ 281,497         \$ 210,943         \$ 159,632           \$ 122,188         239,181         \$ 83,352         57,570           \$ 176,338         94,306         99,027         56,052           \$ 45,321         30,066         22,261         17,028           \$ 343,847         363,553         204,640         130,650           \$ 26,001         (82,056)         6,303         28,982           \$ 5,146         11,025         13,602         10,700           \$ (12,875)         \$ (11,439)         \$ (14,281)         \$ (2,417)           \$ (141)         \$ (226)         \$ (321)         \$ (491)           \$ 636         \$ (1,025)         \$ (826)         \$ 1,199           \$ (7,234)         \$ (1,665)         \$ (1,826)         8,991           \$ 18,767         \$ (83,721)         \$ 4,477         37,973           \$ 695         \$ 34,394         7,876         \$ 34,623           \$ 19,462         \$ (49,327)         \$ 12,353         \$ 72,596           \$ 0.37         \$ (1.08)         \$ 0.29         \$ 1.58           \$ 0.35         \$ (1.08)         \$ 0.28         \$ 1.50  <			

	Year Ended December 31,									
		2009		2008(3)		2007(3)		2006(3)		2005
Consolidated Balance Sheet										
Data:										
Cash, cash equivalents and										
marketable investments(2)	\$	378,120	\$	336,318	\$	299,792	\$	264,163	\$	170,347
Total assets		1,051,544		874,534		585,247		476,317		291,413
Notes payable		220,272		205,691		192,172		179,604		_
Accumulated deficit		(74,746)		(93,927)		(30,375)		(42,729)		(115,325)
Total stockholders' equity		653,009		555,334		352,131		272,559		275,102

<sup>(1)</sup> See Note 11 to the consolidated financial statements included in this Annual Report on Form 10-K for the computation of basic and diluted net income per share. In addition, all share and per share

- data have been adjusted from previously reported amounts to reflect the two-for-one split of our common stock on September 22, 2009.
- (2) Excludes restricted marketable investments and cash.
- (3) Adjusted retrospectively for the adoption of guidance pertaining to convertible debt instruments that may be settled in cash upon conversion included in Financial Accounting Standards Board (FASB) Accounting Standards Codification<sup>TM</sup> (ASC) 470-20, *Debt with Conversion Options and Other Options* (FASB ASC 470-20). See Note 9 to the consolidated financial statements included in this Annual Report on Form 10-K.

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

The following discussion should be read in conjunction with our consolidated financial statements and related notes to the consolidated financial statements included in this Annual Report on Form 10-K. The following discussion contains forward-looking statements made pursuant to the safe harbor provisions of Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. These statements are based on our beliefs and expectations about future outcomes and are subject to risks and uncertainties that could cause actual results to differ materially from anticipated results. Factors that could cause or contribute to such differences include those described under *Part I, Item 1A—Risk Factors—Forward Looking Statements* appearing in this Annual Report on Form 10-K and factors described in other cautionary statements, cautionary language and risk factors set forth in other documents filed with the SEC. We undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise.

#### Overview

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

Our key therapeutic platforms include:

- *Prostacyclin analogues:* stable synthetic forms of prostacyclin, an important molecule produced by the body that has powerful effects on blood vessel health and function;
- *Phosphodiesterase type 5 (PDE-5) inhibitors:* molecules that act to inhibit the degradation of cyclic guanosine monophosphate (cGMP) in cells. cGMP is activated by nitric oxide (NO), a naturally occurring substance in the body that mediates the relaxation of vascular smooth muscle;
- Monoclonal antibodies: antibodies that act by targeting tumor associated antigens on cancer cells; and
- Glycobiology antiviral agents: a novel class of small, sugar-like molecules that have shown pre-clinical indications of efficacy against a broad range of viruses.

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

Our lead product is Remodulin® (treprostinil) Injection (Remodulin) to be administered subcutaneously or intravenously for the treatment of pulmonary arterial hypertension (PAH). The

United States Food and Drug Administration (FDA) initially approved Remodulin in 2002 for subcutaneous (under the skin) administration. Subsequently, the FDA broadened its approval of Remodulin for intravenous (in the vein) use and for the treatment of patients who require transition from Flolan®, the first prostacyclin analogue approved by the FDA for the treatment of PAH. In addition to the United States, Remodulin is approved in many other countries, primarily for subcutaneous use. In May 2009, the FDA approved Adcirca® (tadalafil) tablets (Adcirca), an oral therapy administered once daily for the treatment of PAH to which we acquired certain exclusive commercialization rights from Eli Lilly and Company (Lilly). And, in July 2009, the FDA approved Tyvaso® (treprostinil) Inhalation Solution (Tyvaso), an inhaled therapy for the treatment of PAH. We launched both Adcirca and Tyvaso for commercial sale in the third quarter of 2009. With the introduction of these two new therapies, we are now able to offer treatments to a broader range of patients who suffer from PAH. In addition, we are continuing to develop an oral treprostinil.

#### Revenues

We derive most of our revenues from sales of Remodulin. Beginning with the quarter ended September 30, 2009, we have also recognized revenues from our recently approved therapies, Adcirca and Tyvaso, and expect these sources of revenue to grow over time, as the therapies gain broader acceptance in the market. We sell Remodulin and Tyvaso in the United States to our specialty pharmaceutical distributors: Accredo Therapeutics, Inc. (Accredo), CuraScript, Inc. (CuraScript), and CVS Caremark (Caremark). Adcirca is sold to pharmaceutical wholesalers who are part of Lilly's pharmaceutical wholesaler network. The distribution of Adcirca to patients through pharmaceutical wholesalers is similar to the distribution mechanism used by Adcirca's main competitor, Revatio®. The distribution of Remodulin and Tyvaso through specialty pharmaceutical distributors is similar to the distribution mechanisms of their main competitors, Flolan® and Ventavis®, respectively. We also sell Remodulin to distributors in other countries. Because discontinuation of Remodulin or Tyvaso therapy can be life threatening, we require our distributors to maintain minimum contingent inventory levels; consequently, sales of Remodulin and Tyvaso to our distributors in any given quarter may not be entirely indicative of patient demand. Our distributors typically place one bulk order per month based on their estimates of future demand and considerations of contractual minimum inventory requirements. As such, sales of Remodulin and Tyvaso can be affected by the timing and magnitude of distributor orders.

Other sources of revenue include telemedicine products and services in the United States. Our telemedicine products and services are designed to detect cardiac arrhythmias and ischemic heart disease, a condition that causes poor blood flow to the heart.

We operate in a highly competitive market. For instance, a small number of pharmaceutical companies control a majority of the current PAH therapies that are approved for use. There are also a number of investigational products currently in development that, if approved, may erode the market share of our existing commercial therapies. Competing therapies may have a significant impact on our revenues. We expect that the competition within our industry will only continue to increase.

#### **Expenses**

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

## **Major Research and Development Projects**

Our major research and development projects focus on the use of prostacyclin analogues and PDE-5 inhibitors to treat cardiovascular diseases, monoclonal antibodies to treat a variety of cancers, and glycobiology antiviral agents to treat infectious diseases.

## Cardiovascular Disease Projects

Tyvaso

In November 2007, we completed a Phase III clinical trial of Tyvaso in patients with PAH who were also treated with either Tracleer®, an oral endothelin receptor antagonist (ETRA), or Revatio, a PDE-5 inhibitor. This clinical trial, called TRIUMPH-1, demonstrated a highly statistically significant improvement in median six-minute walk distance, the endpoint primarily used to measure improvement in PAH patients.

Based on the favorable results of TRIUMPH-1, we submitted a New Drug Application (NDA) in June 2008 to obtain FDA approval to market Tyvaso in the United States. In addition, we filed a Marketing Authorization Application (MAA) in December 2008 for Tyvaso with the European Medicines Agency (EMA) using the centralized filing process. In February 2010, we withdrew our MAA from consideration by the EMA due to the EMA's major objection related to findings of non-compliance with good clinical practice (GCP) at two clinical sites. The EMA stated that these findings would preclude a recommendation for approval of Tyvaso in the EU. The EMA had no major objections at the time of withdrawal related to the safety or efficacy of Tyvaso.

On July 30, 2009, the FDA approved Tyvaso for the treatment of PAH using the Tyvaso Inhalation System. Commercial sales of Tyvaso began in September 2009. In connection with the Tyvaso approval, we have agreed to a post-marketing requirement (PMR) and certain post-marketing commitments (PMCs). PMRs and PMCs are studies that sponsors conduct after FDA approval to gather additional information about a product's safety, efficacy, or optimal use. PMRs are required studies; whereas, a sponsor voluntarily commits to conduct PMCs. We are required to provide the FDA annual updates on our PMR and PMCs. Failure to complete the studies or adhere to the timelines set by the FDA for the PMR could result in penalties, including fines or withdrawal of Tyvaso from the market, unless we are able to demonstrate good cause for not completing the studies or adhering to our timelines.

In accordance with the PMR, we will conduct a long-term observational study in the U.S. that will include 1,000 patient-years of follow-up in Tyvaso-treated patients, and 1,000 patient-years of follow-up in matched control patients receiving other PAH treatments to evaluate the potential association between Tyvaso and oropharyngeal and pulmonary toxicity. We have submitted a draft protocol of the PMR to the FDA for review, and have committed to submitting the results by December 15, 2013.

The PMC requires us to modify the Tyvaso Inhalation System in the following ways: (1) create a titratable breath counter; (2) align/key the dome of the device; (3) add a battery back-up power pack; and (4) permanently fix the baffle plate to the dome. As part of the re-engineering process, we have also agreed to perform a usability analysis incorporating the evaluation and prioritization of user-related risk followed by a human factors study, and we will conduct a study in healthy volunteers to collect pharmacokinetic data to verify expected dosing with the modified device. We have submitted draft protocols for these PMCs to the FDA for review, and we have committed to submitting a Supplement to our Tyvaso NDA describing the results no later than October 31, 2010. The human factors study will commence in March 2010; therefore, we believe we are well on track to meet the timeline for final report submission.

In December 2008, we began enrolling patients in an open-label study in the United States to investigate what occurs when patients on Ventavis®, another inhaled prostacyclin analogue, are switched to Tyvaso. The study is almost complete, but remains ongoing while we finish assessing study patients

prior to their transition to commercial Tyvaso. Data is being prepared for presentation at scientific symposia.

Oral treprostinil

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

The FREEDOM-C Phase III clinical trial was a study of patients currently on approved background therapy using a PDE-5 inhibitor, such as Revatio, or an ETRA, such as Tracleer, or a combination of both. We completed enrollment for FREEDOM-C in May 2008 and in November 2008, we announced that FREEDOM-C failed to achieve statistical significance. Preliminary analysis of the data revealed that the initial tablet strength was too high, which contributed to an inability to dose titrate (increase the dose to tolerability) and prevented the attainment of optimal dosing levels. Consequently, the overall treatment effect of the therapy was muted. However, we believe that the results of the FREEDOM-C clinical trial, particularly as they relate to treatment effect and dosing, support our continued development of oral treprostinil. Accordingly, we commenced a second Phase III clinical trial, FREEDOM-C <sup>2</sup>, to continue studying dosage and efficacy of oral treprostinil in PAH patients on an approved background therapy. Enrollment in FREEDOM-C <sup>2</sup> began in June 2009.

The FREEDOM-M Phase III clinical trial is a 12-week study of newly-diagnosed PAH patients not currently on any background therapy. Based on our observations from the FREEDOM-C clinical trial relating to patient tolerability and tablet strength, we submitted a protocol amendment to the FDA in February 2009 to add patients to the ongoing FREEDOM-M trial. These additional patients will be provided a lower-strength tablet (0.25 mg) when they begin the trial and their doses will be titrated in 0.25 mg increments, which we believe will improve tolerability. In addition, our amendment to the FREEDOM-M protocol specifies that the primary statistical analysis of the trial will include only those patients who started the trial using the 0.25 mg tablet. By amending FREEDOM-M we hope to achieve the following objectives: (1) to assess more accurately the effectiveness of oral treprostinil; (2) to improve patient tolerability of oral treprostinil so that an effective maintenance dose can be attained; and (3) to reduce the rate of premature discontinuation due to adverse events. The statistical assumptions of the amended protocol provide for 90% power to observe a 45-meter treatment benefit in six-minute walk distance at the significance level of 0.01. We believe the results of the protocol amendments will reflect the benefits of a favorable dosing regimen for oral treprostinil. In April 2009, we began enrolling patients in FREEDOM-M under the amended protocol.

#### Beraprost-MR

Pursuant to our license agreement with Toray Industries, Inc. (Toray), we are developing a modified release formulation of beraprost (beraprost-MR), an oral prostacyclin analogue, for the treatment of PAH. We have completed enrollment of a Phase II clinical trial of beraprost-MR to explore multiple-dose tolerability in patients with PAH, and began a second Phase II clinical trial during the fourth quarter of 2009. The drug substance beraprost consists of equal amounts of four optical isomers, one of which is primarily responsible for the pharmacologic activity of the drug. As we continue clinical development, we plan to explore the development of a modified release drug product containing only the most pharmacologically active isomer. In October 2007, beraprost-MR received regulatory approval in Japan for the treatment of PAH, and in July 2008, beraprost-MR was designated an orphan medicinal product by the EMA.

From inception to December 31, 2009, we have spent approximately \$515.5 million on these and other cardiovascular programs.

## Cancer Disease Projects

In December 2007, we entered into two agreements with Memorial Sloan-Kettering Cancer Center to license certain rights to two investigational monoclonal antibodies (3F8 and 8H9) for the treatment of neuroblastoma and metastatic brain cancer. We have been granted orphan drug exclusivity in the United States and received a positive opinion from the committee on orphan medicinal products in the European Union (EU) for the use of the 3F8 monoclonal antibody for the treatment of neuroblastoma. In August 2009, we began enrolling patients in a Phase II clinical trial of 3F8 for primary refractory neuroblastoma. We have spent approximately \$62.7 million from inception to December 31, 2009, on this and earlier programs in our cancer platform.

## Infectious Disease Projects

Pursuant to our research agreement with the University of Oxford (Oxford), we have the exclusive right to commercialize a platform of glycobiology antiviral drug candidates in various preclinical and clinical stages of testing for the treatment of a wide variety of viruses. Through our research agreement with Oxford, we are also supporting research into new glycobiology antiviral drug candidates and technologies. We are currently testing many of these compounds in preclinical studies and Oxford continues to synthesize new agents. We have spent approximately \$42.1 million from inception to December 31, 2009, on our infectious disease programs.

#### **Cost of Product Sales**

Cost of product sales comprises costs to manufacture or acquire products sold to customers. We manufacture treprostinil using advanced intermediate compounds purchased in bulk from several third-party vendors who have the capacity to produce greater quantities of these compounds more cost effectively than we do. In 2009, we received both FDA and EU approval to produce treprostinil in our Silver Spring, Maryland, laboratory facility (Phase I Laboratory). Our manufacturing process has been designed to give us the flexibility to produce both treprostinil diethanolamine (the form of treprostinil used in our oral tablet) and treprostinil (used to produce Tyvaso and subcutaneous and intravenous Remodulin) efficiently in proportion to forecasted demand.

We acquired the rights to the Tyvaso Inhalation System from NEBU-TEC in September 2009. For 2009 and for part of 2010, the Tyvaso starter kits, consisting of two nebulizers and 28 days of drug and daily supplies, contain nebulizers manufactured by NEBU-TEC prior to our acquisition of that business. Because the starter kits contain two nebulizers, the cost of product sales for the starter kits is higher than the monthly resupply kits, which contain 28 days of drug and daily supplies but no nebulizer.

We use contract manufacturers to produce all of our products for commercial use. We extended our contract with Baxter Pharmaceutical Solutions, LLC (Baxter), through 2013 and as part of that contract amendment we have agreed that Remodulin will be manufactured on larger production equipment and in larger quantities than the current manufacturing process. This new manufacturing process and related equipment will require FDA approval.

We are also evaluating alternative supply arrangements, including other third-party production arrangements and the manufacture of Remodulin and Tyvaso in our combination office and laboratory facility that we recently completed in Silver Spring, Maryland (Phase II Facility). During 2009, we increased our inventory of Remodulin and Tyvaso from two years of expected demand to three years of expected demand to ensure that we maintain adequate levels at all times. In addition, we have increased our inventory levels of treprostinil-based compounds to meet similar levels. In conjunction with this projected increase in inventory, we obtained approval in the U.S. and Europe to extend the shelf life of Remodulin from 30 months to 36 months.

## **Future Prospects**

Because PAH is a progressive disease without a cure, many patients continue to deteriorate on currently approved therapies. This presents market growth opportunities for Remodulin, Tyvaso and Adcirca as viable alternatives or complements to existing therapies. Furthermore, we anticipate that the market for our commercial products will continue to expand as more patients are diagnosed with PAH each year. We have experienced annual revenue growth in excess of 30 percent since Remodulin was first approved in 2002. One of our principal objectives is to maintain this level of growth. The continued achievement of this objective will depend upon the success of our commercial development of products within our pipeline and our ability to treat a broader spectrum of PAH patients. To this end, we continue to develop oral treprostinil and seek to expand the use of our therapies to treat patients at earlier stages in the PAH disease pathway. With the commercial introduction of Tyvaso and Adcirca, we now expect to reach PAH patients along the full continuum of the disease.

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

#### **Financial Position**

Cash, cash equivalents and marketable investments (excluding all restricted amounts) at December 31, 2009, were \$378.1 million, compared to approximately \$336.3 million as of December 31, 2008. The increase in cash and marketable investments was driven mainly by: (1) continued significant sales growth and related cash receipts from sales of Remodulin and the launch of Adcirca and Tyvaso; (2) the reduction in construction-related expenditures as we completed the construction of our facility in Research Triangle Park, North Carolina, during the first quarter of 2009; and (3) \$24.4 million in net proceeds received from the exercise of stock options less cash paid for the exercise of awards granted under the United Therapeutics Corporation Share Tracking Awards Plan (STAP) during the twelve-month period ended December 31, 2009

Restricted cash and marketable investments were \$40.0 million at December 31, 2009, and were comprised of \$34.9 million pledged as security for our Phase I Laboratory and \$5.1 million placed in the United Therapeutics Corporation Supplemental Executive Retirement Plan Rabbi Trust Document (Rabbi Trust). At December 31, 2008, the components of our restricted cash and marketable investments were \$40.7 million pledged as security for our Phase I Laboratory and \$5.1 million placed in the Rabbi Trust.

Accounts receivable at December 31, 2009, was \$50.6 million, as compared to \$28.3 million at December 31, 2008. The \$22.3 million increase was due to higher Remodulin sales in the quarter ended December 31, 2009, as compared to the quarter ended December 31, 2008, and the commercial launch of Tyvaso September 2009.

Inventory increased \$12.0 million during the year ended December 31, 2009, to \$26.4 million as a result of our efforts to increase our inventories of Remodulin, Tyvaso and treprostinil from a two-year supply to a three-year supply based on current demand.

Goodwill and other intangible assets increased by approximately \$10.6 million, from \$7.8 million at December 31, 2008, to \$18.4 million at December 31, 2009. The increase resulted from the acquisition of the Tyvaso Inhalation Systems business from NEBU-TEC in September 2009.

Property, plant and equipment at December 31, 2009, was \$303.9 million, an increase of \$81.2 million from \$222.7 million at December 31, 2008. The increase was driven by expenditures for our construction projects in Maryland and North Carolina during the twelvementh period ended December 31, 2009. Construction of our North Carolina facility was completed in February 2009 and construction of our Phase II Facility in Silver Spring, Maryland, was completed in December 2009.

Other current liabilities increased by \$44.9 million from \$16.5 million at December 31, 2008, to \$61.4 million at December 31, 2009. Since December 31, 2008, our liability for the STAP has increased by approximately \$55.7 million primarily as a result of the appreciation in the price of our common stock and the normal vesting accrual of outstanding awards. The increase in STAP liability was partially offset by a \$5.4 million reduction in taxes payable, which resulted from estimated tax payments.

The classification of our \$250.0 million 0.50% Convertible Senior Notes due October 2011 (Convertible Senior Notes) shifted from a non-current liability at December 31, 2008, to a current liability at December 31, 2009, because the contingent conversion criteria had been satisfied at December 31, 2009, and the Convertible Senior Notes are therefore convertible at the election of their holders (Note Holders). Specifically, the closing price of our common stock exceeded 120% of the initial conversion price for more than 20 days during the 30 consecutive trading day period ending on December 31, 2009. This conversion determination is measured as of the end of each quarter. Accordingly, classification of the Convertible Senior Notes may change in future quarters.

Other noncurrent liabilities at December 31, 2009, were \$27.1 million as compared to \$15.7 million at December 31, 2008. The \$11.4 million increase is primarily the result of the \$6.6 million contingent consideration liability recorded in connection with the purchase of the Tyvaso Inhalation System business from NEBU-TEC. See Note 18 to the consolidated financial statements included in this Annual Report on Form 10-K for more details on this arrangement.

Stockholders' equity was approximately \$653.0 million at December 31, 2009, compared to approximately \$555.3 million at December 31, 2008. The increase of \$97.7 million in stockholders' equity was driven in large part by the following: (1) net income of \$19.5 million; (2) \$32.1 million in net proceeds from the exercise of stock options; and (3) the recognition of \$40.1 million in share-based compensation.

#### **Results of Operations**

## Years ended December 31, 2009 and 2008

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

	Year Decem	Percentage	
	2009	2008	Change
Cardiovascular products:			
Remodulin	\$ 331,579	\$ 269,718	22.9%
Tyvaso	20,268	_	100.0%
Adcirca	5,789	_	100.0%
Telemedicine services and			
products	10,968	9,485	15.6%
License fees	1,244	2,294	(45.8)%
Total revenues	\$ 369,848	\$ 281,497	31.4%

The growth in revenues experienced during 2009 resulted in large part from the increase in the number of patients prescribed Remodulin and the commercial launches of both Tyvaso and Adcirca. For the years ended December 31, 2009 and 2008, approximately 88% and 89%, respectively, of net Remodulin revenues were earned from our three distributors located in the United States. 100% of our Tyvaso revenues were earned from the same three distributors. Adcirca revenues are earned from sales to national and regional pharmaceutical wholesalers.

Total revenues are reported net of: (1) estimated government rebates; (2) prompt pay discounts; (3) fees to our distributors for services; (4) allowances for sales returns or exchanges; (5) estimated rebates to third-party payers; and (6) reimbursements to Lilly for sales of Adcirca that are not for the treatment of pulmonary hypertension in accordance with the terms of our license agreement. We pay government rebates to state Medicaid agencies that pay for our Commercial Products. In addition, we may enter into contractual arrangements with third-party payers to provide a rebate to these payers for the cost of therapy. We estimate our liability for these rebates based on the historical level of invoices received from state Medicaid agencies and third-party payers by product relative to the specific sales of each product in the United States. For 2009, no third-party payer rebates were contractually due. Prompt pay discounts are offered on sales of our Commercial Products if the related invoices are paid in full within a specific time period from the date of sale. We estimate our liability for prompt pay discounts based on historical payment patterns. Fees paid to our distributors for services are estimated based on contractual rates for specific services applied to the estimated units of service provided by our distributors for the period. The allowance for sales returns for Adcirca is based on published industry data related to specialty pharmaceuticals, as that segment of industry data is most relevant to Adcirca. The allowance for exchanges for Remodulin is based on historical sale exchanges, which have been too immaterial to record. Since Tyvaso is distributed in the same manner and under similar contractual arrangements as Remodulin, we are estimating that Tyvaso will experience the same sales exchange pattern as Remodulin.

The table below presents a reconciliation of the liability accounts associated with estimated government and third-party rebates, prompt pay discounts, fees due to our distributors for services, allowances for sales returns, reimbursements to Lilly for sales of Adcirca not related to pulmonary hypertension and the net reductions to revenues related to these items (in thousands):

	er 31,
009	2008
4,096	\$ 2,879
1,338	14,498
_	129
3,979)	(10,725)
4,816)	(2,685)
6,639	\$ 4,096
1,338	\$ 14,627
	1,338 

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

		Year I Decem	Percentage		
	_	2009		2008	Change
Project and non-project:					
Cardiovascular	\$	61,574	\$	60,549	1.7%
License fees—Adcirca		_		150,000	N/A
Share-based					
compensation		36,294		16,200	124.0%
Other		24,320		12,432	95.6%
Total research and development	Φ.	122 100	_	220.101	(40.0)
expense	\$	122,188	\$	239,181	(48.9)%

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

Share-based compensation. The increase in share-based compensation expense of \$20.1 million for the year ended December 31, 2009, compared to the year ended December 31, 2008, can be attributed to the following: (1) the increase in the fair value of awards granted under the STAP as a result of the increase in the price of our common stock; (2) increases in the number of outstanding STAP awards; and (3) the number of STAP awards vested and the time that unvested awards have accrued toward vesting as of December 31, 2009.

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

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

		Year E	Donaontogo		
	December 31, 2009 2008				Percentage Change
Category:					
General and administrative	\$	68,606	\$	41,284	66.2%
Sales and marketing		43,593		32,899	32.5%
Share-based compensation		64,139		20,123	218.7%
Total selling, general and			_		
administrative expense	\$ 1	176,338	\$	94,306	87.0%

General and administrative. During the year ended December 31, 2009, general and administrative expense increased \$27.3 million as compared to the year ended December 31, 2008, for the following reasons: (1) an impairment charge of \$4.2 million recognized on three of our Silver Spring, Maryland, properties that housed employees prior to relocating to our newly-completed Phase II Facility, which are scheduled to be demolished in 2010 in connection with commencement of construction on the last phase of our Silver Spring campus; (2) increases in professional fees of approximately \$4.2 million for the year ended December 31, 2009, related to our ongoing litigation, reviewing potential acquisitions,

entering new license agreements, and other matters; (3) \$3.7 million of expenses for validation work to manufacture Remodulin on different equipment; and (4) an increase in general operating expenses of \$13.7 million resulting from our overall growth this year.

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

Share-based compensation. For the year ended December 31, 2009, share-based compensation increased by \$44.0 million over the same period in 2008. During the quarter ended December 31, 2008, we reversed approximately \$6.4 million in estimated compensation expense that had been accrued through September 30, 2008, for a potential year-end stock option grant to our Chief Executive Officer, which is based on a formula set forth in her employment agreement. Our Chief Executive Officer did not receive a stock option grant for the year ended December 31, 2008. By contrast, our Chief Executive Officer did receive a year-end stock option grant at the end of 2009 in accordance with the formula in her employment agreement, and we recognized approximately \$14.5 million in share-based compensation expense for the year ended December 31, 2009. The remainder of the increase in share-based compensation expense can be attributed to the following: (1) the increase in the fair value of awards granted under the STAP as a result of the increase in the price of our common stock; (2) an increase in the number of outstanding STAP awards; and (3) the number of STAP awards vested and the time that unvested STAP awards had accrued toward vesting as of December 31, 2009.

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

#### Years ended December 31, 2008 and 2007

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

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

The growth in revenues experienced during 2008 resulted in large part from the increase in the number of patients prescribed Remodulin. For the years ended December 31, 2008 and 2007, approximately 89% and 87%, respectively, of net Remodulin revenues were earned from our three distributors located in the United States.

Total revenues are reported net of estimated government rebates, prompt pay discounts and fees due to our distributors for services. We pay government rebates to state Medicaid agencies that pay for Remodulin. We estimate our liability for such rebates based on the historical level of government rebates invoiced by state Medicaid agencies relative to sales of Remodulin in the United States. Prompt pay discounts are offered on sales of Remodulin if the related invoices are paid in full, generally within 60 days from the date of sale. We estimate our liability for prompt pay discounts based on historical payment patterns. Fees paid to our distributors for services are estimated based on contractual rates for

specific services applied to the estimated units of service provided by our distributors for the period. In addition, we evaluate the sales exchanges that have occurred during the period to see if a sales exchange reserve is required. Based on the low level of sales exchanges, no reserves for sales exchanges has been in our opinion required.

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

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

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

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

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

Cardiovascular license fees. During the quarter ended December 31, 2008, we made a one-time, upfront payment of \$150.0 million pursuant to a license agreement and a related manufacturing and

supply agreement entered into with Lilly regarding the commercialization of Adcirca. We expensed these payments as research and development since Adcirca had not yet been approved for marketing by the FDA and therefore commercial feasibility had not been demonstrated at that time.

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

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

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

		Percentage
2008	2007	Change
\$ 41,284	\$ 38,515	7.2%
32,899	24,159	36.2%
20,123	36,353	(44.6)%
\$ 94,306	\$ 99,027	(4.8)%
	Decem 2008 \$ 41,284 32,899 20,123	\$ 41,284 \$ 38,515 32,899 24,159 20,123 36,353

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

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

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

*Income Tax Benefit.* As a result of our net loss incurred before income taxes for the year ended December 31, 2008, we recognized income tax benefits of \$34.4 million for the year then ended. For the year ended December 31, 2007, we recognized income tax benefits of approximately \$7.9 million, resulting principally from the generation of business tax credits during the year for our orphan drug related research and development activities.

## **Liquidity and Capital Resources**

Since FDA approval of Remodulin in 2002, funding for our operations has been derived principally from related revenues. We believe that our existing revenues and working capital resources will be adequate to fund our operations as demand for Remodulin has grown steadily since 2002. Furthermore, our customer base remains stable and, we believe, presents minimal credit risk. During the quarter ended September 30, 2009, we launched Adcirca and Tyvaso for commercial sale. We anticipate that these new products will generate significant future revenues and cash flows. However, any projections of future cash flows are inherently subject to uncertainty. To compensate for such uncertainty, we may seek other sources of funding and believe we have the ability to do so. See *Item 1A—Risk Factors—We have a history of losses and may not maintain profitability* and *Item 1A—Risk Factors—We may fail to meet third-party projections for our revenues or profits*.

## Operating Cash Flows and Working Capital

Net cash provided by operating activities was \$97.6 million for the year ended December 31, 2009, compared to \$49.2 million in net cash used by operating activities for the year ended December 31, 2008. In 2009, net cash provided by operating activities increased primarily due to our significantly higher revenues in 2009 over 2008 and the one-time, upfront, non-refundable payment in 2008 of \$150.0 million to Lilly in connection with our license for the commercial rights to Adcirca. The effect of this acquisition expense, net of tax, reduced our cash provided by operating activities in 2008 by approximately \$60.0 million.

At December 31, 2009, we had negative working capital of \$5.7 million compared to positive working capital of \$239.8 million at December 31, 2008. The decrease is primarily due to the reclassification of our Convertible Senior Notes from long-term debt to short-term debt as of December 31, 2009, because they became eligible for conversion by the Note Holders. Our expectation, based on our understanding of historical behavior of holders of convertible notes with terms similar to ours, is that our Convertible Senior Notes will continue to be held until they mature in October 2011. Consequently, we believe that we have approximately \$214.6 million of working capital available at December 31, 2009, for our operating needs.

In addition, at December 31, 2009, we had approximately \$148.6 million of long-term (meaning the security is set to mature more than one year from December 31, 2009) marketable securities that could be liquidated if necessary to fund our operations. Most of these securities are scheduled to mature prior to October 2011 when our Convertible Senior Notes are set to mature.

Lastly, we had approximately 7.6 million shares of vested stock options outstanding at December 31, 2009, with a weighted average exercise price of \$29.78 per share. These vested stock options, if exercised, would provide us with \$226.3 million of additional cash.

#### **Auction-Rate Securities**

As of December 31, 2009, we hold approximately \$36.2 million (par value) of illiquid auction-rate securities (ARS). The decline in fair value of ARS, including ours, reflects conditions relating to the general collapse of the credit markets. Our ARS are collateralized by student loan portfolios that are approximately 91% guaranteed by the federal government and maintain a credit rating of AAA. Historically, ARS provided liquidity to investors through their interest rate reset feature—i.e., interest rates on these securities are reset through a bidding process (or auction) at frequent, pre-determined intervals (typically every 7 to 28 days). At each reset date, investors can choose to either maintain their holdings or liquidate them at par value. Since February 2008, auctions related to our ARS have failed, rendering these securities illiquid.

To mitigate the risks associated with our ARS, we entered into an Auction Rate Securities Rights Offer (Rights Offer) during the fourth quarter of 2008 with the investment firm that maintains our

ARS account. Pursuant to the Rights Offer, we can sell our ARS to the investment firm for a price equal to their par value at any time between June 30, 2010, and July 2, 2012. In addition, to help meet any immediate liquidity needs, the Rights Offer permits us to borrow up to the par value of the ARS. The Rights Offer provides us with additional flexibility to recover the full cost of our investment prior to the maturity of these securities. We expect to sell our ARS to the investment firm on the earliest date agreed to under the Rights Offer and do not anticipate borrowing against the ARS while the Rights Offer remains open.

#### Construction Projects

In February 2009, we completed the construction of our facility in Research Triangle Park, North Carolina (RTP Facility) at a cost of approximately \$106.8 million. The RTP Facility is approximately 200,000 square feet and consists of a manufacturing operation and office space. The manufacturing operation will be used primarily for the production of oral treprostinil. In addition, it is expected that the RTP Facility will support the production and distribution of other drug candidates that we are developing. Currently, we warehouse and distribute Tyvaso from our RTP Facility. Our clinical development, regulatory and sales and marketing personnel occupy the facility's office space.

In December 2009, we completed construction of our Phase II Facility, which is attached to our Phase I Laboratory, at a cost of approximately \$96.3 million. The Phase II Facility will serve as our corporate headquarters and we anticipate manufacturing Remodulin, Tyvaso and monoclonal antibodies in the new facility. In May 2009, we amended the terms of our November 2008 guaranteed maximum price construction management agreement with the Whiting-Turner Contracting Company (Whiting-Turner) for the construction of the Phase II Facility. The May 2009 amendment converted the guaranteed maximum price into a lump sum and increased our total obligation from approximately \$61.3 million to \$67.5 million, as a result of several change orders previously agreed upon with Whiting-Turner. Our remaining obligation associated with this contract is \$5.3 million as of December 31, 2009.

Both the RTP Facility and the Phase II Facility were funded using cash provided by our operations. During the years ended December 31, 2009 and 2008, we spent approximately \$78.4 million and \$93.8 million, respectively, on to the construction of the RTP Facility and the Phase II Facility. As of December 31, 2009, inception-to-date expenditures related to these construction projects approached \$197.8 million.

## Share Tracking Awards Plan

Awards granted under the STAP entitle participants to receive in cash the appreciation in our common stock, which is calculated as the positive difference between the closing price of our common stock on the date of grant and the date of exercise. Accordingly, the STAP will require substantial cash payments as awards continue to vest and participants continue to exercise them. Our operating budgets incorporate anticipated outlays of cash relating to the STAP. Beginning in 2010, we have modified the metrics used to calculate the number of Awards to be granted to each eligible employee to reduce such grants. Additionally, beginning in November 2009, we extended the vesting period for new Awards from three years to four years. We believe future cash flows will be sufficient to accommodate our obligations under the STAP and the future operating requirements of our business.

## Convertible Senior Notes

On October 30, 2006, we issued at par value \$250.0 million of Convertible Senior Notes. We pay interest on the Convertible Senior Notes semi-annually on April 15 and October 15 of each year—approximately \$1.3 million annually. The Convertible Senior Notes are unsecured, unsubordinated debt obligations that rank equally with all of our other unsecured and unsubordinated indebtedness.

Conversion can occur: (1) anytime after July 15, 2011; (2) during any calendar quarter that follows a calendar quarter in which the price of our common stock exceeded 120% of the conversion price for at least 20 days during the 30 consecutive trading-day period ending on the last trading day of the quarter; (3) during the ten consecutive trading-day period following any five consecutive trading-day period in which the trading price of the Convertible Senior Notes was less than 95% of the closing price of our common stock multiplied by the then current number of shares underlying the Convertible Senior Notes; (4) upon specified distributions to our shareholders; (5) in connection with corporate transactions; or (6) in the event that our common stock ceases to be listed on the NASDAQ Global Select Market and is not listed for trading on another U.S. national or regional securities exchange.

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

Because the Convertible Senior Notes include contingent conversion provisions, Note Holders may be able to convert their Convertible Senior Notes prior to October 2011. As of December 31, 2009, the Convertible Senior Notes were convertible at the election of their holders as the closing price of our common stock satisfied quarterly contingent conversion requirements. However, it is our expectation, based on our understanding of the historical behavior of holders of convertible notes with terms similar to ours, that most, if not all of our outstanding Convertible Senior Notes will be held until maturity.

#### Lease Obligation

We lease our Phase I Laboratory pursuant to a synthetic lease arrangement (Lease) entered into in June 2004 with Wachovia Development Corporation and its affiliates (Wachovia). Under the Lease, Wachovia funded \$32.0 million toward the construction of the Phase I Laboratory on land that we own. After completing construction in May 2006, Wachovia leased the Phase I Laboratory to us. Monthly rent is equal to the 30-day London Interbank Offered Rate (LIBOR) plus 55 basis points (0.78% as of December 31, 2009) applied to the amount Wachovia funded toward construction. The base term of the Lease ends in May 2011 (Base Term). Upon the expiration of the Base Term, we will have the right to exercise one of the following options under the Lease: (1) renew the Lease for an additional five-year term (subject to the approval of both parties); (2) purchase the Phase I Laboratory from Wachovia for approximately \$32.0 million; or (3) sell the Phase I Laboratory and repay Wachovia's construction costs with the proceeds from the sale. If the sale proceeds are insufficient to repay Wachovia's construction costs, we must fund the shortfall up to a maximum residual value guarantee of approximately \$27.5 million.

From the inception of the Lease through August 2008, we accounted for the Lease as an operating lease. In December 2007, we began constructing the Phase II Facility with funds generated from our operations. As of September 30, 2008, we received Wachovia's acknowledgement of our plan to make structural modifications to the Phase I Laboratory in order to connect it to the Phase II Facility. As a result, we could no longer consider the Phase I Laboratory a standalone structure, which was required to maintain off-balance sheet accounting for the Lease. Consequently, since September 30, 2008, we have been considered the owners of the Phase I Laboratory for accounting purposes and began accounting for the Lease as a financing obligation. Accordingly, we capitalized \$29.0 million, the estimated fair value of the Phase I Laboratory, and recognized a corresponding lease obligation on our consolidated balance sheet. We are accreting the lease obligation to \$32.0 million, the purchase price of the Phase I Laboratory, through the recognition of periodic interest charges using the effective interest

method. The accretion period will run through the end of the Base Term. In addition, we are depreciating the Phase I Laboratory over the estimated useful lives of its various components.

Approximately \$34.9 million of our marketable investments at December 31, 2009, have been pledged as collateral for the Lease and are included within restricted marketable investments and cash on our consolidated balance sheet.

## Common Stock Subject to Repurchase

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

#### License Fees

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

## **Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements.

## **Contractual Obligations**

At December 31, 2009, we had the following contractual obligations (in thousands):

	Payments Due by Period					
	Less than				More than	
	Total	1 year	1-3 Years	3-5 Years	5 Years	
Convertible Senior Notes(1)	\$ 249,978	\$ —	\$ 249,978	\$ —	\$ —	
Lease obligations(2)	32,000	_	32,000	_	_	
Obligations under construction						
commitments(3)	5,271	5,271	_	_	_	
Operating lease obligations	5,364	2,376	2,126	834	28	
Obligations under the STAP(4)	189,737	97,023	92,647	67	_	
Obligations under the Supplemental Executive Retirement Plan (SERP)						
(5)	22,110	_	_	_	22,110	
Purchase commitments	3,666	2,666	1,000	_	_	
Milestone payments(6)	32,850	6,618	11,917	3,965	10,350	
Total(7)	\$ 540,976	\$ 113,954	\$ 389,668	\$ 4,866	\$ 32,488	

- (1) The principal balance of the Convertible Senior Notes is to be repaid in cash. While the convertibility of the Convertible Senior Notes may vary depending on whether our stock price meets specified criteria, which is determined on a quarterly basis, we estimate that the note holders will not convert their notes until maturity.
- (2) The lease obligation assumes we elect the purchase option under our Wachovia Lease at the end of the Base Term. Refer to Note 10 to the consolidated financial statements included in this Annual Report on Form 10-K for more details on this arrangement.
- (3) Amounts remaining due on the Whiting-Turner construction management contract.

- (4) We estimated the obligation based on the intrinsic value of outstanding STAP awards expected to vest as of December 31, 2009 assuming that awards will be exercised immediately upon vesting. Refer to Note 8 to the consolidated financial statements included in this Annual Report on Form 10-K for more details on this arrangement.
- Obligations under the SERP are actuarially derived and represent the estimated future payout of this benefit to certain members of our management team. Refer to Note 14 to the consolidated financial statements included in this Annual Report on Form 10-K for more details on this arrangement.
- (6) We license products from other companies under various license agreements. These agreements require that we make specific cash payments upon the achievement of specific product development milestones and commercialization. The timing and amounts of related milestone payments have been estimated based on: (1) when we believe milestones will be achieved; and (2) the assumption that all milestones established within these license agreements will be successfully attained.
- (7) As of December 31, 2009, we had approximately \$6.7 million of unrecognized tax benefits. The contractual obligations disclosed above exclude these amounts due to the uncertainty surrounding the amounts and timing of future payments.

## **Summary of Critical Accounting Policies and Estimates**

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

#### Revenue Recognition

Remodulin and Tyvaso

We sell both Remodulin and Tyvaso to our specialty pharmaceutical distributors under similar terms. Sales of Remodulin and Tyvaso, including the Tyvaso Inhalation System, are recognized when title and risk of ownership pass to our distributors upon delivery to our distributors' facilities. We record sales of Remodulin and Tyvaso net of product sales allowances. These sales allowances consist of prompt payment discounts, Medicaid and third-party payer rebates and fees for services provided by our distributors. Calculating these allowances involves the use of significant estimates and judgments and information from external sources.

Sales allowances are estimated and recognized as reductions to revenue in the period that associated revenues are recognized. Prompt pay discounts are calculated based on the gross amount of invoices and are recorded on a net basis as our distributors have routinely taken advantage of these discounts.

Medicaid rebates are generally invoiced and paid in the subsequent quarter from the date of sale. Accruals and related revenue reductions for Medicaid rebates are based on historical rebate data adjusted for anticipated changes in product sales trends and government rebate programs with regard to eligibility requirements and/or rebate pricing. We analyze rebate data separately for Remodulin and Tyvaso, as these therapies have been developed to treat PAH patients at different stages in the disease continuum and therefore, rebate eligibility and pricing requirements can differ for each therapy.

In the future we may be contractually obligated pay a rebate to certain third-party payers to offset the cost of our therapies. While we had no such contractual rebate obligations to third-party payers in 2009 or in prior years, we expect to be contractually obligated to pay rebates to certain third-party payers a rebate in 2010 and beyond. As a result, we have included the review of third-party payer data into our revenue recognition policy.

We pay our distributors for contractual services rendered. Accruals for these fees are estimated based on contracted rates applied to the estimated units of service provided by distributors for a given period.

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

With respect to Remodulin, the financial effects of this exchange right have been immaterial and we expect the historic volume of exchanges to remain consistent in the future. Obsolescence due to dating expiration has been minimal given the fast pace at which Remodulin moves through the distribution channel. Specifically, Remodulin exchanges have comprised substantially less than one percent of the volume of vials that we sell. Because historical and anticipated future returns associated with exchange rights for Remodulin have been, and are expected to be, immaterial, we do not record a reserve for estimated exchange rights in the period of sale. Because our distribution system for Tyvaso is so similar to that for Remodulin, we expect a similarly immaterial financial impact of exchange rights with respect to Tyvaso. Accordingly, we have not recognized a reserve for anticipated future exchanges of Tyvaso. Lastly, we closely monitor exchange data for both of these therapies to ensure that our assumptions continue to be reasonable, appropriate and current.

#### Adcirca

Adcirca is manufactured for us by Lilly and distributed through Lilly's well-established pharmaceutical wholesaler network. This type of distribution is similar to the way Adcirca's main competitor, Revatio, is distributed. 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 because:

(1) we are responsible for the acceptability of the product purchased by Lilly's wholesalers; (2) we bear all inventory risk, as title and risk of loss pass to us at the shipping point from Lilly's manufacturing facility; (3) we assume credit risk if Lilly is unable to collect amounts due from customers; and (4) we assume the risk and cost of a product recall, if required.

Adcirca revenues are recognized net of the following sales allowances: reserves for product returns, Medicaid and third-party payer rebates, prompt pay discounts, non-PAH sales, if any, and wholesaler fees. Calculation of these allowances involves the use of significant judgments and estimates. We have based initial estimates for returns on published industry data related to specialty pharmaceuticals, as that segment of industry data is most relevant to Adcirca. In addition, we compare patient prescription data to sales quarterly to see if both the prescription and sales patterns are reasonably similar. Allowances for Medicaid rebates are derived from our experience with Remodulin as we believe that the treatment population as it relates to Medicaid patients is similar. While we had no contractual obligation to pay a rebate to third-party payers in 2009, we expect to be contractually obligated to pay

a rebate to certain third-party payers in 2010. As a result, we include the review of third-party payer data into our revenue recognition policy. Prompt pay discounts are based on contractual terms with our distributors, and they generally take advantage of such discounts. We analyze our sales data to determine if any sales of Adcirca are for the treatment of an illness other than pulmonary hypertension. Pursuant to our agreements with Lilly, we do not recognize non-pulmonary hypertension sales of Adcirca as revenue. Lastly, wholesaler fees are based on the contractual fee percentage for each wholesaler and sales to that wholesaler.

## Marketable Investments

Most of our marketable securities are classified as held-to-maturity. For those marketable investments whose fair value is lower than its book value, we are required to periodically review whether the decline in the value of the security is other than temporary. This review requires us to make judgments, particularly as they relate to: (1) the extent and duration of a decline in the fair value of a security; (2) the probability, extent and timing of a recovery of a security's value; (3) our assessment as to whether it is more likely than not that we will be required to sell a security prior to recovery of its amortized cost and (4) our estimation of the present value of the cash flows we would expect to collect that are attributable to an impaired debt security to determine whether a credit loss exists. The scope of this evaluation requires forward-looking assessments pertaining to a security and the relevant financial markets, an issuer's financial condition and business outlook, and our estimation of the value of cash flows we would expect to collect from an issuer upon maturity of an impaired security. Accordingly, we must make assessments regarding current conditions and future events, which involve a considerable degree of uncertainty and judgment. When we determine that the decline in value of a security is other than temporary, we are required to recognize the credit loss portion as a charge within our consolidated statement of operations.

In addition, we classify certain marketable investments as held-to-maturity because we believe we have the positive intent and ability to hold related securities until they mature. This assertion requires us to make forward-looking judgments regarding our future cash flow requirements relative to the maturity dates of such securities. To reduce the level of uncertainty associated in making this determination, we invest in debt securities that mature within two years.

#### Fair Value Measurements

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

## Investment in Affiliate

We use the equity method of accounting for our investment in Northern Therapeutics, Inc. (Northern). The equity method of accounting requires that we report our share of Northern's net losses or earnings in our consolidated financial statements. Consolidation is not required unless we possess the ability to control Northern. Generally, the ability to exercise control over an entity occurs when voting interests in that entity exceed 50%. We maintain an ownership interest in Northern of approximately 68%. However, because Northern's minority owners have substantive participation rights, we concluded that we do not have the ability to control Northern's operations. Therefore, Northern's financial statements have not been included in our consolidated financial statements.

#### Income Taxes

Income taxes are accounted for in accordance with the asset and liability method set forth under ASC740. 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 amounts and the availability of future taxable income.

Financial statement recognition of a tax position taken or expected to be taken in a tax return is determined based on a more likely than not threshold of that position being sustained. If the tax position meets this threshold, the benefit to be recognized is measured as the largest amount that is more than 50 percent likely to be realized upon ultimate settlement. Accounting for uncertain tax positions involves considerable judgment in assessing the future tax consequences of amounts that have been recognized in our financial statements or tax returns. The ultimate resolution of uncertain tax positions could result in amounts different from those recognized on our consolidated financial statements.

## Goodwill and Intangible Assets

We are required to test goodwill at the reporting unit level for impairment annually or more frequently if impairment indicators exist. Evaluating goodwill for impairment requires judgment particularly as it relates to determining the fair value of a reporting unit to which goodwill has been assigned. We 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 future cash flows, future growth rates and profitability of a reporting unit and the expected life related cash flows will occur. Changes in our business strategy or adverse changes in market conditions could impact impairment analyses and require the recognition of an impairment charge equal to the excess of the carrying value of goodwill over its estimated fair value.

We also test our intangible assets for impairment annually or more frequently if impairment indicators exist. Evaluating intangible assets for impairment requires judgment particularly as it relates to determining the fair value of the license or business to which the intangible asset represents. We use a discounted cash flow model to test an intangible asset for impairment, which involves the use of significant and subjective inputs. Related inputs, among others, requiring our judgment include the estimation of future cash flows, future growth rates and profitability of business activity and the expected life related cash flows will occur. Changes in our business strategy or adverse changes in

market conditions could impact impairment analyses and require the recognition of an impairment charge equal to the excess of the carrying value of the intangible asset over its estimated fair value.

The creation of goodwill or an intangible asset through an acquisition, such as our acquisition of the Tyvaso Inhalation System business from NEBU-TEC, requires significant judgment. The acquisition of a business requires us to determine the fair value of assets acquired or liabilities assumed and what rights acquired have a value, and then determining the fair value of those acquired rights using the same inputs that we use to determine if goodwill or an intangible asset is impaired. We use consultants who are experts on valuation techniques to aid us in our determination of the fair value of assets and liabilities we acquire.

## Phase I Laboratory Lease

We lease our Phase I Laboratory pursuant to a synthetic lease arrangement (Lease) entered into in June 2004 with Wachovia. Under the Lease, Wachovia funded \$32.0 million toward the construction of the Phase I Laboratory on land that we own. After completing construction in May 2006, Wachovia leased the Phase I Laboratory to us. From the inception of the Lease through August 2008, we accounted for the Lease as an operating lease.

In December 2007, we began constructing the Phase II Facility with funds generated from our operations. As of September 30, 2008, we received Wachovia's acknowledgement of our plan to make structural modifications to the Phase I Laboratory in order to connect it to the Phase II Facility. As a result, we could no longer consider the Phase I Laboratory a standalone structure, which was required to maintain off-balance sheet accounting for the Lease. Consequently, beginning September 30, 2008, we have been considered the owner of the Phase I Laboratory for accounting purposes and have accounted for the Lease as a financing obligation. Accordingly, we capitalized \$29.0 million, the estimated fair value of the Phase I Laboratory, and recognized a corresponding lease obligation on our consolidated balance sheet. We are accreting the lease obligation to \$32.0 million, the purchase price of the Phase I Laboratory, through the recognition of periodic interest charges using the effective interest method. The accretion period will run through the end of the Base Term. In addition, we are depreciating the Phase I Laboratory over the estimated useful lives of its various components.

### Pension Benefit Obligation

Accounting for our Supplemental Executive Retirement Plan (SERP) requires that we recognize on our consolidated balance sheet a liability equal to the unfunded status of the SERP (equal to the projected benefit obligation, as we do not fund the SERP) and measure our projected benefit obligation as of the end of our fiscal year. Estimating the SERP obligation involves the use of judgment and estimates. The SERP obligation and related pension expense are derived from actuarial valuations that are developed using a number of assumptions. A key assumption to the valuation is the discount rate. The discount rate should be representative of the rate associated with high-quality, fixed-income debt securities. With the overall economic downturn and the tightening of the credit markets that began in 2008, interest rates, in general, have been decreasing. We must consider these economic factors when determining an appropriate discount rate to employ. Consequently, the discount rate we used to measure our obligation as of December 31, 2009, was approximately 100 basis points lower than the rate we used as of December 31, 2008. Changes in the discount rate can significantly decrease or increase our SERP obligation. For instance, a reduction in the discount rate would increase our projected benefit obligation, result in an actuarial loss and possibly cause additional pension expense to be recognized in future financial reporting periods on our consolidated statements of operations if certain thresholds have been met as of the beginning of a given financial reporting period. Other actuarial assumptions include participant demographics such as the expected rate of salary increases and withdrawal rates, among other factors. Actual experience may differ from actuarial assumptions. Changes in any of these assumptions can also affect the measurement of the SERP obligation.

## **Share-based Compensation**

Our share-based awards are classified as either equity (stock options) or as liabilities (STAP awards) and compensation expense to be recognized is determined based on the fair value of related awards. We estimate the fair value of 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.

## **Recently Issued Accounting Standards**

In January 2010, the Financial Accounting Standards Board (FASB) issued accounting standards update (ASU) No. 2010-06, Fair Value Measurements and Disclosures (Topic 820)—Improving Disclosures about Fair Value Measurements (ASU No. 2010-06). ASU No. 2010-06 requires: (1) fair value disclosures of assets and liabilities by class; (2) disclosures about significant transfers in and out of Levels 1 and 2 on the fair value hierarchy, in addition to Level 3; (3) purchases, sales, issuances and settlements be disclosed on gross basis on the reconciliation of beginning and ending balances of Level 3 assets and liabilities, and (4) disclosures about valuation methods and inputs used to measure the fair value of Level 2 assets and liabilities. ASU No. 2010-06 becomes effective for the first financial reporting period beginning after December 15, 2009, except for disclosures about purchases, sales, issuances and settlements of Level 3 assets and liabilities, which will be effective for fiscal years beginning after December 15, 2010. We are currently assessing what impact, if any, ASU No. 2010-06 will have on our fair value disclosures; however, we do not expect the adoption of the guidance provided in this codification update to have any material impact on our consolidated financial statements.

In December 2009, the FASB issued ASU No. 2009-17, Consolidations (Topic 810)—Improvements to Financial Reporting By Enterprises Involved with Variable Interest Entities (ASU No. 2009-17). ASU 2009-17 requires a qualitative approach for determining the primary beneficiary of a variable interest entity and replaces the quantitative evaluation previously set forth under FASB Interpretation No. 46 (revised December 2003), Consolidation of Variable Interest Entities. This approach is focused on identifying the reporting entity that has the ability to direct the activities of a variable interest entity that most significantly affects the entity's economic performance and has the obligation to absorb the entity's losses or has the right to receive benefits from the entity. ASU No. 2009-17, among other things, will require enhanced disclosures about a reporting entity's involvement in variable interest entities. The guidance under ASU No. 2009-17 will be effective for the first annual period beginning after November 15, 2009, and interim periods within that first annual period. We are assessing what impact, if any, adoption of this standard will have on our consolidated financial statements.

In October 2009, the FASB issued ASU No. 2009-13, *Revenue Recognition (Topic 605)—Multiple-Deliverable Revenue Arrangements: a consensus of the FASB Emerging Issues Task Force* (ASU 2009-13). ASU 2009-13 establishes a selling-price hierarchy for determining the selling price of each element within a multiple-deliverable arrangement. Specifically, the selling price assigned to each deliverable is to be based on vendor-specific objective evidence (VSOE) if available, third-party evidence, if VSOE is unavailable, and estimated selling prices if neither VSOE or third-party evidence is available. In addition, ASU 2009-13 eliminates the residual method of allocating arrangement consideration and instead requires allocation using the relative selling price method. ASU 2009-13 will be effective prospectively for multiple-deliverable revenue arrangements entered into, or materially modified, in fiscal years beginning on or after June 15, 2010. Presently, we are assessing what impact, if any, the adoption of ASU 2009-13 may have on our consolidated financial statements.

In August 2009, the FASB issued ASU No. 2009-05, Fair Value Measurements and Disclosures (Topic 820)—Measuring Liabilities at Fair Value (ASU 2009-05). ASU 2009-05 provides guidance in

measuring the fair value of a liability when a quoted price in an active market does not exist for an identical liability or when a liability is subject to restrictions on its transfer. ASU 2009-15 was effective for us beginning with the quarter ended December 31, 2009. The adoption of ASU 2009-05 had no impact on the fair value measurements of our liabilities.

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

As of December 31, 2009, we held investments of approximately \$36.2 million (par value) in auction-rate securities (ARS). We are exposed to market risk related to our ARS as a result of the general collapse of the credit markets and the continued uncertainty surrounding the financial markets. The ARS maintain an AAA credit rating and are backed by student loan portfolios that are approximately 91% guaranteed by the federal government. However, since February 2008, auctions for the ARS have failed, rendering these securities illiquid. Consequently, the fair value of our ARS has declined significantly. As of December 31, 2009, the estimated fair value of these securities was approximately \$29.3 million. Because we classify our ARS as trading securities, all future changes in fair value will be recognized within earnings until the securities are liquidated or otherwise disposed. Furthermore, there can be no assurances that the ARS will ever fully recover their value.

To mitigate market-related risks associated with our investment, we entered into an Auction Rate Securities Rights Offer (Rights Offer), under which we have an option to require the investment firm (the counterparty to the Rights Offer) to repurchase the ARS at a price equal to their par value anytime between June 30, 2010 and July 2, 2012 (Put Option). The Put Option has been recognized at fair value as a financial asset on our consolidated balance sheets and subsequent changes in its fair value will be recognized within earnings. We expect the future price movements relating to the ARS and the Put Option to largely offset one another—i.e., as the value of the ARS decreases, we would expect the rights associated with the Put Option to increase in value. However, the Rights Offer and the related Put Option still expose us to counterparty credit risk.

As of December 31, 2009, we have invested approximately \$269.2 million in debt securities issued by corporations and federally sponsored agencies. The market value of these investments varies inversely with changes in current market interest rates. In general, as rates increase, the market value of a debt investment would be expected to decrease. Similarly, as rates decrease, the market value of a debt investment would be expected to increase. To address market risk, we invest in debt securities that mature within two years and hold these investments to maturity so that they can be redeemed at their stated or face value. At December 31, 2009, our investments in debt securities issued by corporations and federally-sponsored agencies had a weighted average stated interest rate of approximately 1.27 percent. These investments mature at various times through 2011 and many are callable annually.

There has been a prolonged period of significant deterioration and instability in the financial markets that has persisted into 2010. This period of extraordinary disruption and readjustment in the financial markets exposes us to additional investment risk. The value and liquidity of the securities in which we invest could deteriorate and the issuers of such securities could be subject to credit rating downgrades. In light of the current market conditions and the additional risks to which we may be exposed, we actively monitor market conditions and developments specific to the securities and security classes in which we invest. We believe that we take a conservative approach to investing our funds in that we invest exclusively in highly rated securities with relatively short maturities. Furthermore, we do not invest in the types of securities that expose us to undue risk. 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.

## ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

# UNITED THERAPEUTICS CORPORATION INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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Consolidated Statements of Stockholders' Equity for the years ended December 31, 2009, 2008 and 2007	F-6
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## Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders United Therapeutics Corporation

We have audited the accompanying consolidated balance sheets of United Therapeutics Corporation as of December 31, 2009 and 2008, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2009. 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, 2009 and 2008, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2009, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

As discussed in Note 9 to the Consolidated Financial Statements, the Company changed its method of accounting for convertible debt that may be settled in cash upon conversion, effective January 1, 2009.

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, 2009, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 26, 2010 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

McLean, Virginia February 26, 2010

## 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, 2009, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). United Therapeutics Corporation's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying *Management's Report on Internal Control Over Financial Reporting*. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

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

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

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

In our opinion United Therapeutics Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2009, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the 2009 consolidated financial statements of United Therapeutics Corporation, and our report dated February 26, 2010, expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

McLean, Virginia February 26, 2010

## UNITED THERAPEUTICS CORPORATION

## **Consolidated Balance Sheets**

## (In thousands, except share and per share data)

		December 31,			
		2009		2008 As	
	· ·				
			a	djusted(1)	
Assets					
Current assets:		100.050	ф	100 150	
Cash and cash equivalents	\$	100,352	\$	129,452	
Marketable investments		129,140		106,596	
Accounts receivable, net of allowance of none for 2009 and 2008		50,626		28,311	
Other receivable		1,357		752	
Interest receivable		1,281		1,537	
Prepaid expenses		8,199		11,600	
Inventories, net		26,360		14,372	
Deferred tax assets		7,192		4,827	
Total current assets		324,507		297,447	
Marketable investments		148,628		100,270	
Marketable investments and cash—restricted		39,976		45,755	
Goodwill and other intangible assets, net		18,418		7,838	
Property, plant, and equipment, net		303,859		222,717	
Deferred tax assets, net		200,969		178,842	
Other assets (\$6,741 and \$7,685, respectively, measured under the fair value option)		15,187		21,665	
Total assets	\$	1,051,544	\$	874,534	
Total assets	Ψ	1,031,344	Ψ	074,334	
Liabilities and Stockholders' Equity					
Current liabilities:					
Accounts payable	\$	18,750	\$	20,334	
Accrued expenses		29,764		20,853	
Notes payable		220,272		_	
Other current liabilities		61,401		16,506	
Total current liabilities	_	330,187		57,693	
Notes payable				205,691	
Lease obligation		30,327		29,261	
Other liabilities		27,139		15,673	
Total liabilities		387,653	_	308,318	
Commitments and contingencies:		367,033		300,310	
Common stock subject to repurchase		10.882		10.882	
Stockholders' equity:		10,002		10,002	
Preferred stock, par value \$.01, 10,000,000 shares authorized, no shares issued		_		_	
Series A junior participating preferred stock, par value \$.01, 100,000 shares authorized, no shares issued		_		_	
Common stock, par value \$.01, 100,000,000 shares authorized, 56,682,369 and 55,324,302 shares					
issued at December 31, 2009 and 2008, respectively, and 54,220,779 and 52,862,712					
outstanding at December 31, 2009 and 2008, respectively		567		276	
Additional paid-in capital		798,897		722,293	
Accumulated other comprehensive (loss)		(4,314)		(5,913)	
Treasury stock at cost, 2,461,590 shares at December 31, 2009 and 2008		(67,395)		(67,395)	
Accumulated deficit		(74,746)		(93,927)	
Accumulated deficit			_	, , ,	
	_	652 000			
Total stockholders' equity  Total liabilities and stockholders' equity	\$	653,009 1.051,544	\$	555,334 874,534	

<sup>(1)</sup> Adjusted retrospectively for the adoption of guidance pertaining to convertible debt instruments that may be settled in cash upon conversion included in Financial Accounting Standards Board (FASB) Accounting Standards Codification<sup>TM</sup> (ASC) 470-20, *Debt with Conversion Options and Other Options* (FASB ASC 470-20). Prior to the introduction of FASB ASC 470-20, this guidance was formerly provided under FASB Staff Position No. APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash Upon Conversion (Including Partial Cash Settlement)* (FSP APB 14-1). See Note 9 — *Debt*—Adoption of FASB ASC 470-20 (Formerly FSP APB 14-1).

See accompanying notes to consolidated financial statements.

# **Consolidated Statements of Operations**

(In thousands, except per share data)

	For Years Ended December 31,						
	2009 2008					2007	
			As Adjusted(1)			As djusted(1)	
Revenues:			A	ujusteu(1)	A	ajustea(1)	
Net product sales	\$	357,870	\$	270,005	\$	201,348	
Service sales	Ψ	10,751	Ψ	9,258	Ψ	7,435	
License fees		1,227		2,234		2,160	
Total revenue		369,848		281,497		210,943	
Operating expenses:		100 100		220 101		02.252	
Research and development		122,188		239,181		83,352	
Selling, general and administrative.		176,338		94,306		99,027	
Cost of product sales Cost of service sales		40,890		26,957		19,919	
		4,431	_	3,109	_	2,342	
Total operating expenses		343,847		363,553		204,640	
Income (loss) from operations		26,001		(82,056)		6,303	
Other income (expense):							
Interest income		5,146		11,025		13,602	
Interest expense		(12,875)		(11,439)		(14,281)	
Equity loss in affiliate		(141)		(226)		(321)	
Other, net		636		(1,025)		(826)	
Total other income (expense), net		(7,234)		(1,665)		(1,826)	
Net income (loss) before income tax		18,767		(83,721)		4,477	
Income tax benefit		695		34,394		7,876	
Net income (loss)	\$	19,462	\$	(49,327)	\$	12,353	
	_		_		_		
Net income (loss) per common share:							
Basic	\$	0.37	\$	(1.08)	\$	0.29	
Diluted	\$	0.35	\$	(1.08)	\$	0.28	
Weighted average number of common shares outstanding:							
Basic		53,314		45,802		42,448	
Diluted		56,133		45,802		44,902	
	_						

<sup>(1)</sup> Adjusted for the retrospective adoption of guidance set forth under FASB ASC 470-20, formerly FSP APB 14-1. See Note 9— *Debt—Adoption of FASB ASC 470-20 (Formerly FSP APB 14-1).* 

See accompanying notes to consolidated financial statements.

# Consolidated Statements of Stockholders' Equity

# (In thousands, except share data)

	Common	Stock	Accumulated Additional Other		T	A	
	Shares	Amount	Paid-in <u>Capital</u> As	Comprehensive Income	Treasury Stock	Accumulated Deficit As	Total
D 1			Adjusted(1)			Adjusted(1)	
Balance, December 31, 2006	24,632,153	\$ 246	\$ 478,126	\$ 1,476	\$ (164,560)	\$ (42,729)	\$ 272,559
Net income Foreign currency	_	_	_	_	_	12,353	12,353
translation adjustments Unrealized loss	_	_	_	285	_	_	285
on available- for-sale				(202)			(902)
securities Unrealized loss				(892)	_	_	(892)
on pension liability				(552)			(552)
Total other comprehensi income	_	_	_	(1,159)	_	12,353	11,194
Exercise of				` '		,	ŕ
stock	1.707.025	10	50.005				50.244
options Tax benefit from	1,797,036	18	58,326	_	_	_	58,344
exercises of non- qualified							
stock options	_	_	27,983	_	_	_	27,983
Treasury stock					(67.050)		(67.050)
repurchases Options issued	_	_	_	_	(67,059)	_	(67,059)
in exchange for services	_	_	48,979	_	_	_	48,979
Stock issued in exchange for license	200.000	2	129				121
rights Balance, December 31,	200,000		129				131
2007	26,629,189	266	613,543	317	(231,619)	(30,376)	352,131
Net loss	_	_	_	_	_	(49,327)	(49,327)
Foreign currency translation adjustments				(5.490)			(5.490)
Unrealized loss on available-	_	_	_	(5,489)	_	_	(5,489)
for-sale securities	_	_	_	(191)	_	_	(191)
Unrealized loss on pension liability	_	_	_	(550)	_	_	(550)
Total other comprehensi							
income Issuance of treasury	_	_	_	(6,230)	_	(49,327)	(55,557)
stock Exercise of	_	_	<u> </u>	_	164,224	(14,224)	150,000
stock options	1,032,962	10	41,926	_	_	_	41,936
Tax benefit from exercises of non- qualified stock							
Options issued	_	_	38,356			_	38,356
Options issued in exchange	WATEO	N I AROB	ATODIES IN	IC. , IPR2017-01	624 Ev 44	151 n 74 of 3	044

for services	_	_	28,468	_	_	_	28,468
Balance, December 31 2008	27,662,151	276	722,293	(5,913)	(67,395)	(93,927)	555,334
Net income	27,002,131	270	122,293	(3,913)	(07,393)	19,462	19,462
Foreign currency translation adjustments	_	_	_	2,802	_		2,802
Unrealized gain on available- for-sale securities				44			44
Unrealized gain on pension liability	_	_	_	(1,247)	_	_	(1,247)
Total other comprehensi income			_	1,599		19,462	21,061
Issuance of treasury stock	_	_	_	_	_	_	_
Issuance of stock dividend	28,064,279	281	_	_	_	(281)	_
Exercise of stock options	955,939	10	32,061	_	_	_	32,071
Tax benefit from exercises of non- qualified stock							
options Options issued in exchange	_	_	4,406	_	_	_	4,406
for services			40,137				40,137
Balance, December 31, 2009	56,682,369	\$ 567	\$ 798,897	\$ (4,314)	\$ (67,395)	\$ (74,746)	\$ 653,009
2009	30,084,309	φ <i>3</i> 07	φ 190,891	φ (4,314)	φ (07,393)	φ (/4,/40)	φ 033,009

<sup>(1)</sup> Adjusted for the retrospective adoption of guidance set forth under FASB ASC 470-20, formerly FSP APB 14-1. See Note 9— Debt—Adoption of FASB ASC 470-20 (Formerly FSP APB 14-1).

See accompanying notes to consolidated financial statements.

# **Consolidated Statements of Cash Flows**

# (In thousands)

		Years Ended December 31,				,
		2009		2008	2008 200	
				As		As
			Ad	justed(1)	Ad	justed(1)
Cash flows from operating activities:	\$	19.462	\$	(49,327)	\$	12,353
Net income (loss) Adjustments to reconcile net (loss) income to net cash provided by operating	Ф	19,402	Ф	(49,327)	Ф	12,333
activities:						
Depreciation and amortization		11.394		4,536		3,427
Provisions for bad debt and inventory write offs and reserves		4,675		586		1,975
Share-based compensation		101,015		28,703		48,704
Unrealized gains/losses on trading securities and impairments		4,494		1,595		3,582
Amortization of debt discount and issue costs		15,714		14,670		13,701
Deferred tax benefit		(1,038)		(34,394)		(7,876
Amortization of discount or premium on investments		1,551		(999)		(4,065
Equity loss in affiliate and other		(1,848)		(2,514)		1,530
Excess tax benefit from share-based compensation		(4,406)		(21,090)		(29,604
Issuance of stock for license		_		_		11,013
Changes in assets and liabilities:						
Restrictions on cash		(2,099)		(8,766)		(5,176
Accounts receivable		(21,956)		(2,329)		(4,030
Inventories		(9,061)		(2,630)		(2,339
Prepaid expenses		3,422		(5,682)		3,642
Other assets		(196)		(16,123)		(2,463
Accounts payable Accrued expenses		(3,645) 9,203		18,509 3,641		(1,072 2,667
Other liabilities		(29,057)		22,419		2,968
Net cash provided by (used in) operating activities		97,624		(49,195)		48,937
Cash flows from investing activities:						
Purchases of property, plant and equipment		(95,400)		(124,415)		(38,658
Purchases of held-to-maturity investments		(310,634)		(321,363)		(221,986
Purchases of available-for-sale investments				(24,600)		(80,000
Maturities of held-to-maturity investments		249,083		266,051		260,888
Sales of available-for-sale investments		(2.5(0)		31,850		58,050
Purchase of Tyvaso Inhalation System business		(3,568)				
Net cash used in investing activities		(160,519)		(172,477)		(21,706
Cash flows from financing activities:						
Proceeds from the sale of treasury stock		_		150,000		_
Proceeds from exercise of stock options		32,071		41,936		58,344
Payments to repurchase common stock		_		_		(67,059
Excess tax benefits associated with share-based compensation		4,406		21,090		29,604
Net cash provided by financing activities		36,477		213,026		20,889
Effect of exchange rate changes on cash and cash equivalents	-	(2,682)		(1,225)		136
Net (decrease) increase in cash and cash equivalents		(29,100)		(9,871)		48,256
Cash and cash equivalents, beginning of year		129,452		139,323		91,067
Cash and cash equivalents, end of year	\$	100.352	\$	129,452	\$	139,323
	Ψ	100,332	Ψ	127,432	Ψ	137,323
Supplemental cash flow information :						
Cash paid for interest	\$	1,250	\$	1,250	\$	1,210
Cash paid for income taxes	\$	23,931	\$	1,628	\$	1,555
Non-cash investing and financing activities:	\$	_	\$	29,000	\$	
Lease obligation incurred			_	29,000		
Acquisition of Tyvaso Inhalation System Business	\$	4,776	\$	_	\$	
Non-cash additions of property, plant and equipment	\$	2,571	\$	6,391	\$	4
	_					

<sup>(1)</sup> Adjusted for the retrospective adoption of guidance set forth under FASB ASC 470-20, formerly FSP APB 14-1. See Note 9— Debt—Adoption of FASB ASC 470-20 (Formerly FSP APB 14-1).

See accompanying notes to consolidated financial statements.

## **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. We were incorporated in 1996 under the laws of the State of Delaware and our wholly-owned subsidiaries include Lung Rx, LLC, Unither Pharmaceuticals, LLC, Unither Telmed, Ltd., Unither.com, Inc., United Therapeutics Europe, Ltd., Unither Therapeutik GmbH, Unither Pharma, LLC, Medicomp, Inc., Unither Neurosciences, Inc., LungRx Limited, Unither Biotech Inc., and Unither Virology, LLC. As used in these notes to the consolidated financial statements, unless the context requires otherwise, the terms "we," "us," "our," and similar terms refer to United Therapeutics Corporation and its consolidated subsidiaries.

Our lead product is Remodulin® (treprostinil) Injection (Remodulin), which was initially approved in 2002 by the United States Food and Drug Administration (FDA). Remodulin is also approved for use in countries outside of the United States, predominantly for subcutaneous administration. In 2009, we received FDA approval for Adcirca® (tadalafil) Tablets (Adcirca) and for Tyvaso® (treprostinil) Inhalation Solution (Tyvaso). We have generated pharmaceutical revenues and license fees in the United States, Canada, the European Union (EU), South America and Asia. In addition, we have generated non-pharmaceutical revenues from telemedicine products and services in the United States.

# 2. Summary of Significant Accounting Policies

#### Principles of Consolidation

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

#### Use of Estimates

The preparation of the consolidated financial statements in accordance with accounting principles generally accepted in the United States (GAAP) requires management to make estimates and assumptions that affect reported amounts of assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Estimates are based on historical experience, current and anticipated circumstances that are believed to be relevant to a particular estimate, and various other assumptions believed to be reasonable. Consequently, actual results could differ from those estimates. Our significant accounting policies that require the use of subjective and/or complex judgments and estimates impact the following financial statement areas: revenue recognition, marketable investments, fair value measurements that are derived using unobservable estimates, income taxes, share-based compensation, obligations related to our Supplemental Executive Retirement Plan, and goodwill and other intangible assets. Estimates relating to these areas are discussed in *Part II, ITEM 7. Management's Discussion and Analysis of Financial Condition and Results of Operation—Summary of Critical Accounting Policies and Estimates* included in this Annual Report on Form 10-K.

#### 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

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

# 2. Summary of Significant Accounting Policies (Continued)

marketable investments and our 0.50% Convertible Senior Notes due October 2011 (Convertible Senior Notes) are reported in Notes 4 and 5, respectively.

#### Fair Value Measurements

The fair value of an asset or liability should represent the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. Such transactions to sell an asset or transfer a liability are assumed to occur in the principal or most advantageous market for the asset or liability. Accordingly, fair value is determined based on a hypothetical transaction at the measurement date, considered from the perspective of a market participant rather than from a reporting entity's perspective. New fair value measurements are not required if existing accounting guidance in the Financial Accounting Standard Board (FASB) codification requires or permits fair value measurements.

Disclosure of assets and liabilities subject to fair value disclosures are to be classified according to a three level fair value hierarchy with respect to the inputs (or assumptions) used in fair value measurements. Observable inputs such as unadjusted quoted market prices for identical assets or liabilities are given the highest priority within the hierarchy (Level 1). When observable inputs are unavailable, the use of unobservable inputs is permitted—i.e., inputs that a reporting entity believes market participants would use in pricing that are developed based on the best information available. Unobservable inputs are given the lowest priority within the hierarchy (Level 3). The level within the hierarchy at which a fair value measurement lies is determined based on the lowest level input that is significant to the fair value measurement in its entirety. Refer to related disclosures at Note 5 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. At December 31, 2008, we were subject to a compensating balance arrangement of \$1.0 million in order to reduce bank-related fees. We had no such arrangement at December 31, 2009.

## Trade Receivables

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

#### Marketable Investments

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

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

# 2. Summary of Significant Accounting Policies (Continued)

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

We 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 for held-to-maturity debt securities. In determining whether a decline in the value of an investment is other-than-temporary, we evaluate available quantitative and qualitative factors. These factors include, among others, general market conditions, the duration and extent to which fair value has been less than the carrying value, the investment issuer's financial condition and business outlook and our assessment as to whether it is more likely than not that we will be required to sell a security prior to recovery of its amortized cost basis.

#### Inventories

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

31,
2008
3,387
6,558
4,085
342
14,372

Inventories include pharmaceutical products and cardiac monitoring equipment that are produced by third-party manufacturers.

# Goodwill and Other Intangible Assets

Goodwill represents the excess of purchase price over the fair value of net identifiable assets associated with previous acquisitions. Other intangible assets consist primarily of technology and customer relationships, and are being amortized over a weighted average life of 6.8 years.

We review the carrying value of goodwill for impairment annually during the fourth quarter or more frequently if impairment indicators exist. In determining whether goodwill is impaired, we compare the estimated fair value of the reporting unit to which goodwill has been assigned to its carrying value. We estimate the fair value of a reporting unit by calculating its expected future discounted cash flows based on historical operating results adjusted for anticipated future market and operating conditions. Estimating the fair value of a reporting unit involves judgment particularly as it relates to the determination of expected future cash flows and a discount rate that is reasonable and appropriate in relation to our business profile. If the carrying amount of a reporting unit exceeds its

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

# 2. Summary of Significant Accounting Policies (Continued)

fair value, then the amount of an impairment loss is measured as the excess of the carrying amount of goodwill over its implied fair value.

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

On September 2, 2009, we acquired all of the assets, properties and rights used to manufacture the Tyvaso Inhalation System from NEBU-TEC International Med Products Eike Kern GmbH (NEBU-TEC) pursuant to the terms of our December 2008 Agreement of Sale and Transfer. See Note 18 to these consolidated financial statements for more information. We acquired approximately \$1.3 million in goodwill and \$10.1 million of intangible assets comprised of \$4.9 million in technology, patents and tradenames and \$5.2 million in customer relationships and non-compete agreements.

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

	As of December 31, 2009				As of December 31, 2008						
	Gross		Accumulated Amortization		Net		Gross		cumulated nortization		Net
Goodwill	\$ 8,7	53	\$ —	\$	8,763	\$	7,465	\$		\$	7,465
Other intangible assets:											
Technology, patents and tradenames	9,3	54	(4,586)		4,778		4,532		(4,159)		373
Customer relationships and non-compete	,				ŕ		·				
agreements	5,1:	50	(273)		4,877		_		_		_
Total	\$ 23,2	77	\$ (4,859)	\$	18,418	\$	11,997	\$	(4,159)	\$	7,838

Total amortization expense for the years ended December 31, 2009, 2008 and 2007, was approximately \$717,000, \$588,000 and \$545,000, respectively. As of December 31, 2009, the aggregate amortization expense related to intangible assets for each of the five succeeding years and thereafter is estimated as follows (in thousands):

Years ending December 31,	
2010	\$ 1,686
2011	1,596
2012	1,439
2013	1,416
2014	1,409
Thereafter	2,109
	\$ 9,655

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

# 2. Summary of Significant Accounting Policies (Continued)

#### Property, Plant and Equipment

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

Buildings	39 Years
Building improvements	10-39 Years
Furniture, equipment and vehicles	3-15 Years
Holter and event cardiac monitoring systems	3-7 Years
Leasehold improvements	Remaining lease term, or the estimated useful life of the improvement, whichever is shorter

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

	As of December 31,				
	2009	2008			
Land	\$ 20,024	\$ 11,987			
Buildings, building improvements and					
leasehold improvements	236,198	61,511			
Buildings under construction	_	116,673			
Holter and event cardiac monitoring					
systems	5,550	4,552			
Furniture, equipment and vehicle	65,430	41,743			
	327,202	236,466			
Less—accumulated depreciation	(23,343)	(13,749)			
Property, plant and equipment, net	\$ 303,859	\$ 222,717			

Depreciation expense for the years ended December 31, 2009, 2008 and 2007, was approximately \$10.7 million, \$3.9 million and \$2.9 million, respectively.

Buildings under construction related to the construction of our facilities in Silver Spring, Maryland, and Research Triangle Park, North Carolina, which were completed during the year ended December 31, 2009. During the years ended December 31, 2009 and 2008, we capitalized \$5.2 and \$4.8 million, respectively, in interest cost incurred on funds used to construct these facilities.

In December 2009, we recognized an impairment charge of \$4.2 million representing the remaining book value of three of our Silver Spring, Maryland, properties that housed employees prior to relocating to our newly-completed Phase II facility in Silver Spring. The old buildings, which are now considered abandoned (not in productive use), are scheduled to be demolished in 2010 in connection with commencement of construction of the last phase of our Silver Spring campus. The impairment charge is recorded in selling, general and administrative expenses in our consolidated statement of operations and is included in pharmaceutical segment in Note 19 to these consolidated financial statements.

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

# 2. Summary of Significant Accounting Policies (Continued)

## 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 generally similar terms. Sales of Remodulin and Tyvaso, including the Tyvaso Inhalation System, are recognized when title and risk of ownership pass to our distributors, upon delivery to our distributors' facilities. We record sales of Remodulin and Tyvaso net of product sales allowances. These sales allowances consist of prompt payment discounts, Medicaid and third-party payer rebates and fees for services provided by our distributors. Calculating these allowances involves the use of significant estimates and judgments and information from external sources.

Sales allowances are estimated and recognized as reductions to revenue in the period that associated revenues are recognized. Prompt pay discounts are calculated based on the gross amount of invoices and are recorded on a net basis as our distributors have routinely taken advantage of these discounts.

Medicaid rebates are generally invoiced and paid in the subsequent quarter from the date of sale. Accruals and related revenue reductions for Medicaid rebates are based on historical rebate data adjusted for anticipated changes in product sales trends and government rebate programs with regard to eligibility requirements and/or rebate pricing. We analyze rebate data separately for Remodulin and Tyvaso, as these therapies have been developed to treat PAH patients at different stages in the disease continuum and therefore, rebate eligibility and pricing requirements can differ for each therapy.

We may in the future be contractually obligated to pay a rebate to certain third-party payers to offset the cost of our therapies. While we had no such contractual rebate obligations to third-party payers in 2009 or in years prior to 2009, we expect to be contractually obligated to pay certain third-party payers a rebate in 2010 and beyond. As a result, we now include the review of third-party payer data into our revenue recognition policy.

We pay our distributors for contractual services rendered. Accruals for these fees are estimated based on contracted rates applied to the estimated units of service provided by distributors for a given period.

Our specialty pharmaceutical distributors do not possess return rights; however, we provide exchange rights in the event that product was damaged during shipment, or has expired. The shelf life of Remodulin and Tyvaso is three years from the date of manufacture. The number of product exchanges has been very small because we sell Remodulin and Tyvaso with a shelf life generally in excess of one year before its expiration and our distributors generally hold a 30 to 60 day inventory of our products. In addition, we do not require, nor do we provide incentives for our distributors to assume, inventory levels of Remodulin or Tyvaso beyond what would be considered reasonable and customary in the ordinary course of business and we closely track inventory levels in the distribution channels. Accordingly, any exchange for expired product has generally occurred many months after the period of initial sale. In addition, exchanges for damaged product have occurred infrequently. When a shipment of Remodulin or Tyvaso has been damaged in transit to the distributor, we have been

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

# 2. Summary of Significant Accounting Policies (Continued)

promptly notified and we do not recognize revenue on that shipment until the damaged product has been replaced, generally within several days after we receive notification of the damage.

With respect to Remodulin, the financial effects of this exchange right have been immaterial and we expect the historic volume of exchanges to remain consistent in the future. Obsolescence due to dating expiration has been minimal given the fast pace at which Remodulin moves through the distribution channel. Specifically, product exchanges have comprised substantially less than one percent of the volume of vials that we sell. Because historical and anticipated future returns associated with exchange rights for Remodulin have been, and are expected to be, immaterial, we do not record a reserve for estimated exchange rights in the period of sale. In addition, we expect a similarly immaterial financial impact of exchange rights with respect to Tyvaso. Accordingly, we have not recognized a reserve for anticipated future exchanges of Tyvaso. Lastly, we closely monitor exchange data for both of these therapies to ensure that our assumptions continue to be reasonable, appropriate and current.

#### Adcirca

Adcirca is manufactured for us by Eli Lilly and Company (Lilly) distributed through Lilly's well-established pharmaceutical wholesaler network. This type of distribution is similar to the way Adcirca's main competitor, Revatio, is distributed. 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 because: (1) we are responsible for the acceptability of the product purchased by Lilly's wholesalers; (2) we bear all inventory risk, as title and risk of loss pass to us at the shipping point from Lilly's manufacturing facility; (3) we assume credit risk if Lilly is unable to collect amounts due from customers; and (4) we assume the risk and cost of a product recall, if required.

Adcirca revenues are recognized net of the following sales allowances: reserves for product returns, Medicaid and third-party payer rebates, prompt pay discounts, non-PAH sales, if any, and wholesaler fees. Calculation of these allowances involves the use of significant judgments and estimates. In our determination of the allowance, we consider Lilly's return experience across all of their product lines especially with respect to those products that resemble Adcirca's expected sales and utilization. We also considered our experience with PAH product sales, customers, returns, distributors and inventory management. Lastly, we also consider national product return averages for all pharmaceutical products or specialty pharmaceutical products. Consequently, we have based initial estimates for returns on published industry data related to specialty pharmaceuticals, as that segment of industry data is most relevant to Adcirca. In addition, we compare patient prescription data to sales quarterly to see if both the prescription and sales patterns are reasonably similar. Allowances for Medicaid rebates are derived from our Remodulin-related experience as we believe that the treatment population as it relates to Medicaid patients is similar. While we had no contractual obligation to pay a rebate to third-party payer in 2009, we expect to be contractually obligated to pay a rebate to certain third-party payers in 2010. Prompt pay discounts are based on contractual terms with our distributors, and they generally take advantage of such discounts. We analyze our sales data to determine if any sales of Adcirca are for the treatment of an illness other than pulmonary hypertension. We do not recognize non-pulmonary hypertension sales of Adcirca as revenue. Lastly, wholesaler fees are based on the contractual fee percentage for each wholesaler and sales to that wholesaler.

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

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

#### Research and Development

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

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

- Costs associated with production activities in our manufacturing facilities prior to receiving FDA approval for such facilities; 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;
- Up-front payments made pursuant to license and distribution rights arrangements prior to regulatory approval of the underlying pharmaceutical product absent any alternative future uses.

# **Share-Based Compensation**

For stock option awards, the amount of compensation expense to be recognized is based on the grant date fair value of the award. Related compensation expense is recognized on a straight-line basis over the requisite service period, or vesting period of option awards that are expected to vest.

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

## **Advertising Costs**

Advertising costs are expensed as incurred. Advertising expense recognized during the years ended December 31, 2009, 2008 and 2007, was approximately \$1.6 million, \$1.2 million and \$1.2 million, respectively.

#### Income Taxes

Income taxes are accounted for in accordance with the asset and liability method. Accordingly, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their tax bases. Deferred tax assets and liabilities are measured using the enacted tax rates that are expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in the period that includes the enactment date. Deferred tax assets are reduced by a valuation allowance when, in our opinion, it is more likely than not that some or all of the deferred tax assets will not be realized.

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

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

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

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

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

Concentration of suppliers. We rely on a single supplier to perform stability studies on Remodulin and Tyvaso, manufacture Tyvaso and to analyze other products we are developing. In addition, Remodulin is manufactured and packaged by a single producer. Lilly, the manufacturer of Adcirca, also provides distribution and collection services for us. Although our current suppliers could be replaced, we believe that a change in one of our suppliers could disrupt the distribution of our commercial products or services and impede the progress of our clinical trials and other research and development.

Concentration of products, revenues and customers. During the years ended December 31, 2009, 2008 and 2007, sales of Remodulin accounted for approximately 90%, 96% and 95%, respectively, of our total net revenues. Net sales of Remodulin in the United States to our three distributors comprised approximately 88%, 89% and 88%, respectively, of such revenues. In addition, these three U.S.-based distributors are our sole customers for Tyvaso. Sales of Tyvaso during the year ended December 31, 2009 (its first year of commercial sale) comprised approximately 5% of our net revenues. At December 31, 2009 and 2008, approximately 80% and 79%, respectively, of accounts receivable were due from our three U.S.-based distributors. While we rely on our distributors to market Remodulin and

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

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

Tyvaso, there are several other qualified distributors that could replace any one of our current distributors should the need arise.

During the year ended December 31, 2009, we derived approximately 77% of our total net domestic revenues from one customer in our pharmaceutical segment. Gross revenues from that customer are as follows (in thousands):

	Years	Years Ended December 31,							
	2009	2008	2007						
Accredo Health									
Group, Inc.	\$ 269,770	\$ 184,865	\$ 136,975						

#### 3. Recently Issued Accounting Standards

In January 2010, the FASB issued accounting standards update (ASU) No. 2010-06, Fair Value Measurements and Disclosures (Topic 820)—Improving Disclosures about Fair Value Measurements (ASU No. 2010-06). ASU No. 2010-06 requires: (1) fair value disclosures of assets and liabilities by class; (2) disclosures about significant transfers in and out of Levels 1 and 2 on the fair value hierarchy, in addition to Level 3; (3) purchases, sales, issuances and settlements be disclosed on gross basis on the reconciliation of beginning and ending balances of Level 3 assets and liabilities; and (4) disclosures about valuation methods and inputs used to measure the fair value of Level 2 assets and liabilities. ASU No. 2010-06 becomes effective for the first financial reporting period beginning after December 15, 2009, except for disclosures about purchases, sales, issuances and settlements of Level 3 assets and liabilities which will be effective for fiscal years beginning after December 15, 2010. We are currently assessing what impact, if any, ASU No. 2010-06 will have on our fair value disclosures; however, we do not expect the adoption of the guidance provided in this codification update to have any material impact on our consolidated financial statements.

In December 2009, the FASB issued ASU No. 2009-17, Consolidations (Topic 810)—Improvements to Financial Reporting By Enterprises Involved with Variable Interest Entities (ASU No. 2009-17). ASU 2009-17 requires a qualitative approach for determining the primary beneficiary of a variable interest entity and replaces the quantitative evaluation previously set forth under FASB Interpretation No. 46 (revised December 2003), Consolidation of Variable Interest Entities. This approach is focused on identifying the reporting entity that has the ability to direct the activities of a variable interest entity that most significantly affects the entity's economic performance and has the obligation to absorb the entity's losses or has the right to receive benefits from the entity. ASU No. 2009-17, among other things, will require enhanced disclosures about a reporting entity's involvement in variable interest entities. The guidance under ASU No. 2009-17 will be effective for the first annual period beginning after November 15, 2009, and interim periods within that first annual period. We are assessing what impact, if any, adoption of this standard will have on our consolidated financial statements.

In October 2009, the FASB issued ASU No. 2009-13, Revenue Recognition (Topic 605)—Multiple-Deliverable Revenue Arrangements: a consensus of the FASB Emerging Issues Task Force (ASU 2009-13). ASU 2009-13 establishes a selling-price hierarchy for determining the selling price of each element within a multiple-deliverable arrangement. Specifically, the selling price assigned to each deliverable is to be based on vendor-specific objective evidence (VSOE) if available, third-party evidence, if VSOE is unavailable, and estimated selling prices if neither VSOE or third-party evidence is available. In

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

# 3. Recently Issued Accounting Standards (Continued)

addition, ASU 2009-13 eliminates the residual method of allocating arrangement consideration and instead requires allocation using the relative selling price method. ASU 2009-13 will be effective prospectively for multiple-deliverable revenue arrangements entered into, or materially modified, in fiscal years beginning on or after June 15, 2010. Presently, we are assessing what impact, if any, the adoption of ASU 2009-13 may have on our consolidated financial statements.

In August 2009, the FASB issued ASU No. 2009-05, *Fair Value Measurements and Disclosures (Topic 820)—Measuring Liabilities at Fair Value* (ASU 2009-05). ASU 2009-05 provides guidance in measuring the fair value of a liability when a quoted price in an active market does not exist for an identical liability or when a liability is subject to restrictions on its transfer. ASU 2009-15 was effective for us beginning with the quarter ended December 31, 2009. The adoption of ASU 2009-05 had no impact on the fair value measurements of our liabilities.

#### 4. Marketable Investments

#### Held-to-maturity Investments

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

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Government sponsored enterprises at				
December 31, 2009	\$ 172,531	\$ 559	\$ (247)	\$ 172,843
Corporate notes and bonds at December 31, 2009	96,697	158	(49)	96,806
Total	\$ 269,228	\$ 717	\$ (296)	\$ 269,649
As reported on the consolidated balance sheet at December 31, 2009:				
Current marketable securities	\$ 129,140			
Noncurrent marketable securities	140,088			
	\$ 269,228			

Amortized Cost	Gross Unrealized Gains		Gross Unrealized Losses			Fair Value
\$ 154,115	\$	1,718	\$	(18)	\$	155,815
53,509		140		(151)		53,498
\$ 207,624	\$	1,858	\$	(169)	\$	209,313
			:			
\$ 106,596						
101,028						
\$ 207,624						
	Cost  \$ 154,115     53,509  \$ 207,624  \$ 106,596     101,028	Amortized Cost Un 53,509 \$ 207,624 \$ \$ 106,596 101,028	Amortized Cost Unrealized Gains  \$ 154,115 \$ 1,718	Amortized Cost         Unrealized Gains         Unrealized United Interest           \$ 154,115         \$ 1,718         \$ 53,509           \$ 207,624         \$ 1,858         \$ 106,596           \$ 101,028         \$ 101,028	Amortized Cost         Unrealized Gains         Unrealized Losses           \$ 154,115         \$ 1,718         \$ (18)           53,509         140         (151)           \$ 207,624         \$ 1,858         \$ (169)           \$ 106,596         101,028	Amortized Cost         Unrealized Gains         Unrealized Losses           \$ 154,115         \$ 1,718         \$ (18)           \$ 53,509         140         (151)           \$ 207,624         \$ 1,858         \$ (169)           \$ 106,596         101,028

Certain held-to-maturity investments have been pledged as collateral to Wachovia Development Corporation under the laboratory lease described in Note 10 to these consolidated financial

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

# 4. Marketable Investments (Continued)

statements— Commitments and Contingencies, and are classified as restricted marketable investments and cash on our consolidated balance sheets as of December 31, 2009 and 2008.

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

	December 31,									
		20	09			2008				
		Fair Value	Uı	Gross nrealized Loss	Fair Value					
Government sponsored:										
Less than one year	\$	54,299	\$	(247)	\$	9,886	\$	(18)		
Greater than one year								_		
one year	_	54,299	_	(247)	_	9,886	_	(18)		
Corporate notes:										
Less than one year		64,499		(49)		21,278		(151)		
Greater than one year		_		_				_		
,		64,499		(49)		21,278		(151)		
Total	\$	118,798	\$	(296)	\$	31,164	\$	(169)		

We attribute the unrealized losses on held-to-maturity securities as of December 31, 2009 and 2008, to the variability in related market interest rates. We do not intend to sell these securities, nor is it more likely than not that we will be required to sell them prior to the end of their contractual term. Furthermore, we believe these securities do not subject us to undue market risk or counterparty credit risk. As such, we do not consider these securities to be other than temporarily impaired.

The following table summarizes the contractual maturities of held-to-maturity marketable investments at December 31, 2009 (in thousands):

	December 31, 2009				
	Amortized Cost	Fair Value			
Due in less than one year	\$ 150,092	\$ 150,617			
Due in one to two years	119,136	119,032			
Due in three to five years	_	_			
Due after five years	_	_			
Total	\$ 269,228	\$ 269,649			

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

## 4. Marketable Investments (Continued)

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

	Yea	Years Ended December 31,							
	2009	2008	2007						
Gross proceeds	\$ —	\$ 31,850(1)	\$ 58,050						
Realized gains	\$ —	\$ — 5	\$ —						
Realized losses	\$ —	\$ — 3	\$ —						

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

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

#### **Trading Investments**

Trading securities consisted of the following (in thousands):

	 rtized Cost Par Value	_	Cumulative oss Trading Gains	Cumulative ross Trading Losses	Other Than emporary npairment	Es	timated Fair Value
Municipal notes at December 31,							
2009	\$ 36,200	\$	2,044	\$ (2,604)	\$ (6,308)	\$	29,332
Municipal notes at December 31, 2008	\$ 36,750	\$	_	\$ (2,466)	\$ (6,308)	\$	27,976

We recognized trading gains of \$1.9 million, trading losses of \$2.5 million and no trading gains or losses for years ended December 31, 2009, 2008 and 2007, respectively.

# **Equity Investments**

As of December 31, 2009 and 2008, we owned less than 1% of the common stock of Twin Butte Energy Ltd. (Twin Butte). Our investment in Twin Butte is classified as available-for-sale and reported at fair value based on the quoted market price.

As of December 31, 2009, we maintain an investment totaling approximately \$4.9 million in the preferred stock of a privately held corporation. We account for this investment at cost, as its fair value is not readily determinable. The fair value of our investment has not been estimated at December 31, 2009, as there have been no events or developments indicating that the investment may be impaired. This investment is included within non-current other assets on our consolidated balance sheets.

#### 5. Fair Value Measurements

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

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

## 5. Fair Value Measurements (Continued)

value to be classified and disclosed in one of the following categories based on the lowest level input used that is significant to a particular fair value measurement:

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

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

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

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

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

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

## 5. Fair Value Measurements (Continued)

		As of December 31, 2008						
	]	Level 1		Level 2		Level 3		Balance
Assets								
Auction-rate securities(1)	\$	_	\$	_	\$	27,976	\$	27,976
Equity securities		97		_		_		97
Auction-rate securities put option(2)		_		_		7,685		7,685
Money market funds(3)		96,179		_		_		96,179
Federally-sponsored and corporate debt								
securities(4)		_	2	09,313		_		209,313
Total Assets	\$	96,276	\$ 2	09,313	\$	35,661	\$	341,250
Liabilities								
Convertible Senior Notes	\$	239,429	\$		\$	_	\$	239,429
			_		_		_	

- (1) Included in non-current marketable investments on the accompanying consolidated balance sheets—refer to the section below entitled *Auction-Rate Securities* for a discussion of the valuation techniques used to estimate the fair value of these securities.
- (2) Included within non-current other assets on the accompanying consolidated balance sheets—see the section below entitled *Auction-Rate Securities* for further information regarding the approach used to estimate the fair value of this option.
- (3) Included in cash and cash equivalents and marketable investments and cash—restricted on the accompanying consolidated balance sheets.
- (4) Included in current and non-current marketable investments on the accompanying consolidated balance sheets. The fair value of these securities is derived using a market approach—i.e. from pricing models that rely on relevant observable market data including interest rates, yield curves, recently reported trades of comparable securities, credit spreads and benchmark securities to determine the fair value of such securities. See also Note 4— *Held-to-Maturity Investments* to these consolidated financial statements.
- (5) Included in non-current liabilities on the accompanying consolidated balance sheet. See also Note 18— *Acquisition of Assets* to these consolidated financial statements.

The tables below provide a reconciliation of the beginning and ending balances of assets and liabilities measured at fair value using significant unobservable inputs (Level 3) for the years ended December 31, 2009 and 2008 (in thousands):

	 		auction-rate ecurities Put Option	Total
Balance January 1, 2009	\$ 27,976	\$	7,685	\$ 35,661
Transfers to (from) Level 3	_		_	_
Total gains/(losses) realized/unrealized included in				
earnings(1)	1,906		(944)	962
Total gains/(losses) included in other comprehensive				
income	_		_	_
Purchases/issuances/settlements, net	(550)		_	(550)
Balance December 31, 2009	\$ 29,332	\$	6,741	\$ 36,073

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

## 5. Fair Value Measurements (Continued)

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

(1) Includes gains of \$1.9 million and losses of \$2.5 million for the years ended December 31, 2009 and 2008, respectively, attributable to the change in unrealized gains (losses) relating to trading securities held at December 31, 2009 and 2008—(recognized within other income on our consolidated statements of operations)

#### **Auction-Rate Securities**

Our marketable investments include AAA-rated, auction-rate securities (ARS) collateralized by student loans that are approximately 91% guaranteed by the federal government. Since February 2008, our ARS have been rendered illiquid as a result of the collapse of the credit markets. Consequently, the fair value of our ARS has been estimated using both a discounted cash flow (DCF) approach and a market comparables method. For the market comparables method, we consider market data pricing to estimate the discount being applied to similar securities upon sale in the secondary market. Although the volume of secondary market activity has been increasing, we do not believe it occurs with sufficient frequency to rely solely on such data to determine the fair value of our ARS. As such, we also utilize a DCF model to estimate their fair value. The key assumptions of the DCF model are subjective and include the following: a reference, or benchmark rate of interest based on the London Interbank Offered Rate (LIBOR), the amounts and timing of cash flows, and the weighted average expected life of a security and its underlying collateral. In addition, the model considers the risks associated with: (1) the creditworthiness of the issuer; (2) the quality of the collateral underlying the investment; and (3) illiquidity. The benchmark interest rate is then adjusted upward depending on the degree of risk associated with each security within our auction-rate portfolio. We estimate illiquidity premiums based on an analysis of the average discounts applied to recent sales of comparable ARS within the secondary market.

To mitigate the risks associated with our ARS, we entered into an Auction-Rate Securities Rights Offer (Rights Offer) in November 2008 with the investment firm that maintains our ARS account. Pursuant to the Rights Offer, we can sell our ARS to the investment firm for a price equal to their par value (approximately \$36.2 million) at any time between June 30, 2010, and July 2, 2012 (Put Option). To help meet any immediate liquidity needs, the Rights Offer permits us to borrow up to the par value of our ARS; however, we do not expect to exercise this right. The Put Option represents a freestanding, non-transferable financial instrument that is being accounted for under the fair value option set forth under FASB ASC Topic 825, Financial Instruments (formerly SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities—Including an amendment of FASB Statement No. 115). Accordingly, all changes in fair value of the Put Option will be recognized within earnings.

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

## 5. Fair Value Measurements (Continued)

For the year ended December 31, 2009, we recognized losses of \$944,000 related to the Put Option, which has been included in other income on the consolidated statements of operations. Since there is not an observable market for the Put Option, its fair value has been estimated using significant unobservable inputs; therefore, it has been categorized as a Level 3 asset within the fair value hierarchy.

We employed a DCF model to estimate the fair value of the Put Option. We believe that the estimated fair value of the Put Option represents the incremental value associated with the ability to recover the full cost of our ARS at a significantly earlier date than would be otherwise possible, if at all, and the ability to obtain an immediate loan under the Rights Offer, as this right possesses value regardless of whether we expect to borrow under the Rights Offer. Key assumptions used in the DCF model are subjective and include the following: (1) a discount factor equal to the rate of interest consistent with the expected term of the Put Option and risk profile of the investment firm subject to the Put Option; (2) the amount and timing of expected cash flows; (3) the expected life of the Put Option prior to its exercise; and (4) assumed loan amounts. This DCF methodology considered two scenarios. The first scenario assumed that we would borrow up to 50% of the par value of our ARS and the second scenario assumed that we would borrow up to 75% of the par value of our ARS. Under the DCF model, increases in the assumed loan balance would result in an increase in the fair value of the Put Option because the risk of counterparty non-performance diminishes. The estimated fair values generated under both scenarios were given equal weight in estimating the fair value of the Put Option.

## 6. Investment in Northern Therapeutics, Inc.

We own approximately 68% of the outstanding common stock of Northern Therapeutics, Inc. (Northern). Northern was formed in 2000 to develop a particular form of gene therapy for the treatment of PAH and to distribute Remodulin and our other products in Canada. Although we own a majority of Northern's outstanding common stock, we may appoint only two of the Northern's seven board seats. Substantially all of Northern's key business decisions require unanimous consent from its board including decisions related to personnel selection and compensation and the establishment of operating and capital budgets. As such, the minority owners of Northern have substantive participating rights. As a result of these substantive participating rights, we do not control Northern; therefore, consolidation is prohibited. We account for our investment in Northern under the equity method and as such, the related investment balance is adjusted for our cumulative share in Northern's losses. At December 31, 2009, the investment balance is approximately \$880,000 and has been included within other non-current assets on our consolidated balance sheet.

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

## 6. Investment in Northern Therapeutics, Inc. (Continued)

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

	As of, and for the Year ended December 31,						
	2009 \$ 893			2008		2007	
Total assets	\$	893	\$	904	\$	1,404	
Total liabilities	\$	3	\$	83	\$	31	
Total revenues(1)	\$	281	\$	284	\$	485	
Net loss(1)	\$	(64)	\$	(331)	\$	(469)	

(1) Includes milestone payments under our exclusive license agreement with Northern.

# 7. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	Decem	ber 31,
	2009	2008
Royalties and rebates	\$ 15,258	\$ 10,640
Payroll related	8,707	6,727
Research related	2,457	1,930
Other	3,342	1,556
Total	\$ 29,764	\$ 20,853
Payroll related Research related Other	8,707 2,457 3,342	6,727 1,930 1,556

#### 8. Share Tracking Awards Plan

In June 2008, we adopted the United Therapeutics Corporation Share Tracking Awards Plan (STAP). Awards granted under the STAP (Awards) are non-dilutive as they are not settled in shares of our common stock but rather convey the right to receive in cash an amount equal to the appreciation of our common stock, which is calculated as the positive difference between the closing price of our common stock on the date of exercise and the date of grant. Outstanding Awards generally vest in one-third increments on each of the first three anniversaries of the date of grant and expire on the tenth anniversary of the date of grant. However, awards granted after November 2009 will generally vest in one-fourth increments on each of the first four anniversaries of the date of grant. On September 14, 2009, the Compensation Committee of our Board of Directors approved an amendment to the STAP increasing the number of Awards available for grant from 6,000,000 to 9,000,000.

We are required to account for outstanding Awards as a liability due to their cash-settlement provision. Accordingly, we estimate the fair value of Awards using the Black-Scholes-Merton valuation model at each financial reporting date until settlement occurs or Awards are otherwise no longer outstanding. The STAP liability balance was \$64.2 million and \$8.5 million at December 31, 2009, and December 31, 2008, respectively, and has been included in other current liabilities on our consolidated balance sheets. The change in the fair value of outstanding Awards at each reporting date is recognized as compensation expense on our consolidated statement of operations.

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

## 8. Share Tracking Awards Plan (Continued)

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

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

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

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

Expected term of Awards —An Award's expected term reflects the estimated time period we expect an Award to remain outstanding. We apply the use of the simplified method in developing an estimate of the expected term. We employ this methodology for estimating the expected term of Awards until such time that more refined estimates based on historical exercise behavior of the Awards can be established

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

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

The table below presents the inputs used to re-measure the fair value of Awards at December 31, 2009 and 2008:

	Decembe	er 31,
	2009	2008
Expected volatility	47.3%	48.0%
Risk-free interest rate	2.8%	1.6%
Expected term of options (in years)	5.0	5.6
Forfeiture rate	5.4%	6.3%
Expected dividend	0.0%	0.0%

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

# 8. Share Tracking Awards Plan (Continued)

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

	Number of Awards	Weighted- Average Exercise Price		Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in 000s)
Outstanding at January 1, 2009	3,622,996	\$	25.32		
Granted	3,337,888		38.74		
Exercised	(376,739)		25.32		
Forfeited	(220,425)		30.18		
Outstanding at December 31, 2009	6,363,720	\$	32.19	9.0	\$ 130,204
Awards exercisable at December 31, 2009	809,890	\$	25.32	8.5	\$ 22,135
Awards expected to vest at December 31, 2009	5,213,567	\$	33.23	9.0	\$ 101,249

The weighted average fair value of Awards granted during the years ended December 31, 2009 and 2008, was \$29.12 and \$16.13, respectively.

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

	Year Ended December 31, 2009		ear Ended cember 31, 2008
Cost of service sales	\$	331	\$ 17
Research and development		27,106	3,463
Selling, general and administrative		34,209	4,965
Share-based compensation expense		_	
before taxes		61,646	8,445
Related income tax benefits		(22,809)	(3,378)
Share-based compensation expense,		_	-
net of taxes	\$	38,837	\$ 5,067
Total share-based compensation			
expense capitalized in inventory	\$	2,336	\$ 72

Cash used to settle STAP exercises, which represents the intrinsic value of the award at the date of exercise, during the years ended December 31, 2009, and 2008 was approximately \$8.2 million and none, respectively.

#### 9. Debt

#### Convertible Notes

On October 30, 2006, we issued at par value \$250.0 million of Convertible Senior Notes. We pay interest on the Convertible Senior Notes semi-annually on April 15 and October 15 of each year. The Convertible Senior Notes are unsecured, unsubordinated debt obligations that rank equally with all of our other unsecured and unsubordinated indebtedness. The conversion price is \$37.6129 per share and the number of shares on which the aggregate consideration is to be determined upon conversion is

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

# 9. Debt (Continued)

approximately 6,646,000. Pursuant to the terms of the Convertible Senior Notes, the conversion price and number of shares underlying the debt have been proportionately adjusted for the two-for-one split of our common stock.

Conversion can occur: (1) anytime after July 15, 2011; (2) during any calendar quarter that follows a calendar quarter in which the price of our common stock exceeded 120% of the conversion price for at least 20 days during the 30 consecutive trading-day period ending on the last trading day of the quarter; (3) during the ten consecutive trading-day period following any five consecutive trading-day period in which the trading price of the Convertible Senior Notes was less than 95% of the closing price of our common stock multiplied by the then current number of shares underlying the Convertible Senior Notes; (4) upon specified distributions to our shareholders; (5) in connection with corporate transactions; or (6) in the event that our common stock ceases to be listed on the NASDAQ Global Select Market and is not listed for trading on another U.S. national or regional securities exchange.

Upon conversion, a holder of our Convertible Senior Notes will receive: (1) cash equal to the lesser of the principal amount of the note or the conversion value (equal to the number of shares underlying the Convertible Senior Notes multiplied by the then current conversion price per share); and (2) to the extent the conversion value exceeds the principal amount of the Convertible Senior Notes, shares of our common stock. In the event of a change in control, as defined in the indenture under which the Convertible Senior Notes have been issued, holders can require us to purchase from them all or a portion of their Convertible Senior Notes for 100% of the principal value plus any accrued and unpaid interest. At December 31, 2009, the aggregate conversion value of the Convertible Senior Notes exceeded their principal value by approximately \$99.9 million using a conversion price of \$52.65, the closing price of our common stock on that date. We have reserved sufficient shares of our common stock to satisfy the conversion requirements related to the Convertible Senior Notes.

The closing price of our common stock exceeded 120% of the conversion price of the Convertible Senior Notes for more than 20 trading days during the 30 consecutive trading day period ending on December 31, 2009. Consequently, the Convertible Senior Notes are convertible at the election of their holders. As this conversion right is outside of our control, the Convertible Senior Notes have been classified as a current liability on our consolidated balance sheet as of December 31, 2009. This contingent conversion measurement is calculated at the end of each quarterly reporting period. Therefore, the classification of the Convertible Senior Notes may be subject to change depending on the price of our common stock.

# Adoption of FASB ASC 470-20 (Formerly FSP APB 14-1)

On January 1, 2009, we adopted the guidance set forth under FASB ASC 470-20, which applies to certain convertible debt instruments that may be settled in cash or other assets, or partially in cash, upon conversion. Issuers of such convertible debt instruments are required to account for the liability and equity components of these instruments separately in a manner that reflects the issuer's nonconvertible debt borrowing rate when interest expense is subsequently recognized. Adoption of this guidance required retrospective application.

The Convertible Senior Notes fall within the scope of FASB ASC 470-20 because their terms include partial cash settlement. Accordingly, we estimated the fair value of the Convertible Senior Notes without the conversion feature as of the date of issuance (Liability Component). The estimated

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

# 9. Debt (Continued)

fair value of the Liability Component was \$177.6 million and was determined using a discounted cash flow approach.

Key inputs used to estimate the fair value of the Liability Component included the following:

- Our estimated non-convertible borrowing rate as of October 2006—the date the Convertible Senior Notes were issued;
- The amount and timing of cash flows; and
- The expected life of the Convertible Senior Notes.

The excess of the proceeds received over the estimated fair value of the Liability Component totaling \$72.4 million was allocated to the conversion feature (Equity Component) and a corresponding offset was recognized as a discount to reduce the net carrying value of the Convertible Senior Notes. The discount is being amortized to interest expense over a five-year period ending October 2011 (the expected life of the debt) using the interest method and an effective rate of interest of 7.5%.

Interest expense associated with the Convertible Senior Notes' coupon rate of interest and discount amortization consisted of the following (in thousands):

	Years Ended December 31,					
	2009	2009 2008			2007	
Contractual coupon rate of						
interest	\$ 1,2	250 \$	1,250	\$	1,250	
Discount amortization	14,5	581	13,537		12,568	
Interest expense—						
Convertible Senior Notes	\$ 15,8	331 \$	14,787	\$	13,818	

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

	December 31,				
	2009	2008			
Principal balance	\$ 249,978	\$ 249,978			
Discount, net of accumulated	(20.70.5)	(44.00=)			
amortization of \$42,697 and \$28,116	(29,706)	(44,287)			
Carrying amount	\$ 220,272	\$ 205,691			

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

# 9. Debt (Continued)

The impact of the adoption of FASB ASC 470-20 on the results of operations for the years ended December 31, 2009, 2008 and 2007, is presented below (in thousands, except for per share data):

	Year ended December 31, 2009						
	In	fore the npact of C 470-20	of	emental Impact Adoption of ASC 470-20	As	Reported	
Interest expense	\$	_	\$	(12,875)	\$	(12,875)	
Income tax (expense)							
benefit		(4,069)		4,764		695	
Net income		27,573		(8,111)		19,462	
Earnings per share:	-						
Basic	\$	0.52	\$	(0.15)	\$	0.37	
Diluted	\$	0.49	\$	(0.14)	\$	0.35	

	Year ended December 31, 2008							
		As Previously Reported ASC 470-20			As	s Restated		
Interest expense	\$	(16)	\$	(11,423)	\$	(11,439)		
Income tax								
benefit		29,509		4,885		34,394		
Net loss		(42,789)		(6,538)		(49,327)		
Earnings per share:			_					
Basic	\$	(0.93)	\$	(0.15)	\$	(1.08)		
Diluted	\$	(0.93)	\$	(0.15)	\$	(1.08)		

	Year ended December 31, 2007								
	Incremental Impact								
		As Previously of Adoption of Reported ASC 470-20			As	s Restated			
Interest expense	\$	(2,175)	\$	(12,106)	\$	(14,281)			
Income tax									
benefit		3,276		4,600		7,876			
Net income		19,859		(7,506)		12,353			
Earnings per share:									
Basic	\$	0.47	\$	(0.18)	\$	0.29			
Diluted	\$	0.44	\$	(0.16)	\$	0.28			

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

# 9. Debt (Continued)

The impact of the adoption of FASB ASC 470-20 on balance sheet line items as of December 31, 2008, is presented below (in thousands):

		Ι	December 31, 2008		
	Previously Reported	I	of Adoption of ASC 470-20	A	s Adjusted
Property, plant and					
equipment	\$ 221,066	\$	1,651(1	)\$	222,717
Deferred tax assets—non-					
current	175,969		2,873		178,842
Other non- current assets	22,974		(1,309)		21,665
Total	\$ 420,009	\$	3,215	\$	423,224
Other current					
liabilities	\$ 16,639	\$	(133)	\$	16,506
Notes payable	249,978		(44,287)		205,691
Total	\$ 266,617	\$	(44,420)	\$	222,197
Additional paid-in	 				
capital	\$ 659,245	\$	63,048	\$	722,293
Accumulated deficit	(78,514)		(15,413)		(93,927)
Total	\$ 580,731	\$	47,635	\$	628,366

(1) Additional capitalized interest related to our construction projects in Maryland and North Carolina resulting from the incremental interest expense recognized upon the retrospective adoption of FASB ASC 470-20.

#### Call Spread Option

Concurrent with the issuance of the Convertible Senior Notes, we purchased call options on our common stock in a private transaction with Deutsche Bank AG London (Call Option). The Call Option allows us to purchase up to approximately 6.6 million shares of our common stock at a price of \$37.6129 per share, which is equal to the amount of our common stock related to the conversion value that we could deliver to holders of the Convertible Senior Notes upon conversion. We will be required to issue shares of our common stock upon conversion if the price of our common stock exceeds \$37.6129 per share upon conversion. The Call Option will terminate upon the earlier of the maturity date of the Convertible Senior Notes or the first day all of the Convertible Senior Notes are no longer outstanding due to conversion or otherwise. We paid approximately \$80.8 million for the Call Option, which was recorded as a reduction to additional paid-in-capital.

In a separate transaction that took place simultaneously with the issuance of the Convertible Senior Notes, we sold a warrant to Deutsche Bank AG London under which Deutsche Bank AG London has the right to purchase approximately 6.6 million shares of our common stock at an exercise price of \$52.845 per share (Warrant). Proceeds received from the Warrant totaled approximately \$45.4 million and were recorded as additional paid-in-capital.

The shares deliverable to us under the Call Option must be obtained from existing shareholders. Any shares that we may be required to deliver under the Warrant can consist of registered or unregistered shares, subject to potential adjustments to the settlement amount. The maximum number of shares of our common stock that we may be required to deliver in connection with the Warrant is

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

# 9. Debt (Continued)

approximately 6.6 million. We have reserved approximately 6.6 million shares for the settlement of the Warrant and had sufficient shares available as of December 31, 2009, to effect such settlement.

The combination of the Call Option and Warrant effectively reduces the potential dilutive impact of the Convertible Senior Notes. The Call Option has a strike price equal to the conversion price of the Convertible Senior Notes and the Warrant has a higher strike price per share that caps the amount of potential dilution. The Call Option and Warrant can be settled on a net share basis. All share and per share data related to the Call Option and Warrant have been adjusted for the two-for-one split of our common stock (see Note 11 to these consolidated financial statements— *Stockholders' Equity* ).

In accordance with the guidance provided under FASB ASC 815, *Derivatives and Hedging*, these instruments are considered both indexed to our common stock and classified as equity; therefore, the Call Option and Warrant are not accounted for as derivative instruments.

## Interest Expense

Details of interest expense for are presented below (in thousands):

Years Ended December 31,					
	2009		2008		2007
\$	18,029	\$	16,196	\$	14,970
	(5,154)		(4,757)		(689)
\$	12,875	\$	11,439	\$	14,281
	_	\$ 18,029	2009 \$ 18,029 (5,154)	2009 2008 \$ 18,029 \$ 16,196 (5,154) (4,757)	2009 2008 \$ 18,029 \$ 16,196 \$ (5,154) (4,757)

## 10. Commitments and Contingencies

## Lease Obligation

We lease our laboratory facility in Silver Spring, Maryland (Phase I Laboratory), pursuant to a synthetic lease arrangement (Lease) entered into in June 2004 with Wachovia Development Corporation and its affiliates (Wachovia). Under the Lease, Wachovia funded \$32.0 million toward the construction of the Phase I Laboratory on land we own. Subsequent to the completion of construction in May 2006, Wachovia leased the Phase I Laboratory to us. Monthly rent is equal to the 30-day LIBOR plus 55 basis points (0.78% as of December 31, 2009) applied to the amount Wachovia funded toward construction. The base term of the Lease ends in May 2011 (Base Term). Upon the expiration of the Base Term, we will have the right to exercise one of the following options under the Lease: (1) renew the lease for an additional five-year term (subject to the approval of both parties); (2) purchase the Phase I Laboratory from Wachovia for approximately \$32.0 million; or (3) sell the Phase I Laboratory and repay Wachovia's construction costs with the proceeds from the sale. If the sale proceeds are insufficient to repay Wachovia's construction costs, we must fund the shortfall up to the maximum residual value guarantee of approximately \$27.5 million. From the inception of the Lease through August 2008, we accounted for the Lease as an operating lease.

In December 2007, we began constructing a combination office and laboratory facility (Phase II Facility) with funds generated from our operations. Architectural plans included the structural modification of the existing Phase I Facility in order to connect it to the Phase II Facility. As of September 30, 2008, we received Wachovia's acknowledgement of our plan to make structural

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

# 10. Commitments and Contingencies (Continued)

modifications to the Phase I Laboratory. As a result, we could no longer consider the Phase I Laboratory a standalone structure, which was required to maintain off-balance sheet accounting for the Lease. Consequently, as of September 30, 2008, we were considered the owners of the Phase I Laboratory for accounting purposes and are accounting for the Lease as a financing obligation. Accordingly, we capitalized \$29.0 million, the estimated fair value of the Phase I Laboratory, and recognized a corresponding lease obligation on our consolidated balance sheets. We are increasing the lease obligation to \$32.0 million, the purchase price of the Phase I Laboratory, through the recognition of periodic interest charges using the effective interest method. The accretion period will run through the end of the Base Term. Related interest charges for the years ended December 31, 2009 and 2008, were \$1.1 million and \$1.1 million, respectively. In addition, we are depreciating the Phase I Laboratory over the estimated useful lives of its various components.

The Lease and other lease agreements to which we are a party require that we comply with certain covenants throughout the term of these leases. If we are unable to comply with these covenants and cannot reach a satisfactory resolution in the event of a noncompliance, these agreements could terminate. Termination could result in the loss of our liquid collateral, among other consequences. As of December 31, 2009, we pledged \$34.9 million of our marketable securities as collateral for the Lease. Related amounts have been included in restricted marketable investments and cash on our consolidated balance sheet.

#### **Operating Leases**

We lease primarily facilities space and office equipment under operating lease arrangements that have terms expiring at various dates through 2015. Certain lease arrangements include renewal options and escalation clauses.

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

Years ending December 31,	
2010	\$ 2,376
2011	1,150
2012	976
2013	786
2014	48
	\$ 5,336

Total rent expense was \$2.7 million, \$2.5 million and \$3.3 million for the years ended December 31, 2009, 2008 and 2007, respectively.

#### **Construction Commitment**

In May 2009, we amended the terms of our November 2008 guaranteed maximum price construction management agreement with the Whiting-Turner Contracting Company (Whiting-Turner) for the construction of the Phase II Facility, which was completed in December 2009. The May 2009 amendment converted the guaranteed maximum price into a lump sum and increased our total obligation from approximately \$61.3 million to \$67.5 million, as a result of several change orders previously agreed upon with Whiting-Turner. We will not be obligated to Whiting-Turner for costs that

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

# 10. Commitments and Contingencies (Continued)

exceed the lump-sum value of the contract unless such costs result from agreed upon change orders that extend beyond the original scope of work. Amounts outstanding on the contract were approximately \$5.3 million as of December 31, 2009.

## Milestone and Royalty Payments

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

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

Years ending December 31,	(1)
2010	\$ 6,618
2011	9,039
2012	2,878
2013	1,645
2014 and thereafter	12,670
	\$ 32,850

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

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

#### Research agreement

We maintain a research agreement with the University of Oxford (Oxford) to develop antiviral compounds. Under the terms of the agreement, we are required to fund related research and make milestone payments for the successful completion of clinical trials. We are also obligated to pay royalties to Oxford equal to a percentage of our net sales from discoveries and products developed by Oxford. Milestone payments and royalties are subject to reduction depending upon third-party contributions to discoveries and/or third-party licenses necessary to develop products. In October 2006, the term of the research agreement was extended through September 30, 2011. In connection with the agreement's extension, we are obligated to make 60 equal monthly payments totaling approximately \$3.7 million. As of December 31, 2009, approximately \$1.1 million in monthly payments remained outstanding. During the twelve months ended December 31, 2009, 2008 and 2007, we incurred approximately \$588,000, \$734,000 and \$652,000, respectively, in expenses under the terms of the agreement. For the twelve months ended December 31, 2009, we incurred additional expenses of \$309,000 related to a research and development grant to Oxford to build and support a highly-secure laboratory required for working with certain viruses.

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

## 11. Stockholders' Equity

#### **Equity Incentive Plan**

Our Board of Directors adopted an equity incentive plan in November 1997 (EIP). Subsequently, in April 1999, our Board and shareholders approved an amendment and restatement of the EIP to increase the number of shares available for issuance under the EIP. The EIP, as amended and restated, provides for the issuance of up to 29,879,034 shares of our common stock, of which 15,879,034 have been reserved for issuance to our CEO in accordance with her employment agreement. As of December 31, 2009, there were 11,554,693 shares available for issuance under the EIP. Pursuant to the EIP, we may only grant, beginning in November 2007, nonqualified stock options and other share-based awards to participants. Options granted under the EIP are nontransferable, contain a maximum contractual term of ten years, and typically have vested in one-third increments on each of the first three anniversaries of the grant date. The exercise price of related awards can be no less than the fair market value of our common stock on the date of grant. Historically, we have issued new shares of our common stock upon the exercise of options.

#### Stock Split

On September 22, 2009, we completed a stock split in the form of a stock dividend pursuant to which one share of our common stock was distributed for each share issued and outstanding (or held in treasury) at the close of business on the record date, September 14, 2009. All references in the consolidated financial statements and elsewhere in this Annual Report on Form 10-K to the price and number of shares of our common stock and per share data, including data pertaining to share-based awards, have been restated to reflect the effects of the stock split for all periods presented.

# Stock Option Exchange

Pursuant to an Offer to Exchange (the Offer), on December 26, 2008 (Exchange Date), certain outstanding options with exercise prices above \$32.50 (Original Options) were cancelled and replaced with options having an exercise price of \$30.75 (Replacement Options), the closing price of our common stock on the Exchange Date. Original Options submitted for exchange were replaced on a one-for-one basis with Replacement Options. Additionally, the Replacement Options retain all terms and conditions of the Original Options except for the reduction to the exercise price as described above and the following:

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

Under SFAS 123R, the Offer is considered a modification of existing option award terms. As such, total compensation associated with the Replacement Options will consist of the grant date fair value of the Original Options for which the requisite service period is expected to be rendered (or has already been rendered) at the Exchange Date, plus the incremental cost associated with the modification of terms. The incremental compensation expense is measured as the excess of the fair value of the Replacement Options over the fair value of the Original Options re-measured as of the Exchange Date. A total of 3,145,232 Original Options with a weighted average exercise price of \$40.53 were exchanged

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

## 11. Stockholders' Equity (Continued)

for Replacement Options. Incremental compensation expense associated with the Offer was approximately \$7.8 million, of which \$7.3 million has been recognized through December 31, 2009. The remaining unrecognized expense will be recognized through 2011.

## **Employee Stock Options**

We estimate the fair value of stock options using the Black-Scholes-Merton valuation model. Option valuation models, including Black-Scholes-Merton, require the input of highly subjective assumptions that can materially impact the estimation of fair value and related compensation expense. These assumptions include the expected volatility of our common stock, risk-free interest rate, the expected term of stock option awards, expected forfeiture rate and the expected dividend yield.

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

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

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

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

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

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

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

	Year ended December 31,			
	2009	2008	2007	
Expected volatility	47.6%	47.6%	39.8%	
Risk-free interest rate	2.6%	1.6%	4.1%	
Expected term of options (in years)	5.1	4.8	5.7	
Forfeiture rate	0.0%	3.0%	4.7%	
Expected dividend	0.0%	0.0%	0.0%	

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

# 11. Stockholders' Equity (Continued)

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

	Shares	A	eighted- verage xercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in 000s)
Outstanding at January 1, 2009	9,173,382	\$	27.38		
Granted	792,896		49.61		
Exercised	(1,296,555)		23.97		
Forfeited	(90,935)		29.61		
Outstanding at December 31, 2009	8,578,788	\$	29.92	6.4	\$ 195,168
Options exercisable at end of period	7,556,433	\$	29.78	6.3	\$ 172,832
Expected to vest at December 31, 2009	970,063	\$	31.06	7.7	\$ 20,941

The weighted average fair value of employee stock options granted during the year ended December 31, 2009, 2008 and 2007, was \$22.21, \$26.80 and \$31.44, respectively. The total fair value of employee shares vested during the years ended December 31, 2009, 2008 and 2007 was approximately \$42.7 million, \$68.8 million and \$42.2 million, respectively.

Total employee stock option expense recognized for the years ended December 31, 2009, 2008 and 2007, is as follows (in thousands):

	Year ended December 31,					
	2009		2008			2007
Cost of service sales	\$	46	\$	52	\$	42
Research and development		9,188		10,344		10,969
Selling, general and						
administrative		29,930		15,158		36,353
Stock option expense before						
taxes		39,164		25,554		47,364
Related income tax benefits		(14,491)		(10,222)		(17,927)
Total stock option expense,					-	
net of taxes	\$	24,673	\$	15,332	\$	29,437
Total stock option expense						
capitalized in inventory	\$	972	\$	520	\$	213
	_					

As of December 31, 2009, there was approximately \$6.9 million of total unrecognized compensation cost related to unvested employee stock options, which is expected to be recognized through 2011.

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

## 11. Stockholders' Equity (Continued)

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

	Year Ended December 31,						
	2009			2008		2007	
Number of options							
exercised		1,358,067		2,045,944		3,594,072	
Cash received from							
options exercised	\$	32,611	\$	41,936	\$	58,344	
Total intrinsic value							
of options exercised	\$	29,060	\$	58,657	\$	91,119	
Tax benefits realized							
from options							
exercised	\$	4,406	\$	21,090	\$	29,604	

## Stock Options Issued to Non-employees for Services

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

	Number of Options Granted	ighted Average Grant Price
For the years ended		
December 31,		
2009	_	_
2008	82,000	\$ 49.55
2007	82,000	\$ 26.61

We incurred approximately none, \$2.4 million and \$1.4 million during the years ending December 31, 2009 and 2008 and 2007, respectively, in consultant stock option expense. Pursuant to the terms of the Offer, 48,334 options held by members of our Scientific Advisory Board were submitted for exchange with a weighted average exercise price of \$41.42.

## **Treasury Stock Transactions**

On December 18, 2008, we issued 6,301,674 shares of our common stock from treasury to Lilly in exchange for \$150.0 million, pursuant to a November 2008 stock purchase agreement (see Note 15—*License Agreements* to these consolidated financial statements). The total cost of the treasury stock issued in excess of the aggregate sales price of the transaction was approximately \$14.2 million and has been included in the accumulated deficit on our consolidated balance sheet at December 31, 2008.

On October 17, 2006, the Board approved a stock repurchase program that authorized us to acquire up to 8.0 million shares of our outstanding common stock over a two year period ending on October 17, 2008. Approximately 6.2 million shares were acquired for an aggregate cost of \$182.6 million under the stock repurchase program, which concluded in October 2008. We did not repurchase any shares of our outstanding common stock during 2008.

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

# 11. Stockholders' Equity (Continued)

## Earnings (loss) per Share

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

	Years ended December 31,					
		2009		2008		2007
Net income (loss) (numerator)	\$	19,462	\$	(49,327)	\$	12,353
Shares (denominator):						
Basic weighted-average						
shares outstanding		53,314		45,802		42,448
Effect of dilutive securities:						
Convertible Senior Notes		399		_		_
Stock options(1)		2,420		_		2,454
Diluted weighted-average						
shares		56,133		45,802		44,902
Earnings (loss) per share	_				_	
Basic	\$	0.37	\$	(1.08)	\$	0.29
Diluted	\$	0.35	\$	(1.08)	\$	0.28
Stock options and warrants						
excluded from calculation						
(2)		6,786		16,240		9,552
			_			

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

#### Shareholder Rights Plan

On June 30, 2008, we entered into an Amended and Restated Rights Agreement with The Bank of New York, as Rights Agent (the Plan), which amends and restates our original Rights Agreement, dated December 17, 2000. The Plan, as amended and restated, extends the expiration date of the Preferred Share Purchase Rights (Rights) from December 29, 2010, to June 26, 2018, and increases the purchase price of each Right from \$129.50 to \$800.00 (\$64.75 and \$400.00, respectively, after our September 2009 two-for-one stock split). Each Right entitles holders to purchase one one-thousandth of a share of our Series A Junior Participating Preferred Stock. Rights are exercisable only upon our acquisition by another company, or commencement of a tender offer that would result in ownership of 15 percent or more of the outstanding shares of our voting stock by a person or group (as defined under the Plan) without our prior express written consent. We have not issued any shares of our Series A Preferred Stock.

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

# 12. Comprehensive Income (Loss)

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

Year ended December 31,					
	2009		2008		2007
\$	19,462	\$	(49,327)	\$	12,353
	2,802		(5,489)		285
	44		(4,702)		(892)
	_		4,511		_
	44		(191)		(892)
			` ,		
	92		(414)		(587)
					Ì
	(1,339)		(136)		35
\$	21,061	\$	(55,557)	\$	11,194
		2009 \$ 19,462 2,802 44 ——————————————————————————————————	2009 \$ 19,462 \$ 2,802 44 ——————————————————————————————————	2009     2008       \$ 19,462     \$ (49,327)       2,802     (5,489)       44     (4,702)       —     4,511       44     (191)       92     (414)       (1,339)     (136)	2009     2008       \$ 19,462     \$ (49,327)       2,802     (5,489)       44     (4,702)       —     4,511       44     (191)       92     (414)       (1,339)     (136)

# 13. Income Taxes

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

	Year Ended December 31,					
		2009		2008		2007
Current:						
Federal	\$	14,304	\$	_	\$	634
State		1,999		1,275		103
Foreign		158		391		78
Total current		16,461		1,666		815
Deferred						
Federal		(24,397)		(68,695)		(39,025)
State		(2,508)		(5,311)		(83)
Foreign		168		(206)		_
Total deferred	_	(26,737)		(74,212)		(39,108)
Other non-current(1)						
Federal		7,965		36,408		28,289
State		1,616		1,744		2,128
Total other		9,581		38,152		30,417
Total income tax benefit	\$	(695)	\$	(34,394)	\$	(7,876)
	_					

<sup>(1)</sup> Relates primarily to share-based compensation.



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

# 13. Income Taxes (Continued)

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

	Years Ended December 31,					1,
		2009	2008			2007
Federal tax provision computed at 35%	\$	7,738	\$	(29,302)	\$	1,567
State tax provision, net of federal tax provision		748		(2,024)		110
Change in valuation allowance allocated to tax expense		(833)		_		795
General business credits		(10,899)		(7,101)		(12,849)
Incentive stock option expense		(1,354)		1,288		1,234
Section 199 deduction		(2,207)		_		_
Nondeductible compensation expense		4,821		_		_
Change in tax rate		_		_		903
Nondeductible expenses		1,291		2,745		364
Total income tax (benefit) expense	\$	(695)	\$	(34,394)	\$	(7,876)

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

	December 31,		
	2009	2008	
Deferred tax assets:			
Net operating loss carryforwards	\$ —	\$ —	
General business credits	80,882	79,922	
Impairment losses on investments	2,895	2,813	
Realized losses on marketable investments	2,752	2,857	
License fees capitalized for tax purposes	60,200	66,060	
Nonqualified stock option	36,064	26,098	
State net operating losses	845	5,777	
STAP awards	18,696	3,153	
Other	17,847	12,874	
Total deferred tax assets	220,181	199,554	
Deferred tax liabilities:			
Plant and equipment principally due to differences in depreciation	(5,834)	(4,063)	
Net deferred tax asset before valuation allowance	214,347	195,491	
Valuation allowance	(6,186)	(11,822)	
Net deferred tax assets	\$ 208,161	\$ 183,669	

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

# 13. Income Taxes (Continued)

Deferred tax assets are reduced by a valuation allowance when, in the opinion of our management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. In evaluating our ability to realize deferred tax assets, we consider all available positive and negative evidence. Accordingly, we consider past operating results, forecasts of earnings and taxable income, the reversal of temporary differences and any prudent and feasible tax planning strategies. Future increases in the valuation allowance would result in a corresponding charge to earnings in the period such a determination is made. Conversely, future reductions to the valuation allowance would result in either the recognition of a tax benefit or an increase to additional paid-in-capital in the period we conclude a reduction is warranted. In September 2009 we completed a corporate restructuring related to certain of our wholly-owned subsidiaries. Consequently, we reduced our valuation allowance maintained against certain state net operating losses in the amount of \$5.6 million.

At December 31, 2009, we had no net operating losses available for federal income tax purposes, and approximately \$845,000 in state net operating loss carryforwards. In addition, as of December 31, 2009, we had business tax credit carryforwards of approximately \$80.9 million. These carryforwards expire on various dates through 2029. Certain business tax credit carryforwards that were generated at various dates prior to December 2008 may be subject to limitations on their use pursuant to Internal Revenue Code Section 382 (Section 382) as a result of ownership changes as defined by Section 382. However, we do not expect that these business tax credits will expire unused. We are currently reviewing our stock trading history for the year ended December 31, 2009 to ascertain whether any further ownership changes have occurred pursuant to Section 382.

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

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

# 13. Income Taxes (Continued)

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

Unrecognized tax benefit at January 1, 2009	\$ 5,882
Gross increases—tax positions in current period	854
Gross decreases—tax positions in prior period	_
Gross increases—tax positions in the current period	_
Gross decreases—tax positions in current period	_
Settlements	_
Lapse of statute of limitations	_
Unrecognized tax benefit at December 31, 2009	\$ 6,736
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II	Φ 2.000
Unrecognized tax benefit at January 1, 2008	\$ 2,989
Gross increases—tax positions in prior period	2,893
Gross decreases—tax positions in prior period	_
Gross increases—tax positions in the current period	
Gross increases—tax positions in the current period	_
Settlements	
Lapse of statute of limitations	_
Unrecognized tax benefit at December 31, 2008	\$ 5,882
	_ <del></del> _
Unreasonized toy hanefit at January 1, 2007	s —
Unrecognized tax benefit at January 1, 2007	Ψ
Gross increases—tax positions in prior period	2,989
Gross decreases—tax positions in prior period	_
Gross increases—tax positions in the current period	
Gross increases—tax positions in the current period	_
Settlements	
Lapse of statute of limitations	_
Unrecognized tax benefit at December 31, 2007	\$ 2,989

Included in unrecognized tax benefits at December 31, 2009 and 2008 and 2007, is \$538,000, \$1.8 million and \$1.8 million, respectively, of tax benefits that, if recognized, would impact the effective tax rate. For the years ended December 31, 2009, 2008 and 2007, we did not accrue for or recognize any interest and penalties related to uncertain tax positions.

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

We are subject to federal and state taxation in the United States and various foreign jurisdictions. Our tax years from 2006 to 2008 are subject to examination by federal and state tax authorities. We believe that appropriate provisions for all outstanding items have been made for all jurisdictions and open years.

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

# 14. Employee Benefit Plans

# Supplemental Executive Retirement Plan

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

In connection with the SERP, we established a rabbi trust in December 2007, the assets of which will be contributed by us to pay benefits under the SERP. Participants of the SERP will have no preferred claim on, nor any beneficial ownership interest in, any assets of the rabbi trust. The balance in the rabbi trust was approximately \$5.1 million as of December 31, 2009 and 2008. Investments held in the rabbi trust have been included in restricted marketable investments and cash on our consolidated balance sheets.

We recognize on our consolidated balance sheet a liability equal to the unfunded status of the SERP (equal to the projected benefit obligation as we do not fund the SERP) and measure our projected benefit obligation as of the end of our fiscal year. Expenses related to the SERP are reported in selling, general and administrative and research and development expenses in the accompanying consolidated statements of operations.

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

	Year ended December 31,			
		2008		
Projected benefit obligation at beginning of				
year	\$	9,173	\$	4,899
Service cost		2,645		2,664
Interest cost		558		386
Amendments				1,024
Actuarial loss (gain)		2,126		200
Projected benefit obligation at end of year	\$	14,502	\$	9,173
Fair value of plan assets at end of year		_		
Unfunded at end of year(1)	\$	14,502	\$	9,173

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

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

# 14. Employee Benefit Plans (Continued)

The accumulated benefit obligation for the SERP, a measure that does not encompass future increases in participant salaries, was approximately \$9.5 million and \$5.4 million at December 31, 2009 and 2008, respectively.

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

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

Years Ended December 31,	2009	2008
Discount Rate	5.25%	6.35%
Salary Increases	5.00%	5.00%

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

Years Ended December 31,	2009	2008	2007
Service cost	\$ 2,645	\$ 2,664	\$ 2,449
Interest cost	558	386	149
Prior period service cost			
amortization	146	145	59
Total	\$ 3,349	\$ 3,195	\$ 2,657

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

Years Ended December 31,	2009	2008	2007
Net unrecognized actuarial loss			
(gain)	\$ 2,126	\$ 200	\$ (296)
Net unrecognized prior service cost	(146)	879	(60)
Total	1,980	1,079	(356)
Tax	(733)	(529)	63
Total, net of tax	\$ 1,247	\$ 550	\$ (293)

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

December 31,	2009			2008	2	2007
Net unrecognized actuarial loss						
(gain)	\$	2,284	\$	158	\$	(42)
Net unrecognized prior service						
cost		1,445		1,591		712
Total		3,729		1,749		670
Tax	(	1,379)		(647)		(118)
Total, net of tax	\$	2,350	\$	1,102	\$	552
			_		_	

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

# 14. Employee Benefit Plans (Continued)

Of the amounts included in accumulated other comprehensive loss/income as of December 31, 2009, above, we expect to recognize \$146,000 in net periodic pension cost relating to net prior service cost during the year ended December 31, 2010. In addition, because net unrealized actuarial losses exceed 10% of the projected benefit obligation as of January 1, 2010, we expect to recognize \$84,000 in amortization associated with these losses during the year ended December 31, 2010.

# Employee Retirement Plan

We maintain a Section 401(k) Salary Reduction Plan (401(k) Plan) which we adopted in January 1999 and is open to all eligible full-time employees. Under the 401(k) Plan, eligible employees can make pre-tax contributions up to statutory limits. We make discretionary matching contributions to the 401(k) Plan currently equal to 40% of a participant's salary deferral. Matching contributions vest immediately for employees who have been employed for three years, otherwise the matching contributions vest in one-third increments over three years until the three-year employment requirement has been met. Expenses related to the 401(k) Plan were \$847,000 and \$407,000 and \$375,000 for the years ended December 31, 2009, 2008 and 2007, respectively.

### 15. License Agreements

#### Glaxo SmithKline PLC

In January 1997, GlaxoSmithKline PLC (Glaxo) assigned to us patents and patent applications for the use of the stable prostacyclin analogue UT-15 (now known as treprostinil) for the treatment of PAH and congestive heart failure. Under the agreement, Glaxo is entitled to receive royalties from us on sales exceeding a specified threshold for a period of ten years following the date of the first commercial sale of any product containing treprostinil, currently Remodulin and Tyvaso. The terms of the agreement provide Glaxo rights to negotiate a license with us if we license any part of the marketing rights under the agreement to a third party. Additionally, if we grant any third-party license rights to Remodulin or Tyvaso, Glaxo would be entitled to a percentage of all related fees that we would receive on such arrangements.

# Pfizer Inc.

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

# Eli Lilly and Company

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

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

# 15. License Agreements (Continued)

License Agreement. Lilly granted us an exclusive right to develop, market, promote and commercialize Adcirca for the treatment of pulmonary hypertension in the United States and Puerto Rico. In connection with these license rights, we made a one-time, upfront payment to Lilly of \$25.0 million. Additionally, we agreed to pay Lilly royalties of 5% of our net sales of Adcirca as a pass through of Lilly's third-party royalty obligations for as long as Lilly is required to make such royalty payments. The term of the license agreement will continue generally until the later of (1) the expiration or lapse of the last to expire claim within a Lilly patent covering commercialization of Adcirca, or (2) expiration of any government conferred exclusivity rights to Adcirca. In addition, at Lilly's discretion the license agreement may be terminated in the event that we undergo a change in control. If this were to occur, Lilly would refund our \$25.0 million payment.

Manufacturing and Supply Agreement. Terms of the manufacturing and supply agreement provide that Lilly will manufacture Adcirca and distribute it via its wholesaler network in the same manner that it distributes its own pharmaceutical products. We agreed to purchase Adcirca from Lilly at a fixed cost, which is subject to adjustment by Lilly from time to time. Under the terms of the manufacturing and supply agreement we made a one-time, upfront, non-refundable, non-creditable payment to Lilly of \$125.0 million. The manufacturing and supply agreement will continue in effect until expiration or termination of the license agreement.

Stock Purchase Agreement. On December 18, 2008, we issued 6,301,674 shares of our common stock from treasury to Lilly in exchange for \$150.0 million. The price per share was equal to 90% of the average closing price of our common stock quoted on the NASDAQ Global Select Market during the five trading day period commencing on (and including) November 17, 2008. Upon the completion of the sale of our common stock to Lilly, the license and manufacturing and distribution agreements discussed above became effective.

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

#### Toray Industries, Inc.

In June 2000, we entered into an agreement with Toray for the exclusive right to develop and market beraprost, a chemically stable oral prostacyclin analogue, in a sustained release formulation (beraprost-SR) in the United States and Canada for the treatment of all cardiovascular indications. In March 2007, the June 2000 agreement was amended to expand our rights to commercialize a modified release formulation of beraprost (beraprost-MR). In accordance with the terms of the amended agreement, we issued 400,000 shares of our common stock to Toray in March 2007. The terms of the amended agreement give Toray the right to request that we repurchase the shares we issued to them at the price of \$27.21 per share. The fair value of the stock issued, which amounted to approximately \$11.0 million, was expensed as research and development during the year ended December 31, 2007, as beraprost-MR had not yet received regulatory approval for marketing and the value of the shares issued has been included within mezzanine equity as common stock subject to repurchase. If Toray requests that we repurchase these shares, we will reclassify the repurchase price of the shares as a liability until settlement occurs. The amended agreement also requires that we make certain milestone payments to Toray during the development period and upon receipt of United States or European

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

# 15. License Agreements (Continued)

Union regulatory approval. Milestone payments made prior to the receipt of regulatory approval will be expensed as incurred.

# Supernus Pharmaceuticals, Inc.

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

# Other

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

# 16. Related Party Transaction

In September 2002, we entered into a technical services agreement for certain telemedicine technology development services for Medicomp, 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 paid KTI a monthly consulting fee. In addition, we agreed to pay KTI a five percent royalty on certain sales of products reasonably attributed to and dependent upon the technology developed by KTI under the technical services agreement and which are covered by claims of an issued and unexpired United States patent(s). We terminated the services performed under this agreement in December 2006, but the royalty obligation survived termination. In late 2009, KTI was awarded a patent based on some of its work performed under the technical services agreement. We are currently evaluating our royalty obligation to KTI under the agreement.

In May 2007, we entered into a new technical services agreement with KTI. Pursuant to this agreement, we agreed to pay KTI consulting fees of up to \$12,000 monthly. We also agreed to reimburse KTI on a monthly basis for all necessary, reasonable and direct out of pocket expenses incurred in connection with his services. Under the agreement, we could pay KTI up to a 5percent royalty on sales of certain products reasonably attributed to and dependent upon certain technology developed by KTI. We incurred approximately \$172,000 and \$145,000 in expenses during the years ended December 31, 2009 and 2008, respectively under this agreement. As of December 31, 2009 and 2008, no amounts were owed to KTI.

# 17. Distribution Agreements

We entered into our distribution agreements for Tyvaso with our U.S.-based specialty pharmaceutical distributors in August 2009. The Tyvaso distribution agreements have one-year terms and renew automatically for additional one-year periods, unless terminated earlier. The Tyvaso

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

# 17. Distribution Agreements (Continued)

distribution agreements are similar to the distribution agreements we have for Remodulin. Both distribution agreements contain similar contractual responsibilities for both the distributor and us, ordering specifications, inventory requirements and similar rights for exchange of product. The Tyvaso distribution agreement contains certain service requirements for our distributors for which we compensate them on a feefor-service basis. If any of our distribution agreements expire or terminate, we may, under certain circumstances, be required to repurchase any unsold Tyvaso inventory held by our distributors. None of our current distribution agreements grants our distributors the distribution rights for oral treprostinil.

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

# 18. Acquisition of Assets

On September 2, 2009, we acquired all of the assets, properties and rights used in the Tyvaso Inhalation System from NEBU-TEC International Med Products Eike Kern GmbH (NEBU-TEC) pursuant to the terms of our December 2008 Agreement of Sale and Transfer. We acquired the Tyvaso Inhalation System business to obtain control over production of the device and related accessories. The assets and rights acquired include the necessary inputs, processes and outputs to be considered to be a business as defined under FASB ASC Topic 805, *Business Combinations*. Accordingly, we accounted for the transaction as a business combination. The acquisition date fair value of the consideration transferred included \$6.8 million in cash and \$4.8 million in contingent consideration. Contingent consideration of up to €10.0 million is to be paid in specified increments if the number of patients using the Tyvaso Inhalation System meets or exceeds certain thresholds measured at designed intervals. We also have the option to purchase NEBU-TEC's next generation nebulizer, the SIM-Neb. The fair value of the contingent consideration was measured using a probability weighted discounted cash flow model which considered our estimate of patients on therapy, the possible impact of using the SIM-Neb and the impact of future new therapies. As such, the fair value of the contingent consideration has been estimated using significant unobservable inputs, which are classified as Level 3 inputs in the fair value hierarchy. The acquisition was not significant to our consolidated financial statements.

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

# 18. Acquisition of Assets (Continued)

The acquisition-date fair value of the assets acquired is presented below (in thousands):

	Sep	tember 2, 2009
Tangible assets	\$	558
Technology		4,350
Customer relationships		4,530
Other intangibles		890
Goodwill		1,256
Total assets acquired	\$	11,584

Goodwill associated with the acquisition is tax deductible and has been assigned to the pharmaceutical reporting segment. Intangible assets are subject to amortization and will be amortized over a weighted average period of 6.8 years.

At December 31, 2009, based on our initial experience with the commercial launch of Tyvaso, we revised our estimate of the number of patients using Tyvaso. As a result of this revision, we increased the amount of the contingent consideration due NEBU-TEC by \$1.8 million. Our methodology in calculating the contingent consideration did not change from that used for the initial valuation. The increase in the contingent consideration was recorded as a charge to selling, general and administrative expense in our consolidated results of operations and to other non-current liabilities on our consolidated balance sheet. We review the contingent consideration model at least once every quarter.

# 19. Segment Information

We have two reportable business segments: pharmaceutical and telemedicine. The pharmaceutical segment includes all activities associated with the research, development, manufacturing and commercialization of our therapeutic products. The telemedicine segment includes all activities associated with the development and manufacturing of patient cardiac monitoring products and services. The telemedicine segment is managed separately because diagnostic services require different technology and marketing strategies than therapeutic products.

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

# 19. Segment Information (Continued)

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

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

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

					Consolidated
	Pharma	Pharmaceutical(1)		cine	Totals(1)
Revenues from external customers	\$	272,012	\$ 9	,485 \$	8 281,497
Net (loss) income		(49,997)		670	(49,327)
Interest income		11,025		_	11,025
Interest expense		(11,439)		_	(11,439)
Income tax benefit		34,394		_	34,394
Depreciation and amortization		(4,026)	(	(510)	(4,536)
Equity loss in affiliate		(226)		_	(226)
Investments in equity method investees		1,021		_	1,021
Expenditures for long-lived assets		(122,992)	(1,	,423)	(124,415)
Goodwill		1,287	6.	,178	7,465
Total assets		856,950	17,	,584	874,534

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

# 19. Segment Information (Continued)

Segment information as of and for the year ended December 31, 2007, is presented below (in thousands):

	Phar	maceutical(1)	Teler	nedicine	 onsolidated Totals(1)
Revenues from external customers	\$	203,218	\$	7,725	\$ 210,943
Net income		12,310		43	12,353
Interest income		13,595		7	13,602
Interest expense		(14,271)		(10)	(14,281)
Income tax benefit		7,876		_	7,876
Depreciation and amortization		(3,037)		(390)	(3,427)
Equity loss in affiliate		(321)		_	(321)
Investments in equity method investees		1,247		_	1,247
Expenditures for long-lived assets		(37,601)		(1,057)	(38,658)
Goodwill		1,287		6,178	7,465
Total assets		553,265		31,982	585,247

(1) Adjusted for the retrospective adoption of guidance set forth under FASB ASC 470-20, formerly FSP APB 14-1. See Note 9 — *Debt—Adoption of FASB ASC 470-20 (Formerly FSP APB 14-1).* 

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

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

Year Ended December 31,	2009	2008	2007
United States	\$ 328,939	\$ 249,209	\$ 183,523
Rest-of-World(1)	40,909	32,288	27,420
Total	\$ 369,848	\$ 281,497	\$ 210,943

(1) Sales primarily to countries located in Europe

For the years ended December 31, 2009, 2008 and 2007, sales to one customer within our pharmaceutical segment comprised 71%, 66% and 60%, respectively, of total consolidated net revenues.

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

# 19. Segment Information (Continued)

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

Year Ended December 31,	2009	2008	2007
United States	\$ 281,330	\$ 209,578	\$ 68,879
Rest-of-World(1)	22,529	13,139	475
Total	\$ 303,859	\$ 222,717	\$ 69,354

(1) Long-lived assets as of December 31, 2009 and 2008, consisted of facilities acquired during 2008 and are primarily located in the United Kingdom.

# 20. Quarterly Financial Information (Unaudited)

The following presents summarized quarterly financial information for each of the years ended December 31, 2009 and 2008 (in thousands, except per share amounts):

				Quarter En	ded			
	De	cember 31, 2009	Se	ptember 30, 2009		June 30, 2009	N	Iarch 31, 2009
Net sales	\$	108,923	\$	97,215	\$	83,980	\$	79,730
Gross profit		95,146		84,179		73,573		70,402
Net (loss) income		(3,330)		11,937		(2,344)		13,197
(Loss) income per share—basic	\$	(0.06)	\$	0.22	\$	(0.04)	\$	0.25
(Loss) income per share—diluted	\$	(0.06)	\$	0.21	\$	(0.04)	\$	0.24

				Quarter End	ed(2	3)				
	Dec	December 31, 2008		1, September 30, 2008		• /		,	March 31, 2008	
Net sales	\$	75,862	\$	75,032	\$	68,556	\$	62,047		
Gross profit		67,414		66,732		60,558		54,494		
Net (loss) income(1)		(82,070)		10,790		12,062		9,712		
(Loss) income per share—basic	\$	(1.73)	\$	0.24	\$	0.27	\$	0.22		
(Loss) income per share—diluted	\$	(1.73)	\$	0.22	\$	0.25	\$	0.20		

- (1) During the three months ended December 31, 2008, research and development expense included a charge of \$150.0 million relating to a one-time upfront fee paid to Lilly in connection with the acquisition of certain license rights to Adcirca.
- (2) Adjusted for the retrospective adoption of guidance set forth under FASB ASC 470-20, formerly FSP APB 14-1. See Note 9 Debt—Adoption of FASB ASC 470-20 (Formerly FSP APB 14-1).

# 21. Legal proceedings

As previously disclosed in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2009, on May 7, 2009, purported shareholder Jeffrey Benison IRA filed a derivative complaint in the Court of Chancery for the State of Delaware against those of our directors who were

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

# 21. Legal proceedings (Continued)

members of our Board of Directors as of December 31, 2008, and us as a nominal defendant. An amended complaint, which the plaintiff filed on August 27, 2009 (purportedly on our behalf), alleged, among other things, that the named director defendants breached their fiduciary duties of loyalty in connection with the 2008 modification of awards granted under the United Therapeutics Corporation Share Tracking Awards Plan (STAP) and the exchange of certain stock options granted under our Amended and Restated Equity Incentive Plan. The amended complaint also alleged that our Chief Executive Officer should not have been able to exchange certain of the stock options she exchanged pursuant to the same 2008 exchange. On October 2, 2009, a second plaintiff, the Retirement Board of Allegheny County, filed a derivative complaint asserting similar challenges as the *Benison* complaint described above, also in the Court of Chancery for the State of Delaware. On November 9, 2009, the Court of Chancery entered an order consolidating these two derivative actions. The order authorizes the plaintiffs to file a consolidated amended complaint and provides that the defendants are not required to respond further to the previously filed complaints. As of February 22, 2010, a consolidated amended complaint has not yet been filed.

We disclosed the amendment of awards granted under the STAP and exchange of options (including by our Chief Executive Officer) in our filings with the Securities and Exchange Commission, including our Current Reports on Form 8-K filed on June 6, 2008, November 26, 2008, and December 31, 2008, our tender offer statement on Schedule TO, filed on November 26, 2008, and amendments thereto filed on December 5 and 31, 2008, our Annual Report on Form 10-K, filed on February 26, 2009, our Definitive Proxy Statement on Schedule 14A, filed on April 29, 2009, and our Quarterly Reports on Form 10-Q, filed on May 1, 2009, and July 31, 2009. The plaintiffs are seeking unspecified monetary damages, purportedly for United Therapeutics Corporation, as well as attorneys' fees and costs and injunctive relief. We believe the plaintiffs' allegations are without merit and have defended and intend to continue to defend against these claims vigorously. Furthermore, we have been advised that the individual director and officer defendants also intend to defend against these claims vigorously.

On July 28, 2009, the Retirement Board of Allegheny County also filed a complaint against us in the Court of Chancery for the State of Delaware seeking an order allowing the plaintiff to inspect our records relating principally to the same issues addressed in its derivative lawsuit summarized above, as well as attorneys' fees and costs. We have reached an agreement-in-principle with the plaintiff to resolve this matter, with each party to bear its own fees and costs, and pursuant to which we produced certain corporate books and records in November 2009.

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

# **United Therapeutics Corporation**

# Schedule II—Valuation and Qualifying Accounts

# **Years Ended December 31, 2009, 2008, and 2007**

(In thousands)

	Valuation Allowance on Deferred Tax Assets							S
	Ba	lance at	Ac	ditions				
	Ве	eginning	Ch	arged to			Ba	alance at
		of Year	E	xpense	De	ductions	En	d of Year
Year ended December 31, 2009	\$	11,822	\$	100	\$	(5,736)	\$	6,186
Year ended December 31, 2008	\$	7,548	\$	6,414	\$	(2,140)	\$	11,822
Year ended December 31, 2007	\$	6,754	\$	794	\$		\$	7,548

	 Reserve for Inventory Obsolescence						
	nce at nning		lditions arged to			Ba	lance at
	 Year		xpense	Dec	ductions		d of Year
Year ended December 31, 2009	\$ 411	\$	1,222	\$	(362)	\$	1,271
Year ended December 31, 2008	\$ 508	\$	183	\$	(280)	\$	411
Year ended December 31, 2007	\$ 440	\$	570	\$	(502)	\$	508

	Allowance for Doubtful Accounts Receivable							
	Balan Begin of Y	ning	Cha	litions rged to pense	Dedi	uctions		ance at of Year
Year ended December 31, 2009	\$	_	\$	_	\$	_	\$	_
Year ended December 31, 2008	\$	_	\$	_	\$	_	\$	_
Year ended December 31, 2007	\$	1	\$	_	\$	(1)	\$	_

#### 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, 2009. 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, 2009.

# Management's Report on Internal Control Over Financial Reporting

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

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2009, based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control—Integrated Framework*. Management's assessment included an evaluation of the design of our internal control over financial reporting and testing of the operational effectiveness of our internal control over financial reporting. Based on this assessment, our management concluded that, as of December 31, 2009, 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, 2009 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

# ITEM 9B. OTHER INFORMATION

None.

#### **PART III**

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

Information required by Item 10 regarding nominees and directors appearing under Proposal No. 1: *Election of Directors* in our definitive proxy statement for our 2010 annual meeting of shareholders scheduled for June 28, 2010 (the 2010 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 2010 Proxy Statement is hereby incorporated herein by this reference.

Information appearing under the heading Section 16(a) Beneficial Ownership Reporting Compliance in our 2010 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 <a href="http://www.unither.com">http://www.unither.com</a>. A copy of the Code of Conduct and Ethics will be provided free of charge by making a written request and mailing it to our corporate headquarters offices to the attention of Senior Vice President, Investor Relations. If any amendment to, or a waiver from, a provision of the Code of Conduct and Ethics that applies to the principal executive officer, principal financial officer and principal accounting officer is made, such information will be posted on our Internet website at <a href="https://www.unither.com">www.unither.com</a>.

# ITEM 11. EXECUTIVE COMPENSATION

Information concerning executive compensation required by Item 11 appears under the headings *Corporate Governance, Board of Directors, Committees—Non - Employee Director Compensation , Compensation Discussion and Analysis, Summary Compensation Table and Grants of Plan-Based Awards Table, and Narratives to Summary Compensation Table and Grants of Plan-Based Awards Table in our 2010* Proxy Statement and is hereby incorporated herein by this reference.

Information concerning the Compensation Committee required by Item 11 appears under the heading *Compensation Committee Report* in our 2010 Proxy Statement and is hereby incorporated herein by this reference.

# ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information regarding beneficial ownership of our common stock required by Item 12 appears under *Beneficial Ownership of Common Stock* in our 2010 Proxy Statement and is hereby incorporated herein by this reference.

# Securities Authorized for Issuance Under Equity Compensation Plans

The following table presents information as of December 31, 2009, 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 aver price of outstar (b	nding options	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	8,536,702	\$	30.82	11,554,693
Equity compensation plans not approved by				
security holders	373,610		10.05	N/A
Total	8,910,312	\$	29.94	11,554,693

We have one equity incentive plan approved by security holders in 1997. In addition, prior to 2005, we granted options to employees and consultants outside of the plan approved by security holders (non-plan options). Information regarding the security holder approved plan and the non-plan options is contained in Note 11 to the consolidated financial statements included in this Annual Report on Form 10-K. We do not have any warrants or rights that are outstanding or available for issuance as described in Regulation S-K Item 201(d). Securities issued pursuant to the non-plan awards were made under a standard agreement generally consistent with the form contained in Exhibits 10.10.

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

Information concerning related party transactions and director independence required by Item 13 appears under the heading Corporate Governance, Board of Directors, Committees—Certain Relationships and Related Party Transactions, Corporate Governance, Board of Directors, Committees—Related Party Transaction Policy, Corporate Governance, Board of Directors, Committees—Director Independence and Committees of our Board of Directors in our 2010 Proxy Statement and is hereby incorporated herein by this reference.

# ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Information required by this item, concerning the principal accounting fees paid by the Registrant and the Audit Committee's pre-approval policies and procedures, is incorporated by reference to the information under the heading *Report of the Audit Committee and Information on our Independent Auditors* in our 2010 Proxy Statement and is hereby incorporated herein by this reference.

#### **PART IV**

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

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

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

- (a)(1) Our financial statements filed as part of this report on Form 10-K are set forth in the Index to Consolidated Financial Statements under Part II, Item 8 of this Form 10-K.
- (a)(2) The Schedule II—Valuation and Qualifying Accounts is filed as part of this Form 10-K. All other schedules are omitted because they are not applicable or not required, or because the required information is included in the consolidated statements or notes thereto.
- (a)(3) Exhibits filed as a part of this Form 10-K:

Certain exhibits to this report have been included only with the copies of this report filed with the Securities and Exchange Commission. Copies of individual exhibits will be furnished to 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.

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's
	Registration Statement on Form S-1 (Registration No. 333-76409).
3.2	Second Amended and Restated By-laws of the Registrant, incorporated by reference to Exhibit 3.2 of the Registrant's Quarterly
	Report on Form 10-Q for the fiscal quarter ended March 31, 2008.
3.3	Form of Certificate of Designations, Preferences and Rights of Series A Junior Participating Preferred Stock, incorporated by
	reference to Exhibit A to Exhibit 4 to the Registrant's Current Report on Form 8-K, filed December 18, 2000.
4.1	Reference is made to Exhibits 3.1 and 3.2.
4.2	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.

Exhibit No.	Description
4.3	Indenture, dated October 30, 2006, between the Registrant and The Bank of New York, as trustee (including form of 0.50%
	Convertible Senior Note due October 15, 2011), incorporated by reference to Exhibit 4.1 of Registrant's Current Report on Form 8-
	K filed October 30, 2006.
4.4	Resale Registration Rights Agreement, dated October 30, 2006, between the Registrant and Deutsche Bank Securities Inc., as the
	initial purchaser, incorporated by reference to Exhibit 4.2 of the Registrant's Current Report on Form 8-K filed October 30, 2006.
10.1**	United Therapeutics Corporation Amended and Restated Equity Incentive Plan, as amended effective as of September 24, 2004,
	incorporated by reference to Exhibit 10.1 of the Registrant's Form 10-Q for the quarter ended September 30, 2004.
10.2**	Amended and Restated Executive Employment Agreement dated as of January 1, 2009, between the Registrant and Martine A.
	Rothblatt, incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended
	March 31, 2009.
10.3**	Employment Agreement dated June 16, 2001 between the Registrant and Paul A. Mahon, incorporated by reference to Exhibit 10.4
	of the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2002.
10.4*	Exclusive License Agreement dated as of December 3, 1996, between the Registrant and an affiliate of Pharmacia & Upjohn
	Company, incorporated by reference to Exhibit 10.8 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-
	76409).
10.5*	Assignment Agreement dated as of January 31, 1997, between the Registrant and affiliates of Glaxo Wellcome Inc., incorporated
	by reference to Exhibit 10.9 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
10.6**	Employment Agreement dated November 29, 2000 between the Registrant and Roger Jeffs, incorporated by reference to
	Exhibit 10.9 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2002.
10.7	Form of Indemnification Agreement between the Registrant and each of its Directors and Executive Officers, incorporated by
	reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2009.
10.8	Amendment No. 1 to Exclusive License Agreement, effective as of December 3, 1996, made as of October 1, 2002 by and between
	Pharmacia & Upjohn Company and the Registrant, incorporated by reference to Exhibit 10.25 of the Registrant's Quarterly Report
	on Form 10-Q for the quarter ended September 30, 2002.
10.9	Technical Services Agreement dated August 27, 2002 between the Registrant and Kurzweil Technologies, Inc., incorporated by
	reference to Exhibit 10.26 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.
10.10**	Standard Non-plan Option Award Agreement used by the Registrant, incorporated by reference to Exhibit 10.39 of the Registrant's
	Form 10-K for the fiscal year ended December 31, 2002.
10.11**	Amendment to Employment Agreement dated December 11, 2002 between the Registrant and Roger Jeffs, incorporated by
	reference to Exhibit 10.40 of the Registrant's Form 10-K for the fiscal year ended December 31, 2002.
10.12**	Amendment to Employment Agreement dated December 11, 2002 between the Registrant and Paul Mahon, incorporated by
	reference to Exhibit 10.43 of the Registrant's Form 10-K for the fiscal year ended December 31, 2002.
10.13	Real Estate Purchase Agreement dated October 31, 2003 by and between Unither Pharmaceuticals, Inc. and Montgomery County,
	incorporated by reference to Exhibit 10.34 of the Registrant's Form 10-K for the fiscal year ended December 31, 2003.

Exhibit No.	Description
10.14	Lease Agreement dated as of June 28, 2004, by and among the Registrant and Wachovia Development Corporation, incorporated
	by reference to Exhibit 99.1 of the Registrant's Form 8-K filed on July 6, 2004.
10.15	Assignment of Liquid Collateral Account dated June 28, 2004, by and among the Registrant and Wachovia Development
	Corporation, incorporated by reference to Exhibit 99.2 of the Registrant's Form 8-K filed on July 6, 2004.
10.16	Ground Lease dated June 28, 2004, by and among United Therapeutics Corporation and Wachovia Development Corporation,
	incorporated by reference to Exhibit 99.3 of the Registrant's Form 8-K filed on July 6, 2004.
10.17	Participation Agreement dated June 28, 2004, by and among the Registrant, Wachovia Development Corporation, Various Other
	Banks and Financial Institutions and Wachovia Bank, NA, incorporated by reference to Exhibit 99.4 of the Registrant's Form 8-K
	filed on July 6, 2004.
10.18	Agency Agreement dated June 28, 2004, by and among the Registrant and Wachovia Development Corporation, incorporated by
	reference to Exhibit 99.5 of the Registrant's Form 8-K filed on July 6, 2004.
10.19**	Amendment to Employment Agreement between Roger Jeffs, Ph.D. and the Registrant dated November 29, 2000, as previously
	amended, incorporated by reference to Exhibit 10.2 of the Registrant's Form 8-K filed on December 29, 2004.
10.20**	Amendment to Employment Agreement between Paul A. Mahon and the Registrant dated June 16, 2001, as previously amended,
	incorporated by reference to Exhibit 10.4 of the Registrant's Form 8-K filed on December 29, 2004.
10.21**	Form of terms and conditions for awards granted to Employees by the Registrant under the Amended and Restated Equity Incentive
	Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K filed on December 17, 2004.
10.22**	Form of terms and conditions for awards granted to Non-Employees by the Registrant under the Amended and Restated Equity
	Incentive Plan, incorporated by reference to Exhibit 10.2 of the Registrant's Form 8-K filed on December 17, 2004.
10.23	Turner Construction Contract, incorporated by reference to Exhibits 99.1 and 99.2 of the Registrant's Current Report on Form 8-K
	filed on March 17, 2005.
10.24**	United Therapeutics Corporation Supplemental Executive Retirement Plan, incorporated by reference to Exhibit 10.1 of the
	Registrant's Current Report on Form 8-K filed on May 4, 2006.
10.25**	Employment Agreement, dated August 2, 2006, between John Ferrari and the Registrant, incorporated by reference to Exhibit 10.1
	of the Registrant's Current Report on Form 8-K filed on August 4, 2006.
10.26**	Amendment, dated July 31, 2006, to amended Employment Agreement, dated November 29, 2000, between Roger Jeffs, Ph.D. and
	the Registrant, incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on August 4, 2006.
10.27**	Amendment, dated July 31, 2006, to amended Employment Agreement, dated June 16, 2001, between Paul A. Mahon and the
	Registrant, incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed on August 4, 2006.
10.28	First Amendment to Certain Operative Agreements, dated May 16, 2006, between Wachovia Development Corporation and the
	Registrant, incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended
	June 30, 2006.
10.29	Confirmation, dated October 24, 2006, between Deutsche Bank AG London and the Registrant, incorporated by reference to
	Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on October 30, 2006.

Exhibit No.	Description
10.30	Confirmation, dated October 24, 2006, between Deutsche Bank AG London and the Registrant, incorporated by reference to
	Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on October 30, 2006.
10.31**	Amendment, dated December 28, 2006, to Employment Agreement, dated August 2, 2006, between John Ferrari and the Registran
	incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on December 29, 2006.
10.32	United Therapeutics Corporation Supplemental Executive Retirement Plan Rabbi Trust Document entered into December 28, 2007
	by and between the Registrant and Wilmington Trust Company, as trustee, incorporated by reference to Exhibit 10.1 of the
	Registrant's Current Report on Form 8-K filed on December 28, 2007.
10.33	Standard form of agreement between the Registrant and DPR Construction, Inc., dated March 9, 2007, as amended by Amendment
	No. 1, dated April 19, 2007, incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the
	quarter ended March 31, 2007.
10.34***	Distribution Agreement dated March 20, 2000, between the Registrant and Accredo Therapeutics, Inc., as amended and
	incorporated by reference to Exhibit 10.45 of the Registrant's Annual Report Form 10-K for the fiscal year ended December 31,
	2007.
10.35***	Agreement between the Registrant and the Whiting-Turner Contracting Company, dated November 5, 2007, as amended by
	Amendment No. 1, dated November 21, 2008, incorporated by reference to Exhibit 10.44 of the Registrant's Annual Report on
10.00	Form 10-K for the fiscal year ended December 31, 2008.
10.36**	United Therapeutics Corporation Share Tracking Awards Plan, incorporated by reference to Exhibit 10.1 of the Registrant's
10.37**	Quarterly Report on Form 10-Q for the quarter ended June 30, 2008.
10.5/**	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.
10.38**	Form of terms and conditions for awards granted to Non-Employees by the Registrant under the United Therapeutics Corporation
10.36	Share Tracking Awards Plan, incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q for the
	quarter ended June 30, 2008.
10.39**	Form of terms and conditions for awards granted to Employees by the Registrant prior to January 1, 2010, under the United
10.57	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.
10.40**	Form of Grant Letter used by the 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.
10.41	Stock Purchase Agreement, dated as of November 14, 2008, between the Registrant and Eli Lilly and Company, incorporated by
	reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on December 24, 2008.
10.42***	License Agreement, dated as of November 14, 2008, by and between Eli Lilly and Company and the Registrant, incorporated by
	reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on December 24, 2008.
10.43***	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.

Exhibit No.	Description
10.44**	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.
10.45	Amendment No. 2 to Construction Agreement between the Registrant and the Whiting-Turner Contracting Company, dated
	May 29, 2009, incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended
	June 30, 2009.
10.46**	Form of Amendment to Employment Agreement between the Registrant and each of Roger Jeffs, Paul Mahon and John Ferrari,
	each dated as of February 22, 2010.
10.47	Distribution Agreement dated August 17, 2009, between the Registrant and Accredo Health Group, Inc.
10.48**	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.
12.1	Computation of Earnings to Fixed Charges.
21	Subsidiaries of the Registrant.
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

<sup>\*</sup> Confidential treatment has been granted with respect to certain portions of this exhibit pursuant to Rule 406 of the Securities Act of 1933, as amended.

\*\* Designates management contracts and compensation plans.

<sup>\*\*\*</sup> Confidential treatment has been granted with respect to certain portions of this exhibit pursuant to Rule 24b-2 of the Securities Act of 1934.

# **SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereto duly authorized.

# UNITED THERAPEUTICS CORPORATION

By:	/s/ MARTINE A. ROTHBLATT	
	Martine A. Rothblatt, Ph.D.  Chairman of the Board and Chief Executive Officer	

February 26, 2010

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signatures	<u>Title</u>	<u>Date</u>	
/s/ MARTINE A. ROTHBLATT	Chairman of the Board and Chief  Executive Officer	February 26, 2010	
Martine A. Rothblatt	(Principal Executive Officer)	•	
/s/ JOHN M. FERRARI	Chief Financial Officer and Treasurer	February 26, 2010	
John M. Ferrari	(Principal Financial Officer and Principal Accounting Officer)	rebluary 20, 2010	
/s/ ROGER A. JEFFS	President, Chief Operating Officer	February 26, 2010	
Roger A. Jeffs	and Director	1 cordary 20, 2010	
/s/ CHRISTOPHER CAUSEY	- Director	February 26, 2010	
Christopher Causey	Birector	1 cordary 20, 2010	
/s/ RAYMOND DWEK	- Director	February 26, 2010	
Raymond Dwek	Director	February 26, 2010	
/s/ RICHARD GILTNER	- Director	Fohrmary 26, 2010	
Richard Giltner	Director	February 26, 2010	
/s/ R. PAUL GRAY	- Director	Fahman 26, 2010	
R. Paul Gray	Director	February 26, 2010	
/s/ RAYMOND KURZWEIL	Director	February 26, 2010	
Raymond Kurzweil	Director	1 cordary 20, 2010	

<u>Signatures</u>	<u>Title</u>	<u>Date</u>
/s/ CHRISTOPHER PATUSKY  Christopher Patusky	- Director	February 26, 2010
/s/ LOUIS W. SULLIVAN Louis W. Sullivan	Director	February 26, 2010
/s/ TOMMY G. THOMPSON  Tommy Thompson	· Director	February 26, 2010
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# **EXHIBIT INDEX**

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's
	Registration Statement on Form S-1 (Registration No. 333-76409).
3.2	Second Amended and Restated By-laws of the Registrant, incorporated by reference to Exhibit 3.2 of the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2008.
3.3	Form of Certificate of Designations, Preferences and Rights of Series A Junior Participating Preferred Stock, incorporated by reference to Exhibit A to Exhibit 4 to the Registrant's Current Report on Form 8-K, filed December 18, 2000.
4.1	Reference is made to Exhibits 3.1 and 3.2.
4.2	First Amended and Restated Rights Agreement, incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K filed on July 3, 2008.
4.3	Indenture, dated October 30, 2006, between the Registrant and The Bank of New York, as trustee (including form of 0.50% Convertible Senior Note due October 15, 2011), incorporated by reference to Exhibit 4.1 of Registrant's Current Report on Form 8-K filed October 30, 2006.
4.4	Resale Registration Rights Agreement, dated October 30, 2006, between the Registrant and Deutsche Bank Securities Inc., as the initial purchaser, incorporated by reference to Exhibit 4.2 of the Registrant's Current Report on Form 8-K filed October 30, 2006.
10.1**	United Therapeutics Corporation Amended and Restated Equity Incentive Plan, as amended effective as of September 24, 2004, incorporated by reference to Exhibit 10.1 of the Registrant's Form 10-Q for the quarter ended September 30, 2004.
10.2**	Amended and Restated Executive Employment Agreement dated as of January 1, 2009, between the Registrant and Martine A. Rothblatt, incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2009.
10.3**	Employment Agreement dated June 16, 2001 between the Registrant and Paul A. Mahon, incorporated by reference to Exhibit 10.4 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2002.
10.4*	Exclusive License Agreement dated as of December 3, 1996, between the Registrant and an affiliate of Pharmacia & Upjohn Company, incorporated by reference to Exhibit 10.8 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
10.5*	Assignment Agreement dated as of January 31, 1997, between the Registrant and affiliates of Glaxo Wellcome Inc., incorporated by reference to Exhibit 10.9 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
10.6**	Employment Agreement dated November 29, 2000 between the Registrant and Roger Jeffs, incorporated by reference to Exhibit 10.9 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2002.
10.7	Form of Indemnification Agreement between the Registrant and each of its Directors and Executive Officers, incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2009.
10.8	Amendment No. 1 to Exclusive License Agreement, effective as of December 3, 1996, made as of October 1, 2002 by and between Pharmacia & Upjohn Company and the Registrant, incorporated by reference to Exhibit 10.25 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.
10.9	Technical Services Agreement dated August 27, 2002 between the Registrant and Kurzweil Technologies, Inc., incorporated by reference to Exhibit 10.26 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002.

Exhibit No.	Description
10.10**	Standard Non-plan Option Award Agreement used by the Registrant, incorporated by reference to Exhibit 10.39 of the Registrant's
	Form 10-K for the fiscal year ended December 31, 2002.
10.11**	Amendment to Employment Agreement dated December 11, 2002 between the Registrant and Roger Jeffs, incorporated by
	reference to Exhibit 10.40 of the Registrant's Form 10-K for the fiscal year ended December 31, 2002.
10.12**	Amendment to Employment Agreement dated December 11, 2002 between the Registrant and Paul Mahon, incorporated by
	reference to Exhibit 10.43 of the Registrant's Form 10-K for the fiscal year ended December 31, 2002.
10.13	Real Estate Purchase Agreement dated October 31, 2003 by and between Unither Pharmaceuticals, Inc. and Montgomery County,
	incorporated by reference to Exhibit 10.34 of the Registrant's Form 10-K for the fiscal year ended December 31, 2003.
10.14	Lease Agreement dated as of June 28, 2004, by and among the Registrant and Wachovia Development Corporation, incorporated
	by reference to Exhibit 99.1 of the Registrant's Form 8-K filed on July 6, 2004.
10.15	Assignment of Liquid Collateral Account dated June 28, 2004, by and among the Registrant and Wachovia Development
	Corporation, incorporated by reference to Exhibit 99.2 of the Registrant's Form 8-K filed on July 6, 2004.
10.16	Ground Lease dated June 28, 2004, by and among the Registrant and Wachovia Development Corporation, incorporated by
	reference to Exhibit 99.3 of the Registrant's Form 8-K filed on July 6, 2004.
10.17	Participation Agreement dated June 28, 2004, by and among the Registrant, Wachovia Development Corporation, Various Other
	Banks and Financial Institutions and Wachovia Bank, NA, incorporated by reference to Exhibit 99.4 of the Registrant's Form 8-K
10.10	filed on July 6, 2004.
10.18	Agency Agreement dated June 28, 2004, by and among the Registrant and Wachovia Development Corporation, incorporated by
10.1014	reference to Exhibit 99.5 of the Registrant's Form 8-K filed on July 6, 2004.
10.19**	Amendment to Employment Agreement between Roger Jeffs, Ph.D. and the Registrant dated November 29, 2000, as previously
10.20**	amended, incorporated by reference to Exhibit 10.2 of the Registrant's Form 8-K filed on December 29, 2004.
10.20**	Amendment to Employment Agreement between Paul A. Mahon and the Registrant dated June 16, 2001, as previously amended,
10.21**	incorporated by reference to Exhibit 10.4 of the Registrant's Form 8-K filed on December 29, 2004.
10.21**	Form of terms and conditions for awards granted to Employees by the Registrant under the Amended and Restated Equity Incentive
10.22**	Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K filed on December 17, 2004.
10.22	Form of terms and conditions for awards granted to Non-Employees by the Registrant under the Amended and Restated Equity Incentive Plan, incorporated by reference to Exhibit 10.2 of the Registrant's Form 8-K filed on December 17, 2004.
10.22	Turner Construction Contract, incorporated by reference to Exhibits 99.1 and 99.2 of the Registrant's Current Report on Form 8-K
10.23	filed on March 17, 2005.
10.24**	United Therapeutics Corporation Supplemental Executive Retirement Plan, incorporated by reference to Exhibit 10.1 of the
10.24	Registrant's Current Report on Form 8-K filed on May 4, 2006.
10.25**	Employment Agreement, dated August 2, 2006, between John Ferrari and the Registrant, incorporated by reference to Exhibit 10.1
10.23	of the Registrant's Current Report on Form 8-K filed on August 4, 2006.
	of the Registrant's Current Report on Point of the on August 4, 2000.

Exhibit No.	Description
10.26**	Amendment, dated July 31, 2006, to amended Employment Agreement, dated November 29, 2000, between Roger Jeffs, Ph.D. and
	the Registrant, incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on August 4, 2006.
10.27**	Amendment, dated July 31, 2006, to amended Employment Agreement, dated June 16, 2001, between Paul A. Mahon and the
	Registrant, incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed on August 4, 2006.
10.28	First Amendment to Certain Operative Agreements, dated May 16, 2006, between Wachovia Development Corporation and the
	Registrant, incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended
	June 30, 2006.
10.29	Confirmation, dated October 24, 2006, between Deutsche Bank AG London and the Registrant, incorporated by reference to
	Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on October 30, 2006.
10.30	Confirmation, dated October 24, 2006, between Deutsche Bank AG London and the Registrant, incorporated by reference to
	Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on October 30, 2006.
10.31**	Amendment, dated December 28, 2006, to Employment Agreement, dated August 2, 2006, between John Ferrari and the Registrant
	incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on December 29, 2006.
10.32	United Therapeutics Corporation Supplemental Executive Retirement Plan Rabbi Trust Document entered into December 28, 2007,
	by and between the Registrant and Wilmington Trust Company, as trustee, incorporated by reference to Exhibit 10.1 of the
	Registrant's Current Report on Form 8-K filed on December 28, 2007.
10.33	Standard form of agreement between the Registrant and DPR Construction, Inc., dated March 9, 2007, as amended by Amendment
	No. 1, dated April 19, 2007, incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the
	quarter ended March 31, 2007.
10.34***	Distribution Agreement dated March 20, 2000, between the Registrant and Accredo Therapeutics, Inc., as amended and
	incorporated by reference to Exhibit 10.45 of the Registrant's Annual Report Form 10-K for the fiscal year ended December 31,
	2007.
10.35***	Agreement between the Registrant and the Whiting-Turner Contracting Company, dated November 5, 2007, as amended by
	Amendment No. 1, dated November 21, 2008, incorporated by reference to Exhibit 10.44 of the Registrant's Annual Report on
	Form 10-K for the fiscal year ended December 31, 2008.
10.36**	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.
10.37**	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.
10.38**	Form of terms and conditions for awards granted to Non-Employees by the Registrant under the United Therapeutics Corporation
	Share Tracking Awards Plan, incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q for the
	quarter ended June 30, 2008.
10.39**	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.

Exhibit No.	Description
10.40**	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.
10.41	Stock Purchase Agreement, dated as of November 14, 2008, between the Registrant and Eli Lilly and Company, incorporated by
	reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on December 24, 2008.
10.42***	License Agreement, dated as of November 14, 2008, by and between Eli Lilly and Company and the Registrant, incorporated by
	reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on December 24, 2008.
10.43***	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.
10.44**	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
10.45	the quarter ended March 31, 2009.
10.45	Amendment No. 2 to Construction Agreement between the Registrant and the Whiting-Turner Contracting Company, dated
	May 29, 2009, incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended
10 46**	June 30, 2009.
10.46**	Form of Amendment to Employment Agreement between the Registrant and each of Roger Jeffs, Paul Mahon and John Ferrari, each dated as of February 22, 2010.
10.47	Distribution Agreement dated August 17, 2009 between the Registrant and Accredo Health Group, Inc.
10.47	Form of terms and conditions for awards granted to Employees by the Registrant on or after January 1, 2010, under the United
10.46	Therapeutics Corporation Share Tracking Awards Plan.
12.1	Computation of Earnings to Fixed Charges.
21	Subsidiaries of the Registrant.
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

<sup>\*</sup> 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.

<sup>\*\*</sup> Designates management contracts and compensation plans.

<sup>\*\*\*</sup> Confidential treatment has been granted with respect to certain portions of this exhibit pursuant to Rule 24b-2 of the Securities Act of 1934.

# Form of Amendment to Employment Agreements

THIS AMENDMENT is made effective as of February 22, 2010, to the Employment Agreement between ("Executive") and United Therapeutics Corporation (the "Company"), dated , as amended from time-to-time (the "Agreement").

WHEREAS, the Agreement provides for accelerated vesting of Executive's stock options to purchase shares of the Company's Common Stock in the event of Executive's termination in certain circumstances;

WHEREAS, the parties intend that the Agreement also provide for accelerated vesting of share tracking awards in the event of Executive's termination in certain circumstances;

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereby amend the Agreement, as follows:

1. The final sentence of <u>Section 8(d)</u> of the Agreement presently provides as follows:

"Additionally, in the event of termination contemplated in this Section 8(d), all unvested options granted to Executive prior to Executive's Date of Termination shall immediately vest in Executive upon Executive's Date of Termination, and the exercise period for each such previously-granted option shall be the full remaining duration of the term of each such option."

The foregoing final sentence of <u>Section 8(d)</u> shall be replaced in its entirety with the following sentence, effective as of the date first set forth above:

"Additionally, in the event of termination contemplated in this Section 8(d), (i) all unvested options to purchase shares of the Company's Common Stock; (ii) all unvested share tracking awards; and (iii) all other awards subject to vesting, in each case granted to Executive prior to Executive's Date of Termination, shall immediately vest in Executive upon Executive's Date of Termination, and the exercise period for each such previously-granted option, share tracking award or other award shall be the full remaining duration of the term of each such option, share tracking award or other award."

2. No other provisions of the Agreement shall be affected by this Amendment, and all other provisions of the Agreement shall remain in full force and effect.

In witness whereof, the parties have executed this Amendment effective as of the date first set forth above.

UNITED THERAPEUTICS CORPORATION
Name: Title:
EXECUTIVE:
Printed Name:
2

#### **DISTRIBUTION AGREEMENT**

THIS DISTRIBUTION AGREEMENT (" **Agreement**") is made as of August 17, 2009 (the " **Effective Date**"), by and between United Therapeutics Corporation (" **UT**"), a Delaware corporation, with offices at 1110 Spring Street, Silver Spring, Maryland and Accredo Health Group, Inc (" **DISTRIBUTOR**"), a Delaware corporation, with offices at 1640 Century Center Parkway, Memphis, Tennessee 38134.

#### Recitals

- A. WHEREAS, DISTRIBUTOR has represented that it possesses the necessary expertise, financial resources and marketing organization to dispense and distribute UT Product (as hereinafter defined) and desires to acquire from UT the right to sell, market, distribute and maintain UT Product in the Territory (as hereinafter defined);
- B. WHEREAS, UT is willing to appoint DISTRIBUTOR and DISTRIBUTOR is willing to accept appointment, as a distributor of UT Product in the Territory on the terms and conditions contained herein; and
- C. WHEREAS, the Parties hereto believe that the business relationship regarding UT Product and related support will be mutually advantageous.

NOW, THEREFORE, in consideration of the mutual promises and covenants hereinafter set forth, the Parties agree as follows:

# **ARTICLE 1: INTRODUCTORY PROVISIONS**

- 1.1 <u>Defined Terms</u>. The following terms, when used in capitalized form in this Agreement, shall have the meanings set forth below:
  - (a) "Agreement" shall mean this Distribution Agreement entered into by and between UT and DISTRIBUTOR as of the Effective Date.
  - (b) "Adverse Event" shall mean any "Adverse Drug Experience" as defined in 21 CFR 310.305, 21 CFR 314.80 and/or 21 CFR 600.80 (as applicable) or any replacements thereto.
  - (c) "Affiliate" when used with reference to either Party shall mean any corporation controlling, controlled by or under common control with the said Party and any officer, director or employee of such corporation, as the case may be. For purposes hereof, "control" shall mean ownership, directly or indirectly, of more than fifty percent (50%) of the securities having the right to vote for the election of directors, in the case of a corporation, and more than fifty percent (50%) of the beneficial interest in the capital, in the case of a business entity other than a corporation.
  - (d) "Applicable Laws" shall mean all laws, statutes, ordinances, codes, rules, and regulations that have been enacted by a government authority and which are in force as of the Effective Date or come into force during the term of this Agreement, in each case to the extent that the same are applicable to the performance by the Parties of their respective obligations under this Agreement, including, with respect to the United States, the Prescription Drug Marketing Act, the Federal Food, Drug and Cosmetics Act of 1938, as amended, the Health

Insurance Portability and Accountability Act, the Federal Anti-Kickback Statute, and any applicable FDA regulations.

- (e) "Clean Prescription" shall mean a referral for which benefits have been verified and that includes a valid prescription that does not: (i) require physician, patient, or any third party intervention or information; (ii) involve backorder, short supply, allocation, or recall; or (iii) involve a referral that is subsequently canceled or requested to be held for future processing.
- (f) "Commercially Reasonable Efforts" shall mean with respect to each Party, commercially reasonable efforts in accordance with the business, legal, medical and scientific judgment of a similarly situated company, and in accordance with the efforts and resources a similarly situated company would use taking into account reasonable commercial judgment and other relevant factors.
- "Confidential Information" shall mean all information disclosed by one Party ("Disclosing Party") to the other Party ("Receiving Party"), regardless of the form in which it is disclosed, including information relating to the Disclosing Party's markets, product specific payer policies, databases, customers, products, patents, inventions, procedures, methods, designs, strategies, plans, assets, liabilities, prices, costs, revenues, profits, organization, employees, agents, resellers or business in general, and with respect to UT as Disclosing Party, information embodied in UT Product. The following shall not be considered Confidential Information:
  - (i.) Information which is or becomes in the public domain through no fault or act of the Receiving Party;
  - (ii.) Information which was independently developed by the Receiving Party without the use of or reliance on Confidential Information;
  - (iii.) Information which was provided to the Receiving Party by a third party under no duty of confidentiality to the Disclosing Party; or
  - (iv.) Information that is required to be disclosed by Applicable Laws, provided, however, prompt prior notice thereof shall be given to the Disclosing Party.
- (h) "Customer" shall mean any hospital, physician, health care company, Included Patient, distributor or other person or entity that is legally entitled to purchase the UT Product for use in the Territory.
- (i) "Designated Shipment Location" shall mean the Designated Storage Location(s) to which UT has agreed to ship Units of UT Product as set forth in Attachment E attached hereto.
- (j) "Designated Storage Location" shall mean the locations of DISTRIBUTOR's facilities or pharmacies owned by DISTRIBUTOR or its Affiliate(s) for the storage of the Units of UT Product shipped to DISTRIBUTOR's Designated Storage Locations as set forth in Attachment E attached hereto.
- (k) "DISTRIBUTOR" shall mean Accredo Health Group, Inc. and its wholly owned subsidiaries.

- (1) "**Effective Date**" shall mean the date first above written.
- (m) "Force Majeure" shall mean any event, not existing as of the Effective Date and not reasonably within the control of the Parties as of such date, which, in whole or in material part, prevents or makes commercially unreasonable one Party's performance of its obligations under this Agreement. Force Majeure shall include, without limitation: fire, storm, earthquake, flood, acts of state, war or civil unrest, labor dispute, inability to obtain labor or materials, and prolonged shortage of energy or any other supplies.
- (n) "Good Distribution Practice" shall mean that practice of purchasing, storing and shipping a regulated pharmaceutical product and billing to and collecting from customers for a regulated pharmaceutical product in accordance with legal requirements and the standards and customary industry commercial practices.
- (o) "Included Patient" shall mean an individual diagnosed with pulmonary arterial hypertension ("PAH") who is prescribed UT Product.
- (p) "Level 1 Appeal" shall mean an appeal of a reimbursement claim denial by a Third Party Payer due to an incomplete or improperly submitted reimbursement claim or other similar administrative oversight.
- (q) "Level 2 Appeal" shall mean an appeal of a reimbursement claim denial by a Third Party Payer, whether such denial is first asserted upon verification of reimbursement or following submission of a reimbursement claim, because: (i) the applicable policy covering the Included Patient does not include UT Product as a covered benefit, or (ii) the Included Patient falls within a class of persons who are all denied coverage for UT Product as the result of the application of a general policy.
- (r) "PAP Patient" shall mean any Included Patient who is enrolled in the Patient Assistance Program as established by UT from time to time and operated in accordance with <u>Attachment C</u> hereto. UT shall provide DISTRIBUTOR with the eligibility criteria for this program.
- (s) "Price" shall mean the Wholesale Acquisition Cost for UT Product as set forth on Attachment A hereto.
- (t) "UT Trademarks" shall mean any of the UT trademarks, logotypes and trade names listed on <u>Attachment B</u> hereto, as such attachment may be modified from time to time by UT during the term of this Agreement.
- (u) "Parties" shall mean UT and DISTRIBUTOR collectively.
- (v) "Party" shall mean either UT or DISTRIBUTOR.
- (w) "Territory" shall mean the United States, including its territories and possessions, the fifty states and the District of Columbia only, unless otherwise expressly agreed in writing by the Parties.
- (x) "Third-Party Payers" shall mean managed care providers, health maintenance organizations, insurance companies, self-insurance programs of employers, third-

party administrators, the United States Medicare and Medicaid programs, and other similar entities.

- (y) "Tyvaso Inhalation System" shall mean the Optineb ® portable nebulizer system and all related supplies and accessories.
- (z) "Unit of UT Product" shall mean the combination of UT Product, package insert and other items as may be determined and supplied by UT to DISTRIBUTOR, in each instance contained within a standard outer package supplied by UT and labeled in accordance with applicable legal requirements.
- (aa) "UT Product" or "Product" shall mean treprostinil sodium for inhalation only, a pharmaceutical product administered by the Tyvaso Inhalation System for the treatment of PAH to be marketed in the Territory under the brand name Tyvaso ®.
- (bb) "WAC" shall mean the then-current Wholesale Acquisition Cost of UT Product as determined by UT.
- Other Rules of Interpretation. Unless the context otherwise requires, (i) words of any gender include each other gender; (ii) words using the singular or plural number also include the plural or singular number, respectively; (iii) the terms "hereof," "herein," "hereby" and derivative or similar words refer to this entire Agreement; (iv) the terms "Article" or "Section" refer to the specified Article or Section of this Agreement; (v) the word "including" shall mean "including, without limitation;" (vi) the word "consent" shall mean "consent, not to be unreasonably withheld or delayed"; (vii) the word "or" shall be disjunctive but not exclusive; (viii) the words "made available" shall mean that the information referred to has been made available if requested by the party to whom such information is to be made available; and (ix) all references herein to "days" shall mean calendar days.

#### **ARTICLE 2: MUTUAL REPRESENTATIONS AND WARRANTIES**

- Authority. Each Party represents and warrants that it possesses all corporate power and authority necessary to enter into this Agreement and to perform its obligations under this Agreement. All corporate acts and other proceedings required to be taken by or on the part of each Party to authorize it to perform its obligations under this Agreement have been duly and properly taken. This Agreement has been duly executed and delivered by each Party and constitutes legal, valid and binding obligations of each Party enforceable in accordance with its terms, subject to the application of general principles of equity.
- 2.2 <u>No Conflicts</u>. Each Party represents and warrants that the execution and performance of this Agreement will not conflict with or violate any other agreement or obligation binding on it.
- 2.3 <u>Approvals</u>. Except as expressly provided herein, each Party represents and warrants that no approval, authorization, consent or other order or action of or filing with any court, administrative agency or other governmental authority is required for the execution and delivery by such Party of this Agreement or its consummation of the transactions contemplated by this Agreement.
- 2.4 <u>Debarment and Exclusion Certification Requirements</u>. Each Party certifies that it has not been debarred under the provisions of the Generic Drug Enforcement Act of 1992, 21 U.S.C. § 335(a) and (b), and does not appear on the "list of excluded"

individuals/entities" ("LEIE") maintained by the Office of the Inspector General of the U.S. Department of Health & Human Services, available at http://oig.hhs.gov/fraud/exclusions/listofexcluded.html. In the event that, during the term of this Agreement, either Party (i) becomes debarred, (ii) is placed on the LEIE, or (iii) receives notice of an action or threat of an action with respect to its debarment or placement on the LEIE, such Party shall notify the other Party immediately. Each Party hereby certifies that it has not and will not use in any capacity the services of any individual, corporation, partnership or association that has been debarred under 21 U.S.C. § 335 (a) and (b) or that appears on the LEIE. In the event that either Party becomes aware of the debarment, threatened debarment, appearance or threatened placement on the LEIE of any individual, corporation, partnership or association providing services to the other Party that directly or indirectly relate to activities under this Agreement, the other Party shall be immediately notified. In the event of an actual debarment or exclusion of DISTRIBUTOR or its owners during the term of this Agreement, this Agreement shall, as of, or prior to, the effective date of such debarment or exclusion, automatically terminate. In the event of an actual debarment or exclusion of any DISTRIBUTOR employee, agent or contractor during the term of this Agreement, such employee, agent or contractor must immediately cease providing any services to UT under this Agreement, and UT shall have the option of immediately terminating this Agreement.

# **ARTICLE 3: APPOINTMENT**

- 3.1 <u>Scope; Non-exclusive</u>. UT hereby appoints DISTRIBUTOR, and DISTRIBUTOR hereby accepts such appointment, as a distributor of UT Product during the term of this Agreement, subject to the terms and conditions of this Agreement. This appointment is non-exclusive, and UT reserves the right to appoint additional distributors in the Territory and to distribute UT Product in the Territory on its own behalf.
- 3.2 <u>Sub-distributors</u>. DISTRIBUTOR shall not, without the prior written approval of UT, appoint any distributors or agents to act on behalf of DISTRIBUTOR (collectively, "**Sub-distributors**") to distribute UT Product within the Territory, other than any of its Affiliates. DISTRIBUTOR shall at all times remain fully liable for the performance of any approved sub-distributors and DISTRIBUTOR shall provide UT with a written acknowledgement executed by each Sub-distributor that it has read this Agreement and agrees to be bound by its terms and conditions, including those contained in the attachments hereto.
- 3.3 <u>Sales Outside the Territory</u>. DISTRIBUTOR shall not distribute, sell or otherwise provide UT Product outside of the Territory and shall not advertise, promote or solicit customers for UT Product outside the Territory.

# **ARTICLE 4: OBLIGATIONS OF DISTRIBUTOR**

- 4.1 <u>Marketing</u>. DISTRIBUTOR shall use Commercially Reasonable Efforts to fund and support ongoing marketing of its distribution of UT Product, consistent with DISTRIBUTOR's normal funding and support for its overall distribution activities. In addition, DISTRIBUTOR shall use its Commercially Reasonable Efforts to fund and support ongoing sale of UT Product. Such Commercially Reasonable Efforts shall include, but not be limited to:
  - (a) Maintaining throughout the Territory adequate marketing, sales, and order-fulfillment staff who are adequately trained on PAH and UT Product. The

Parties acknowledge that this obligation requires DISTRIBUTOR to have the capability to provide the foregoing services throughout the Territory, but does not require DISTRIBUTOR to have a physical office within each jurisdiction within the Territory;

- (b) Promptly responding to all inquiries from Customers, including responding to complaints, processing all orders and effecting all shipments of UT Product for Included Patients in accordance with the timelines and other terms and conditions contained within this Agreement;
- (c) Providing UT Product to Included Patients pursuant to physician orders;
  - (i.) Exhibiting at conventions, trade shows, product fairs or other comparable events involving patients, Included Patients and/or physician specialists who have a high propensity to diagnose and treat patients suffering from PAH for the purpose of providing information on UT Product and/or educating attendees.
- (d) Diligently investigating and pursuing all leads and inquiries of potential Customers referred to DISTRIBUTOR by UT and reporting within 7 days on the status of all such leads and inquiries. Notwithstanding the foregoing, nothing in this Agreement shall be construed as requiring DISTRIBUTOR to admit to its service, or provide UT Product to, any particular individual (s) or types of individual(s). Adding Included Patients to its service is in DISTRIBUTOR's sole discretion.
- 4.2 <u>Policies and Procedures</u>. DISTRIBUTOR shall use Commercially Reasonable Efforts to comply with UT's Policies and Procedures as provided and updated by UT from time to time and as accepted by DISTRIBUTOR. If any such Policies and Procedures contradict this Agreement, the terms of this Agreement shall control.
- 4.3 <u>Written Assurance</u>. DISTRIBUTOR hereby assures UT that DISTRIBUTOR shall not export UT Product from the Territory to any destination to which re-export requires a license under the United States Export Administration Regulations.
- 4.4 <u>Product Specifications</u>. DISTRIBUTOR shall store UT Product in accordance with all directions accompanying UT Product in order to maintain UT Product in accordance with UT- and FDA-approved specifications. DISTRIBUTOR shall dispense UT Product as prescribed, in accordance with all applicable pharmacy requirements. The Parties acknowledge that UT shall not have any rights, obligations, responsibilities, oversight or role of any kind or nature concerning DISTRIBUTOR's practice of pharmacy in compliance with all applicable state pharmacy regulations and consistent with DISTRIBUTOR's then current practices.
- 4.5 Pharmacy and Home Health Care Services. DISTRIBUTOR may create its own educational materials concerning UT Product or PAH ("Educational Materials") for distribution by DISTRIBUTOR in accordance with this Agreement and DISTRIBUTOR's obligations as a health care provider and pharmacy; provided, however, that all such Educational Materials shall: (i) be consistent with the contents of UT Product package insert approved by the FDA; (ii) comply with the conditions and requirements of all applicable state pharmacy regulations mandating the provision of patient educational materials on prescription drugs and their administration, and (iii) not be used by DISTRIBUTOR to promote, market or sell UT Product. Further, to the extent

that any UT Trademarks are included in such Educational Materials, then DISTRIBUTOR shall notify UT in writing prior to use of such materials.

- 4.6 <u>Complaints</u>., DISTRIBUTOR shall process any and all complaints received from Customers in the Territory regarding the UT Product in accordance with <u>Section 9.3</u> of this Agreement.
- 4.7 <u>Inventory</u>. DISTRIBUTOR shall maintain at all times adequate inventory of Units of UT Product (the "**Inventory**") as are mutually considered by UT and DISTRIBUTOR to be sufficient to meet Customers' anticipated demands for UT Product. Such requirements may be adjusted by UT and DISTRIBUTOR from time to time. Notwithstanding the foregoing, DISTRIBUTOR shall maintain a minimum Inventory level at all times between the following minimum and maximum:
  - (a) At a minimum: no less than thirty (30) days' inventory on hand at any time based on current demand and usage of UT Product by DISTRIBUTOR's customers; and
  - (b) At a maximum no greater than seventy-five (75) days' inventory on hand based on current demand and usage of UT Product by DISTRIBUTOR's customers; and
  - (c) calculations of inventory levels shall be based on the current monthly average usage of UT Product by Included Patients ("Usage"). Usage shall be equal to the rolling average number of Units of UT Product distributed by DISTRIBUTOR each month for the previous three (3) months.

DISTRIBUTOR shall ensure that it purchases enough Inventory each month to meet Usage demand for UT Product in addition to the thirty (30) day minimum Inventory level requirement. From time to time, UT and DISTRIBUTOR may mutually agree to reasonably change the above-listed minimum and maximum requirements and DISTRIBUTOR shall adjust its Inventory accordingly.

4.8 <u>Storage of UT Product</u>. DISTRIBUTOR shall store and maintain UT Product solely at the Designated Storage Locations described in Attachment E hereto. DISTRIBUTOR shall store, maintain and handle the Product in accordance with Good Distribution Practice, Applicable Laws, the UT Product package insert and UT's written instructions, including any requirements with respect to racking, temperature, light, darkness, vibration and rotation. The UT Product must be stored at the temperature range specified by UT to ensure safety and reliability, and rotated so that the oldest unexpired Units of UT Product are shipped before newer unexpired Units of UT Product, unless UT specifies otherwise. DISTRIBUTOR shall promptly notify UT of any material or significant change in its storage conditions or shipping procedures for UT Product. DISTRIBUTOR shall maintain complete and accurate records for inspection by UT or its representatives, upon ten (10) business days' prior notice during regular business hours, of all movements and transactions involving UT Product. Such records shall reflect unit, lot number and Customer information, including defective or returned Units of UT Product, such that the Units of UT Product may be traced for purposes of stock reconciliation, recall and general marketing and shipping review. UT shall also have the right to inspect DISTRIBUTOR's storage conditions and shipping procedures for UT Product upon ten (10) business days' prior notice, during regular business hours. DISTRIBUTOR shall not manufacture, mix, process, combine or incorporate UT Product alone or into any other substance.

- 4.9 <u>Distributor Expenses</u>. DISTRIBUTOR shall bear all of its own costs and expenses incurred in carrying out its obligations under this Agreement, including, but not limited to, all rents, salaries, commissions, demonstration, travel and accommodation.
- 4.10 <u>Distributor Reporting</u>. DISTRIBUTOR shall complete a series of regular reports as described in <u>Attachment F</u> hereto. The reports are due no later than the 10th of each month following the end of the respective reporting periods and constitute Confidential Information of DISTRIBUTOR. The Parties acknowledge that Applicable Laws or existing contractual relationships with Third-Party Payers may restrict DISTRIBUTOR's ability to collect, use, include and/or disclose as Data certain patient- and physician-specific data. DISTRIBUTOR warrants that it will not provide patient- and physician-specific data and information where so limited by such existing contractual relationships or Applicable Laws. New contracts with Third Party Payers and the enactment of new Applicable Laws which further limit the disclosure of patient- and physician-specific data and information shall not be deemed to be a change in a law for purposes of this Agreement. Neither Party may resell data to IMS, Wolters Kluwer, or any other data aggregation service without the express written consent of the other Party.
- 4.11 Distributor Representations.
  - (a) DISTRIBUTOR acknowledges that UT Product constitutes a sensitive therapeutic drug, and that distribution and handling of the UT Product requires specialized training and dedication to Customer needs. DISTRIBUTOR represents and warrants that it will train and deploy its agents and employees in the manner necessary to meet these special requirements.
  - (b) DISTRIBUTOR represents and warrants that it and its officers, directors, agents and/or employees as applicable are qualified to perform the services and activities described in this Agreement and that all licenses and/or approvals necessary to conduct such services and activities have been obtained and shall be maintained throughout the term of this Agreement.
- 4.12 DISTRIBUTOR provides appropriate pharmacy services as required by Applicable Laws. DISTRIBUTOR shall also perform the following activities in support of the distribution of the UT Product:
  - (a) Inhalation Device: DISTRIBUTOR shall ensure that its personnel are trained on the use of the Tyvaso Inhalation System and capable of providing such training to Customers. Training and education for use must comply with the technical and administrative requirements specified in the package insert for Tyvaso and the instructions for use manual for the Tyvaso Inhalation System.
  - (b) Included Patient Benefit Verification: DISTRIBUTOR shall handle Included Patient enrollment, initial processing, insurance eligibility and benefits verification. If DISTRIBUTOR is unable to service a patient, then DISTRIBUTOR shall immediately, i.e., no more than five (5) business days from the initial receipt of the referral, re-direct the referral to an appropriate specialty pharmacy participating in the Tyvaso distribution network.
    - (i.) Upon receipt of a prescription for UT Product, DISTRIBUTOR shall immediately fax the prescribing physician to confirm receipt of the prescription. No more than one (1) business day from receipt of the prescription, DISTRIBUTOR shall perform verification of insurance

coverage for UT Product. If the prescription is received after 2 p.m. Eastern time, DISTRIBUTOR may have until the end of the next business day to perform verification of insurance coverage for UT Product.

- (ii.) DISTRIBUTOR shall take all necessary actions to verify, or assist Customers in verifying, insurance coverage for UT Product including, without limitation, researching and attempting to determine: (1) all Customer information and coverage parameters, including all relevant clinical documentation; (2) if UT Product is covered, under what type of plan (e.g., a "medical plan" or a "pharmacy plan"), the Included Patient cost share amount, if any, and the rate of reimbursement, if available; (3) whether prior authorization is required for reimbursement; (4) if prior authorization is required, what information the Customer must submit in order to receive such authorization; and (5) whether any other activities, submissions or approvals are required to obtain reimbursement promptly and to the fullest extent permitted by the Third-Party Payer. During the process of benefit verification, DISTRIBUTOR shall communicate with the referral source and provide information to the prescribing physician in a time and manner sufficient for the circumstances.
- (iii.) DISTRIBUTOR shall record the results of its research on the foregoing and shall report such information to the Customer within one (1) business day from receipt. [Rachel & Mike are OK with this]
- (iv.) If the Third-Party Payer requires prior authorization, then DISTRIBUTOR shall, within one (1) business day, notify and assist the Customer with questions relating to the requirements for prior authorization.
- (v.) If, prior to the submission of a claim for reimbursement, a Third-Party Payer informs DISTRIBUTOR that the Customer or UT Product is not eligible for coverage, then, within one (1) business day, DISTRIBUTOR shall make such inquiries of the Third-Party Payer as shall be necessary to determine the requirements for submission of an appeal of the denial of coverage. DISTRIBUTOR shall promptly record the results of this inquiry and report such information to the Customer and to the UT managed markets designee.
- (vi.) If a Customer notifies DISTRIBUTOR of a denial of coverage and DISTRIBUTOR determines that an appeal of the denial of coverage would require a Level 1 Appeal, then DISTRIBUTOR shall immediately notify the Customer. The Customer, at its option, may elect to pursue the Level 1 Appeal directly or request DISTRIBUTOR's assistance. If the Customer elects to have DISTRIBUTOR assist with the Level 1 Appeal, DISTRIBUTOR, at its cost, shall use reasonable efforts to assist Customer, and if an Included Patient is pursuing the Level 1 Appeal on his/her own behalf, DISTRIBUTOR, at its cost, shall promptly initiate (at the latest within one (1) business day) and pursue such Level 1 Appeal in accordance with the Third-Party Payer's processes. Upon request, UT shall provide reasonable assistance to DISTRIBUTOR, including assistance with preparing applications and participation in telephone conferences and meetings with representatives of the Third-

Party Payer. DISTRIBUTOR shall notify the Customer immediately following any interim and final determinations by the Third Party Payer in response to any Level 1 Appeal. All documents prepared as part of a Level 1 Appeal, and any information obtained in connection therewith, shall be promptly recorded.

(vii.) If DISTRIBUTOR determines that an appeal of the denial of coverage would require a Level 2 Appeal, DISTRIBUTOR shall notify the Customer, the Included Patient, and UT (if DISTRIBUTOR deems necessary and if the Included Patient consents) immediately of such determination. The Included Patient, at his or her option, may elect to pursue the Level 2 Appeal directly or to request that Customer assist with pursuit of the Level 2 Appeal. If Customer assists with the pursuit of a Level 2 Appeal, DISTRIBUTOR shall provide reasonable assistance to Customer, including assistance with preparing applications and participation in telephone conferences and meetings with representatives of the Third-Party Payer.

# (c) Dispensing Activities:

- (i.) Upon completion of benefits investigation and, if necessary, after prior authorization, DISTRIBUTOR shall process Customer's order for UT Product if Customer chooses to place an order. If Customer elects not to place an order at the time that Included Patient benefits are reported, DISTRIBUTOR shall attempt to determine the reason for Customer's choice (e.g., "Included Patient to receive UT Product at an alternate facility", "physician elected not to order UT Product", or "Included Patient elected not to receive UT Product"). DISTRIBUTOR shall immediately record this information.
- (ii.) When the prescriber is the Customer, DISTRIBUTOR shall attempt to contact the Included Patient on the same day that the benefit verification has been completed for the Included Patient in order to inform the Included Patient of his or her cost share amount, if any, and to make arrangements with the Included Patient for collection such cost share amount, if any, and to introduce the Included Patient to the DISTRIBUTOR's services. DISTRIBUTOR may delay shipment of UT Product until the Included Patient's cost share amount is satisfied in full. DISTRIBUTOR shall be solely responsible for submitting claims for reimbursement directly to the Third-Party Payer for the applicable reimbursable amount (deducting any Included Patient cost share amount).
- (iii.) DISTRIBUTOR shall dispense the Unit(s) of UT Product (along with a current package insert) to Included Patients pursuant to a valid prescription and in accordance with Applicable Laws. Upon receipt of a Clean Prescription, DISTRIBUTOR shall ensure that the Included Patient receives UT Product within one (1) business day from receipt of such prescription, or at such other time as the Included Patient may request.
- (d) Follow up Activity Generally: Unless DISTRIBUTOR is otherwise required to contact Customer sooner or more often, DISTRIBUTOR shall contact Customer
  - two (2) business days after receipt of a prescription/referral and every two (2) business days thereafter to update Customer on the status of a benefits investigation/prior authorization/appeal or other related matter. When required to obtain additional information to complete a valid prescription/coverage determination/prior authorization/appeal or related matter, DISTRIBUTOR shall communicate all required information to the appropriate party and continue to contact such party every business day until the needed information is received or the matter is otherwise closed.
- (a) Social Services: DISTRIBUTOR shall engage in patient advocacy and upon receipt of inquiries from or Customers, provide notice to such Customers of alternate funding sources, certain hardship reimbursement support, and certain indigent and patient assistance programs, including UT's PAP as described in <a href="https://distribution.org/linearing-new-notice">https://distribution.org/linearing-new-notice</a> to participate in the PAP within one (1) business day from the date of such request, with notice to the referral source (via fax, email or mail) as well.
- (b) Product & Ancillary Supply Distribution: DISTRIBUTOR shall make available and/or dispense with UT Product, as necessary and appropriate for the applicable site of service (e.g., health care provider/physician office, clinic, hospital outpatient setting, pharmacy-owned facility, home), the contents of the UT Product package and supplies necessary for UT Product administration.
- (c) Education: DISTRIBUTOR shall provide its standard educational support (including the provision of any UT Materials or Educational Materials) regarding UT Product administration and safety to Customers and caregivers involved in treating Included Patients. DISTRIBUTOR shall promptly respond to questions from managed care organizations and other Third-Party Payers about UT Product. Notwithstanding the foregoing, the provision of such educational services shall be performed in accordance with the obligations contained in this Agreement including those with respect to training.
- (e) Nursing Services:
  - (i.) DISTRIBUTOR shall make available on an as-needed basis its standard telephonic nursing services in accordance with its standard policies and procedures. If DISTRIBUTOR receives requests for administration for UT Product, it

- shall facilitate such requests in accordance with its standard business practices. DISTRIBUTOR's standard telephonic nursing services shall be rendered by nurses who have the requisite and necessary training, experience, licenses and permits in accordance with Applicable Laws. DISTRIBUTOR may not seek reimbursement for its standard telephonic nursing services directly from UT or from the Included Patient.
- (i.) the Parties shall work together in good faith to develop an integrated nursing program to adequately support UT Product, Included Patients and Customers with the following elements:
  - (a) All nurses shall be trained by DISTRIBUTOR with respect to UT Product and PAH prior to any interaction with an Included Patient or Customer. All nurses (including per diem nurses) shall

pass competency testing on the following topics (at a minimum): PAH and PAH drug classes; UT Product; Patient needs whether naïve or experienced; Administration of UT Product; Training patients on administration of UT Product; Relevant nursing standards of care for administration of UT Product; Any and all devices/pumps that are to be used with UT Product; An "ideal patient encounter"; and HIPAA, patient privacy and any other applicable legal requirements;

- (b) DISTRIBUTOR shall provide updated training as necessary for nurses to excel in the foregoing competency areas;
- (c) DISTRIBUTOR shall update and refresh training and require regularly updated certification testing when new information becomes available or when a nurse has not provided services for an extended period of time;
- (d) DISTRIBUTOR shall make available to UT upon request, for UT's review and comment, training materials related to UT Product and the administration and support of UT Product;
- (e) DISTRIBUTOR shall make available to UT records of completion of related training upon UT's request;
- (f) DISTRIBUTOR shall manage nonperformance of nurses (including per diem nurses) through appropriate measures, including re-training, discipline or removal; and
- (g) DISTRIBUTOR shall reasonably provide nurses who are able to speak the same language as the Included Patient or a translation service.
- (f) Additional Performance Requirements: As part of the overall activities performed in support of the distribution of UT Product, DISTRIBUTOR agrees to keep careful records of the following data points and maintain the requisite levels of competency for each data point and shall provide such data in reports to UT as UT reasonably requests, but no less than quarterly:
  - (i.) **ASA:** meaning the average speed DISTRIBUTOR takes to answer a call measured over a calendar month. DISTRIBUTOR shall use its Best Efforts to ensure that the ASA does not exceed 15 seconds, and in any event, at least 95% of all calls to DISTRIBUTOR shall be answered by a live person within fifteen (15) seconds;
  - (ii.) Calls Dropped: meaning the percentage of calls that are dropped before being answered over the course of a calendar month. DISTRIBUTOR shall use its Best Efforts to ensure that the Calls Dropped does not exceed 2%; and
  - (iii.) AHT: meaning the average hold time experienced by a caller as measured over the course of a calendar month. DISTRIBUTOR shall use its Best Efforts to ensure that the AHT does not exceed 45 seconds,

and in any event, at least 95% of calls placed on hold will be on hold for less than forty-five (45) seconds.

- 4.13 Tyvaso Continuing Patient Compliance, Support and Education Program. As set forth in Attachment G hereto and in accordance with this Section 4.13, DISTRIBUTOR agrees to perform all required services under the Continuing Patient Compliance, Support and Education Program for Tyvaso ("CPCSEP Services") and UT agrees to pay DISTRIBUTOR a fee for such CPCSEP Services ("Service Fee").
  - (a) DISTRIBUTOR warrants that it will perform the CPCSEP Services in a professional manner, in compliance with industry standards, and in accordance with the descriptions and representations set forth on <u>Attachment G</u> hereto or as otherwise mutually agreed by the Parties from time to time.
  - (b) DISTRIBUTOR shall submit detailed monthly invoices to UT setting forth a description of the CPCSEP Services actually performed and the corresponding Service Fee due. The foregoing invoices are due to UT within ten (10) days of the end of each calendar month. UT's shall pay DISTRIBUTOR within sixty (60) days from receipt of each invoice.
  - (c) The Parties agree and acknowledge that the Service Fee paid hereunder has been determined through good faith and armslength negotiation to be the fair market value of the CPCSEP Services to be rendered. No amount paid or reimbursed hereunder is intended to be, nor shall it be construed as, an offer or payment made, whether directly or indirectly, to induce the referral of patients, the purchase, lease or order of any item or service, or the recommending of the purchase, lease or order of any item or service.
  - (d) By accepting payment of the Service Fee from UT, DISTRIBUTOR represents and warrants to UT that DISTRIBUTOR has actually performed the CPCSEP Services as invoiced and was obligated to perform the CPCSEP Services (or any substantially similar activity) solely pursuant to the obligations in this <u>Section 4.13</u> and <u>Attachment G</u> hereto. The Parties each agree that the Service Fee is not a discount but instead represents a fair amount in consideration for the CPCSEP Services described in this <u>Section 4.13</u> and <u>Attachment G</u> hereto. Further, in recognition of the foregoing, DISTRIBUTOR warrants that it will retain the Service Fee for its own account.
  - (e) The CPCSEP Services and corresponding Service Fees will be evaluated by UT on an annual basis and UT may terminate all or a portion of the CPCSEP Services at any time upon thirty (30) days prior written notice to DISTRIBUTOR without any additional fee or expense.
- 4.14 DISTRIBUTOR agrees to make available all personnel responsible for overseeing/managing the activities related to the distribution of UT Product for quarterly meetings with UT personnel at reasonably agreed upon times and places in order to review and assess DISTRIBUTOR performance relative to the various obligations described in this Agreement.

#### ARTICLE 5: OBLIGATIONS OF UT

- 5.1 <u>Training</u>. UT may in its discretion provide training to DISTRIBUTOR for UT Product at a time and in a manner as determined by DISTRIBUTOR.
- 5.2 <u>UT Materials</u>. UT shall provide DISTRIBUTOR, upon DISTRIBUTOR's request, with reasonable quantities of sales and marketing materials for UT Product as they are developed by UT, including but not limited to reprints, brochures, package inserts, peer reviewed articles and other scientific and medical information regarding UT Product, informational material and other marketing literature ("UT Materials"), for use and distribution by DISTRIBUTOR in accordance with this Agreement. DISTRIBUTOR shall use the UT Materials in accordance with UT's written directions, including providing the package insert to Customers until such time as the package insert is included with UT Product. DISTRIBUTOR shall not revise, alter, change, supplement or reproduce in any manner the UT Materials and their content as provided by UT without UT's advance written permission. Nothing in this provision requires UT to create any specific materials.

#### **ARTICLE 6: ORDERS FOR PRODUCTS**

- Purchase Orders. DISTRIBUTOR shall submit written purchase orders to UT by electronic mail or in accordance with written instructions provided by UT. Purchase Orders shall be submitted once per month by the 10 th day of the month. Each such order shall set forth: (a) the package reference for the UT Product ordered (i.e. "Starter Kit", "Re-Supply Kit", or "Supplemental Refill"), including item numbers; (b) quantities in multiples of ten (10) per package reference; (c) requested delivery dates; (d) specific shipping instructions; and (e) if applicable, any relevant export control information or documentation to enable UT to comply with Applicable Laws. Except as otherwise agreed by UT, DISTRIBUTOR shall submit such purchase orders at least five (5) business days prior to the requested delivery dates. DISTRIBUTOR is responsible for good Inventory management processes and subsequent purchases should not deviate negatively by more than 15% from the previous PO unless unexpected events occur and are communicated to UT in advance in writing. DISTRIBUTOR may only purchase UT Product from UT or through the acquisition of all or part of a Pharmacy authorized to dispense Product. DISTRIBUTOR may only sell UT Product for use by an Included Patient and may not sell, transfer or distribute UT Product to any entity that DISTRIBUTOR knows is likely to resell the UT Product.
- Acceptance of Orders. Each purchase order shall be governed by the terms and conditions set forth in this Agreement with respect to such order to the exclusion of any additional or contrary terms set forth in the DISTRIBUTOR purchase order. Any terms or conditions of such purchase order that conflict with the terms and conditions of this Agreement shall be null and void. Notwithstanding the foregoing, in the event of exigent circumstances, UT shall use its Best Efforts to accept an emergency purchase order from DISTRIBUTOR two (2) business days prior to the requested delivery date
- 6.3 <u>Delivery Terms</u>. Units of UT Product ordered by DISTRIBUTOR and accepted by UT shall be packed for shipment and storage in accordance with UT's standard commercial shipping practices. UT shall use its best efforts to deliver Units of UT Product into the possession of a common carrier for delivery within a reasonable period of time after acceptance of a purchase order by UT. Unless mutually agreed upon by DISTRIBUTOR and UT, no UT Product shall be shipped on a Friday, Saturday or Sunday. Each order may only be shipped, and shall be addressed for shipment, to the Designated Shipment

Location specified in Attachment E. Unless UT and DISTRIBUTOR otherwise agree in writing, all deliveries of UT Product shall be F.O.B. DISTRIBUTOR's Designated Shipment Location. UT shall insure each shipment of UT Product with a reputable insurer for the full invoice price of such shipment. Risk of loss and title to UT Product shall pass to DISTRIBUTOR upon delivery at its Designated Shipment Location. UT shall have no liability for any loss, theft, destruction or damage to the Units of UT Product once they have been delivered to a Designated Shipment Location and the exterior has been inspected by DISTRIBUTOR for visible damagewithout necessity of opening. Each individual package of UT Product. shall be inspected within five (5) business days of delivery to DISTRIBUTOR's Designated Shipment Locations. DISTRIBUTOR shall, at its sole cost and expense, insure the Products from the time of delivery at DISTRIBUTOR's Designated Shipment Location until delivery of the Units of UT Product by DISTRIBUTOR to Customer has been completed. In each case such insurance or self-insurance shall be for the UT Product's full replacement value (i.e., market value) against fire, theft, loss or destruction, and such other risks as are customarily insured against by prudent persons in a similar line of business. At UT's request, DISTRIBUTOR shall furnish to UT certificates of insurance evidencing the types and amounts of coverage.

- 6.4 <u>Modification of Orders</u>. No accepted purchase order shall be modified or canceled except upon the written agreement of both Parties.
- 6.5 <u>Change Order Charges</u>. If DISTRIBUTOR requests modifications to an accepted order prior to the scheduled delivery date provided in such order, then, in consideration for accepting such change order, UT may extend the scheduled delivery date and/or require DISTRIBUTOR to pay a change order charge equal to the sum of the actual documented non-recoverable costs incurred by UT by reason of such change order.
- Product Changes. Subject to applicable regulatory approval, UT reserves the right, in its sole discretion and without incurring any liability to DISTRIBUTOR except as otherwise provided in this Agreement, to: (a) alter UT Product; (b) discontinue the manufacture of UT Product; or (c) commence the manufacture and sale of new products having features which make UT Product obsolete. UT also reserves the right, in its sole discretion and without incurring any liability to DISTRIBUTOR except as otherwise provided in this Agreement, immediately to alter the specifications or the manufacturing process for UT Product for reasons of health or safety. UT shall fill all accepted purchase orders from DISTRIBUTOR for altered or discontinued UT Product for which manufacturing and commercial deliveries have commenced prior to the effective date of such a change but otherwise shall have no obligation to do so unless the delivery date requested in the relevant purchase order is prior to the effective date of such a change. UT shall notify DISTRIBUTOR in writing when such modifications or changes occur.
- 6.7 <u>Rolling Forecasts</u>. DISTRIBUTOR shall provide UT with an annual, non-binding twelve (12) month forecast projecting DISTRIBUTOR's intended purchases of UT Product for the coming twelve (12) months, as well as such other mutually agreeable information. UT shall receive this annual forecast no later than January 10 <sup>th</sup> of each calendar year. DISTRIBUTOR shall also update UT on a rolling basis each calendar quarter, and each updated forecast shall be received by UT no later than the 10th day of the month following the end of each calendar quarter.
- 6.8 <u>Chargeback Pricing</u>. Subject to UT's reimbursement of the "Chargebacks" (as described below) DISTRIBUTOR shall provide wholesale distribution to certain entities eligible for discounted government pricing (e.g., FSS, VA, PHS (340B)) ("Discounted")

**Entity**") as described herein. The discounted government pricing is less than the price at which DISTRIBUTOR purchases UT Product (i.e., less than the Price set forth in Attachment A). DISTRIBUTOR shall create an account for each Discounted Entity purchasing UT Product from DISTRIBUTOR. As part of this process, DISTRIBUTOR shall use commercially reasonable efforts to identify whether the proposed Discounted Entity is eligible for discounted government pricing through direct documentation from the proposed Discounted Entity or through review of data on the HRSA eligibility website or other database resource. As an order for Product is received from the Discounted Entity, DISTRIBUTOR shall provide Product to the Discounted Entity at the discounted government price. The difference between the discounted government price and the List Price for the Product is referred to as the "Chargeback." The Chargeback shall be paid by UT to DISTRIBUTOR by check. When submitting a Chargeback request to UT, DISTRIBUTOR shall include the following information: (i) date of sale to Discounted Entity, (ii) the Discounted Entity's name and address, (iii) product(s) purchased from DISTRIBUTOR (iv) UT's price to DISTRIBUTOR for the Product, (v) DISTRIBUTOR's price to the Discounted Entity for the Product, and (vi) the amount of Chargeback requested. Chargeback request(s) shall be submitted to UT by the 10 th of each month for all activity in the previous calendar month. UT shall process Chargeback credits due DISTRIBUTOR within thirty (30) days of receipt of the Chargeback submission. DISTRIBUTOR shall not set off Chargebacks owed by UT against any amounts owed by DISTRIBUTOR to UT. Upon termination of this Agreement, if there are any unapplied credits for a Chargeback, UT shall issue a check in the amount thereof to DISTRIBUTOR. Chargebacks paid hereunder constitute reimbursement to DISTRIBUTOR for debits incurred in administering UT discounts to Discounted Entities, and are not, and should not be construed as, remuneration intended to induce DISTRIBUTOR to purchase, order, lease, or recommend any UT product.

#### **ARTICLE 7: PRICES AND PAYMENTS**

- 7.1 <u>Prices.</u> DISTRIBUTOR shall pay the Prices for UT Product purchased under this Agreement that are in effect at the time of submission of a relevant purchase order by DISTRIBUTOR, except as provided in Section 7.2 below.
- 7.2 <u>Price Changes</u>. At any time during the term of this Agreement, UT may increase or decrease its Prices for UT Product with notice to DISTRIBUTOR of the effective date of the price change. Any such price change shall not apply to purchase orders submitted prior to the effective date of the applicable price change.
- 7.3 Costs. All costs related to shipping, insuring, packing, handling and delivering UT Product to DISTRIBUTOR's facility shall be at the sole expense of UT. All such costs incurred after the instant of delivery to the Designated Shipment Location shall be the responsibility of DISTRIBUTOR. Notwithstanding anything to the contrary in this Agreement, UT may, in its sole discretion, charge DISTRIBUTOR for any and all shipping, packing, handling or delivery charges associated with emergency purchase orders, or if DISTRIBUTOR places three or more orders in a one month period.
- 7.4 <u>Payment Terms; Invoices</u>. DISTRIBUTOR shall make payments for UT Product within sixty (60) days of its receipt of an applicable invoice from UT. DISTRIBUTOR shall be eligible for a two percent (2%) prompt pay discount if

payment is received by UT within thirty (30) days of the date of invoice. All payments shall be made in United States Dollars.

- 7.5 <u>Provision of Invoices to Government Payers</u>. Upon the request of any federal or state agency with jurisdiction over claims for reimbursement of UT Product, DISTRIBUTOR may provide such agency with invoices received from UT that accurately reflect the actual charge to DISTRIBUTOR for UT Product purchased pursuant to this Agreement with prompt written notice to UT of such request.
- 7.6 <u>Overdue Payments</u>. If and for so long as any payment from DISTRIBUTOR to UT or UT to DISTRIBUTOR under this Agreement shall be overdue:
  - (a) Interest shall be due and payable at the rate of twelve percent (12%) per annum, or such lower rate as may be the maximum legally permissible rate of interest, on all balances outstanding from the first date such payment is due until fully paid;
  - (b) Each Party shall have the right to recover its collection costs and expenses (including reasonable attorneys' fees) for late payments. UT reserves the right to withhold or suspend shipment of UT Product if there is any unsettled or outstanding balance owed or caused by DISTRIBUTOR to UT and to revoke any credit terms it may offer DISTRIBUTOR; and
  - (c) Overdue payments automatically forfeit any prompt pay discounts referenced in Section 7.3.
- 7.7 Tax Payments. Each Party shall pay all taxes, duties, import deposits, assessments and other governmental charges, however designated, that are now or hereafter imposed upon such Party by any governmental authority or agency in connection with the performance of its obligations under this Agreement.
- 7.8 <u>Resale Prices</u>. The Parties acknowledge that DISTRIBUTOR may offer the UT Product in the Territory at such prices or discounts as DISTRIBUTOR, in its sole discretion, may determine.
- 7.9 <u>Drug Formulary</u>. The Parties acknowledge and agree that no payment made pursuant to this Agreement is intended in any way as a payment related to a drug formulary or drug formulary activities. The Parties acknowledge and agree that no drug formulary or drug formulary activities have been negotiated or discussed between the Parties in connection with this Agreement.

# ARTICLE 8: ACCEPTANCE, WARRANTY AND PRODUCTS SUPPORT

Acceptance of UT Product. DISTRIBUTOR shall promptly inspect each shipment of UT Product. In the event of any shortage, damage, expiration or discrepancy in a shipment of UT Product on the exterior of the shipment of UT Product that is patently obvious, DISTRIBUTOR shall promptly report the same to UT and furnish such written evidence or other documentation as UT may reasonably request. DISTRIBUTOR shall be deemed to have accepted a shipment and UT shall not be liable for any such shortage, damage, expiration or discrepancy in such shipment unless DISTRIBUTOR provides UT with such notice and substantiating evidence within five (5) days of receipt of the UT Product at DISTRIBUTOR's Designated Shipment Location. Upon receipt of reasonable substantiating evidence of such shortage, damage or discrepancy, UT shall promptly provide additional UT Product or substitute products to DISTRIBUTOR.

- 8.2 <u>Product Warranty</u>. UT hereby authorizes DISTRIBUTOR to pass on the UT standard warranty set forth in <u>Attachment D</u> to DISTRIBUTOR's Customers in the Territory, which may be revised by UT upon written notice to DISTRIBUTOR.
- 8.3 <u>Excluded Claims</u>. UT shall not have any additional warranty obligations to DISTRIBUTOR or Customers under <u>Section 8.2</u> above or otherwise to the extent that DISTRIBUTOR has made any warranties, oral or written, beyond those expressly set forth in the standard UT warranty, set forth in <u>Attachment D</u> hereto. DISTRIBUTOR shall not offer its customers any warranties different from or in addition to those given by UT hereunder.
- 8.4 <u>Limited Warranty</u>. THE WARRANTIES SET FORTH IN THE UT WARRANTY, <u>ATTACHMENT D</u> HERETO, AND THE OTHER TERMS AND CONDITIONS OF THIS AGREEMENT, ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, WHICH ARE HEREBY DISCLAIMED AND EXCLUDED BY UT, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR USE. THE SOLE AND EXCLUSIVE REMEDIES FOR BREACH OF UT'S STANDARD WARRANTIES SHALL BE LIMITED TO THE REMEDIES PROVIDED IN UT'S STANDARD WARRANTIES SET FORTH ON <u>ATTACHMENT D</u> HERETO AND AS OTHERWISE PROVIDED IN THIS AGREEMENT.
- 8.5 <u>Limited Remedy.</u> UT SHALL NOT BE LIABLE TO DISTRIBUTOR OR ANY OF ITS CUSTOMERS FOR LOSS OR DAMAGE CAUSED BY DISTRIBUTOR's DELAY IN FURNISHING THE PRODUCTS UNDER THIS AGREEMENT. UT SHALL NOT BE LIABLE TO DISTRIBUTOR OR ANY OF ITS AFFILIATES, EMPLOYEES, AGENTS OR CONTRACTORS FOR ANY SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL LOSSES OR DAMAGES, EVEN IF UT SHALL HAVE BEEN ADVISED OF THE POSSIBILITY OF SUCH POTENTIAL LOSS OR DAMAGE BY DISTRIBUTOR OR SUCH THIRD PARTY. NOTWITHSTANDING THE FOREGOING, IN CASE OF ANY CONFLICT BETWEEN THE PROVISIONS OF THIS SECTION AND <u>SECTION 12.3</u>, <u>SECTION 12.3</u> AND <u>SECTION 12.4</u> SHALL CONTROL.

#### **ARTICLE 9: REGULATORY APPROVALS, COMPLIANCE AND AUDITS**

- 9.1 Compliance with Applicable Laws. UT shall be solely responsible for, and comply with, Applicable Laws governing the regulation of the manufacture, importation, design, testing, inspection, labeling, sale, warning and instructions for use of UT Product in the Territory, or otherwise applicable to the performance of its obligations under this Agreement. DISTRIBUTOR shall comply with all Applicable Laws governing its distribution and sale of UT Product in the Territory, or otherwise applicable to the performance of its obligations hereunder. Each Party shall comply with Applicable Laws intended to prevent fraud, waste and abuse in federal health care programs, including but not limited to Medicare and Medicaid, and shall conduct its activities hereunder in an ethical and professional manner.
- 9.2 <u>Government Inquiries</u>. In the event that DISTRIBUTOR receives an inquiry, or similar notice from a government agency or entity for information or an inspection (a "**Notice**") which relates to UT Product or this Agreement, DISTRIBUTOR shall: (a) notify and provide a copy to UT of such Notice promptly within three (3) business days of receipt of such Notice; (b) unless expressly prohibited by the Notice, consult with UT regarding its response to the Notice to determine, among other things, whether any of UT's

Confidential Information shall be disclosed (which in all events shall be subject to DISTRIBUTOR's obligations specified in <a href="Article 10">Article 10</a> of this Agreement); (c) keep UT informed of the progress of any inspection and provide UT with prior notice of any documents related to UT Product or UT to be provided to such government entity; and (d) provide UT with a copy of any documents related to UT Product or UT ultimately produced pursuant to such Notice. Further, DISTRIBUTOR shall provide UT with a summary of the results of any inspection and such actions, if any, taken to remedy conditions cited in such inspections. DISTRIBUTOR further agrees to cooperate with any inspection of a shipment of UT Product by a governmental agency.

- Adverse Event Reporting. DISTRIBUTOR shall not be responsible for FDA reporting of adverse events. DISTRIBUTOR shall attempt to warm transfer a caller with potential Adverse Event information to a phone number designated by UT. Otherwise, DISTRIBUTOR shall notify UT by fax to (919) 313-1297 or e-mail at drugsafety@unither.com immediately, or at the latest within three (3) business days, of any complaint of a potential Adverse Event from a third party being reported to DISTRIBUTOR. As directed by UT, such fax or e-mail report sent by DISTRIBUTOR shall include information as required by UT in order to adequately report such Adverse Event to FDA.
- Withdrawal or Recall of Product . Any recalls of UT Product shall be conducted in compliance with FDA requirements and the UT 9.4 standard operating procedure for recalls ("UT Recall SOP") as provided to and accepted by DISTRIBUTOR. DISTRIBUTOR shall prepare and maintain a written standard operating procedure that provides processes for conducting recall-related activities for UT Product as directed by UT and in accordance with the UT Recall SOP. The decision to recall UT Product shall be made solely by UT, unless otherwise dictated by a governmental authority. UT shall be responsible for the expenses related to recall activities as described below, unless the recall results from a breach of any of DISTRIBUTOR's representations and warranties under this Agreement or DISTRIBUTOR's negligence or willful misconduct, in which event DISTRIBUTOR shall be responsible for all of recall-related expenses. For purposes of this Agreement, the expenses of the activities shall be: (i) the reasonable expenses of notification and return or destruction (if authorized by UT) of UT Product, (ii) the cost to replace UT Product, (iii) the costs directly associated with the distribution of replacement UT Product including pharmacist and dispensing labor, cold packs and labels; (iv.) reasonable communications to Included Patients such as patient letters, patient phone calls and follow-up customer service; (v.) labor associated with managing the recall process; (vi.) any expenses associated with dispensing activity missed by DISTRIBUTOR as a result of UT's provision of product to Included Patients beyond that is necessary to replace recalled product; and (vii.) shipping and insurance costs associated with returning recalled UT Product. DISTRIBUTOR and UT shall cooperate fully with one another in conducting any activity contemplated by this Section 9.4. Destruction of recalled product shall be conducted in accordance with the recall plan, as approved by UT under the UT Recall SOP and by any applicable governmental authorities. If instructed by UT, DISTRIBUTOR may return recalled UT Product to UT at UT's expense within thirty (30) days from completion of the recall and UT shall replace the UT Product recalled or refund the cost of such returned UT Product. Any UT Product returned to UT under this Section 9.4 shall be shipped by common carrier in a manner that preserves the integrity of the UT Product shipped, as instructed by UT. Title to the recalled UT Product and risk of loss, theft, destruction or damage to UT Product during shipment as described above shall pass from DISTRIBUTOR to UT upon delivery of recalled UT Product at UT's facility. DISTRIBUTOR's obligation to insure UT

Product shall continue with respect to recalled UT Product until UT's receipt of such recalled UT Product.

- 9.5 <u>Visits by Parties</u>. DISTRIBUTOR shall permit UT to visit its place of business and inspect its records, inventories and other relevant materials and records relating solely to its performance of this Agreement, upon reasonable advance notice and during normal business hours.
- 9.6 No Returns. UT will not accept the return of any UT Product, unless agreed in writing by UT, except if returned pursuant to a recall under Section 9.4 above.

#### ARTICLE 10: PROPERTY OWNERSHIP; CONFIDENTIALITY

All Confidential Information and other proprietary materials, documents, information, databases, complete and incomplete case report forms and all data that one Party (" **Disclosing Party**") supplies to the other Party (" **Receiving Party**") shall be the sole and exclusive property of the Disclosing Party (" **Disclosing Party Property**"). All Confidential Information shall be deemed confidential and proprietary to the Disclosing Party. During the term of this Agreement and for a period of five (5) years following thereafter, the Receiving Party shall: (a) not disclose or provide any Confidential Information to any third party, and (b) take reasonable measures to prevent any unauthorized disclosure of Confidential Information by its employees, agents, contractors or consultants during the term hereof including advising such individuals of applicable confidentiality obligations. Upon termination of this Agreement, the Receiving Party shall return or destroy to the Disclosing Party, at the Disclosing Party's request and expense, all unused Disclosing Party Property, except the Receiving Party may keep one (1) copy of such Disclosing Party Property for legal archival purposes.

#### **ARTICLE 11: TRADEMARKS**

- 11.1 Trademark License Grant. UT hereby grants to DISTRIBUTOR, and DISTRIBUTOR hereby accepts from UT, a nonexclusive, nontransferable, and royalty-free right and license, during the term of this Agreement, to reproduce and use the UT Trademarks in connection with the distribution, marketing and sale or other distribution of UT Product in the Territory and in accordance with UT's standards and instructions and for no other purpose. DISTRIBUTOR shall not use any other marks or trade names in connection with the marketing and distribution of UT Product, except that DISTRIBUTOR may use its marks or trade names in a manner consistent with its normal course of business, such as adding a label on the packaging identifying DISTRIBUTOR as a distributor of UT Product, and such use shall not confer on UT any rights or license in DISTRIBUTOR's marks or trade names. UT may inspect and monitor DISTRIBUTOR's use of the UT Trademarks. DISTRIBUTOR shall not remove or alter any UT trade names, trademarks, copyright notices, serial numbers, labels, tags or other identifying marks, symbols or legends affixed to any UT Product, documentation or containers or packages.
- Registration. In its sole discretion, UT may register the UT Trademarks in the Territory if UT determines that registration is necessary or useful to the successful distribution of UT Product. In addition, if UT believes that it is advisable to effect any filing or obtain any governmental approval or sanction for the use by DISTRIBUTOR of any of UT Trademarks pursuant to this Agreement, the Parties shall cooperate to do so. All expenses relating to the registration of the UT Trademarks in the Territory as well as the making of any filing or obtaining any governmental approvals for the use by DISTRIBUTOR of the Trademarks shall be borne by UT.
- 11.3 Termination of Use. Immediately upon termination of this Agreement, DISTRIBUTOR's license and right granted in Section 11.1 shall be revoked and DISTRIBUTOR shall cease and desist from use of any UT Trademark in any manner, other than to liquidate its then-existing inventory of UT Product within six months of such termination. DISTRIBUTOR hereby grants to UT or its designee, in the event of such termination, full power of attorney, with the right of substitution, to cancel, revoke or withdraw any governmental registration or authorization permitting DISTRIBUTOR to use any UT Trademark in the Territory, and DISTRIBUTOR shall provide such further documentation and assistance as UT may reasonably request in connection therewith.
- 11.4 Reservation of Rights.
  - (a) DISTRIBUTOR acknowledges UT's proprietary rights in and to any UT Trademark, subject to the license and right granted in Section 11.1. DISTRIBUTOR shall not adopt, use or register any words, phrases or symbols that are identical to or confusingly similar to any UT Trademark and shall not use any UT Trademark as part of DISTRIBUTOR's corporate or trade name or permit any third party to do so.
  - (b) UT acknowledges DISTRIBUTOR's proprietary rights in and to any of DISTRIBUTOR's trademarks. UT shall not adopt, use or register any words, phrases or symbols that are identical to or confusingly similar to any of DISTRIBUTOR's trademarks and shall not use any such trademark as part of UT's corporate or trade name or permit any third party to do so.
- Infringements. Each Party shall promptly notify the other Party in writing if it becomes aware of any use in the Territory by any third party of trademark or of any similar mark, which may constitute an infringement of a UT Trademark or DISTRIBUTOR's trademarks. Subject to the provisions of this <a href="Article 11">Article 11</a>, Each Party shall have the exclusive right, in its sole discretion, to institute proceedings against third-party infringers of its trademarks.

- 12.1 <u>Insurance</u>. DISTRIBUTOR shall maintain in effect during the term of this Agreement a comprehensive general liability policy (which may be in the form of primary or excess coverage) in an amount not less than Two Million Dollars (\$2,000,000) per occurrence and Three Million Dollars (\$3,000,000) in the aggregate. The deductible for such policy shall be no more than One Hundred Thousand Dollars (\$100,000) DISTRIBUTOR agrees to provide UT with a certificate of insurance evidencing compliance with this section upon written request of UT.
- 12.2 <u>Claims</u>. For the purposes of this <u>Article 12</u> a "Claim" shall mean any liabilities, damages, costs or expenses, including, without limitation, reasonable attorneys' fees arising from any claim, lawsuit, demand or other action by a third party.
- 12.3 <u>DISTRIBUTOR Indemnification of UT</u>. Except as provided in <u>Section 12.4</u>, DISTRIBUTOR shall indemnify, defend and hold harmless UT, its Affiliates, and their respective officers, directors, employees, agents, successors and assigns from and against any Claim to the extent such Claim relates to or is based on: (a) property damage, personal injury or death resulting from DISTRIBUTOR's negligent or reckless provision or maintenance of UT Product (except to the extent the same results from any wrongful

act or omission of UT); (b) DISTRIBUTOR's violation of Applicable Laws; or (c) any breach by DISTRIBUTOR of any of its representations, warranties, covenants or agreements under this Agreement.

- 12.4 <u>UT Indemnification of DISTRIBUTOR for UT Product</u>. Except as provided in <u>Section 12.3</u>, UT shall indemnify, defend and hold harmless DISTRIBUTOR and its Affiliates, and their respective officers, directors, employees, agents and successors and assigns from and against any Claim to the extent such Claim relates to or is based on: (a) property damage, personal injury or death resulting from use of UT Product (except to the extent the same results from any wrongful action or omission of DISTRIBUTOR); (b) UT's violation of Applicable Laws; or (c) any breach by UT of any of its representations, warranties, covenants or agreements under this Agreement.
- Indemnification Procedure. A Party seeking indemnification under this <a href="Article 12">Article 12</a> ("Indemnified Party") shall give prompt written notice to the indemnifying Party ("Indemnifying Party") of any Claim covered by the indemnification obligations hereunder; provided, however, that a delay in such notice shall not terminate the Indemnifying Party's indemnification obligations hereunder, unless such delay shall have materially impaired the defense of such Claim. Such Indemnifying Party shall have sole and exclusive control of the defense of any such Claim, including the choice and direction of any legal counsel; provided, however, if Indemnifying Party's choice of legal counsel would be subject to a material conflict of interest under the applicable rules of professional conduct governing such counsel, the Indemnified Party shall not be obligated to waive such conflict and may request separate legal counsel at the Indemnifying Party's expense. The Indemnifying Party may not settle or compromise any such Claim without the written consent of the Indemnified Party, which consent shall not be unreasonably withheld.
- 12.6 <u>Litigation Support</u>. In the event and for so long as an Indemnifying Party actively is contesting or defending against any Claim under this <u>Article 12</u>, the Indemnified Party shall cooperate with the Indemnifying Party and its legal counsel in the contest or defense of such Claim, make available its personnel, and provide such testimony and access to its books and records as shall be reasonably necessary in connection with the contest or defense of such Claim, all at the sole cost and expense of the Indemnifying Party.
- 12.7 <u>Subrogation</u>. The Indemnifying Party shall be subrogated to the rights of the Indemnified Party against any third party bringing a Claim, and such Indemnified Party hereby assigns to the Indemnifying Party all claims, causes of action and other rights that the Indemnified Party may then have against such third party. Conversely, and without in any way limiting the obligation of either Party to indemnify the other Party as herein provided, to the extent that an Indemnifying Party fails to perform its indemnification obligations under <u>Section 12.3</u> or <u>Section 12.4</u> above, the Indemnifying Party hereby assigns to the Indemnified Party all claims, causes of action and other rights which the Indemnifying Party may then have against any third party with respect to any Claim for which indemnification is provided hereunder.

#### **ARTICLE 13: ARTICLE 13 JOINT PUBLICITY**

13.1 <u>Public Disclosure</u>. If either Party wishes to make a public disclosure concerning this Agreement or the relationship established hereunder and such disclosure mentions the other Party by name or description, such other Party shall be provided with an advance copy of the disclosure and shall have two (2) business days within which to approve or

disapprove such use or its name of description (including mention of the name of the Product); *provided*, *however*: (a) approval shall not be unreasonably withheld by either Party; (b) failure to respond within two (2) business days shall be deemed approval; and (c) if approval is denied, no disclosure shall use the name of or otherwise describe such Party except to the extent required by Applicable Laws, or the extent that the description of the other Party is limited to public information about the availability of UT Product.

13.2 <u>Filings with Securities and Exchange Commission</u>. Notwithstanding the foregoing, each Party acknowledges that both Parties are, or are affiliates of, a publicly traded company and each Party hereby consents to the disclosure of this Agreement and the relationship between the Parties in their respective filings with the Securities and Exchange Commission and disclosures to their stockholders; *provided, however*, that each Party shall use commercially reasonable efforts not to disclose the specific financial terms and conditions of this Agreement except when such disclosure is required by Applicable Laws or by this Agreement.

# **ARTICLE 14: FORCE MAJEURE**

- 14.1 <u>Notice</u>. A Party affected by an event of Force Majeure shall promptly provide the other Party with written notice describing the event, its cause and foreseeable duration, and its possible consequences upon performance under this Agreement.
- 14.2 <u>Suspension of Performance</u>. After an affected Party has given notice under <u>Section 15.1</u>, that Party shall be relieved of any performance obligation under this Agreement for obligations which the Force Majeure event prevents, but only to the extent and only for so long as the Force Majeure prevents performance. The other Party may likewise suspend the performance of all or part of its obligations, except for the obligation to pay any amount due and owing and those obligations specified in <u>Section 16.4(c)</u> of this Agreement. Notwithstanding the foregoing, UT shall use Commercially Reasonable Efforts to allocate available UT Product to DISTRIBUTOR at least in proportion to DISTRIBUTOR's historical purchases.
- 14.3 <u>Substitute Performance</u>. If DISTRIBUTOR is delayed by an event of Force Majeure, UT shall, at its sole option, allow a third party to cover the services related to the distribution of UT Product that DISTRIBUTOR was unable to complete due to its delay and such third party shall receive the fees DISTRIBUTOR would have received during its period of delay.
- 14.4 <u>Termination</u>. If the period of Force Majeure continues for more than sixty (60) days, either Party may terminate this Agreement upon giving notice to the other Party without incurring liability other than the obligation to make payments due up to and including such date of termination.

# **ARTICLE 15: TERM AND TERMINATION**

15.1 Term. The initial term of this Agreement shall begin on the Effective Date and shall continue in force for one (1) year from the Effective Date. Thereafter, this Agreement shall automatically renew for additional periods of one (1) year each, unless either of the Parties shall have given the other Party written notice of its non-renewal of this Agreement no later than ninety (90) days prior to the end of the initial or any renewal term hereof.

- 15.2 Termination. This Agreement may be terminated prior to the expiration of the then current term as follows:
  - (a) Either Party may terminate this Agreement immediately upon written notice to the other Party if the other Party files a petition of any type as to its bankruptcy, is declared bankrupt, becomes insolvent, makes an assignment for the benefit of creditors, goes into liquidation or receivership, a proceeding is commenced against it which will substantially impair its ability to perform hereunder or such Party otherwise loses legal control of its business;
  - (b) Either Party may terminate this Agreement upon the occurrence of a material breach by the other Party (including, but not limited to, DISTRIBUTOR's failure to promptly pay sums owing to UT), which breach has not been cured within thirty (30) days of written notice of such breach from the non-breaching Party;
  - (c) Either Party may terminate this Agreement upon written notice if an event of Force Majeure continues for more than sixty (60) days as provided in Section 15.4;
  - (d) The Parties may agree in writing to terminate this Agreement for their mutual convenience at any time and for any reason, subject to such terms and conditions as they may then adopt;
  - (e) Either Party may terminate this Agreement at any time, with or without cause, by written notice to the other Party, which shall be effective one hundred and eighty days (180) days after its date; and
  - If at any time in the future, a change in the reimbursement of UT Product or legal requirements of payers would (a) require the Parties to renegotiate or alter significant terms of this Agreement, or (b) result in a substantial adverse change in the respective financial benefits or burdens accruing to any Party under the terms of this Agreement, then upon written request by either Party in the case of (a), or the affected Party in the case of (b), the Parties shall endeavor in good faith to renegotiate and modify the terms of this Agreement to comply with such new requirements or avoid such substantial adverse change. If the Parties are unable to agree to such modifications within one hundred twenty (120) days of receipt of the written request, then either Party (in the case of (a)), or the adversely affected Party (in the case of (b)) may terminate this Agreement immediately upon expiration of the one hundred twenty (120) day period.
- 15.3 <u>Partial Termination</u>. In the event that either Party shall have the right pursuant to the provisions of <u>Section 15.2</u> to terminate this Agreement in its entirety, that Party may elect, in its sole discretion, to terminate this Agreement solely as it applies to a portion of the Territory, or, if applicable, any category of Customer.
- 15.4 <u>Rights and Obligations on Termination</u>. If this Agreement is terminated for any reason, the Parties shall have the following rights and obligations:
  - (a) Termination of this Agreement shall not release either Party from the obligation to make payments of all amounts then or thereafter due and payable, and shall not release UT from its obligations to provide UT Product to DISTRIBUTOR at DISTRIBUTOR's request to service its existing patients as of the effective termination date and until such existing patients are transitioned to another

- distributor. DISTRIBUTOR and UT shall use their Best Efforts to achieve such transition as expeditiously as possible after the effective termination date;
- (b) Each Party's respective obligations of confidentiality under <u>Article 13</u> and record retention under <u>Article 18</u> shall survive as provided in such articles;
- (c) Each Party's respective obligations under <u>Section 7.3</u>, 'Payment Terms; Invoices,' <u>Section 9.2</u>, 'Compliance with Laws,' the indemnification provisions of <u>Article 12</u>, this <u>Article 16</u> and <u>Article 17</u>, 'Dispute Resolution,' shall survive termination of this Agreement; and
- (d) UT shall cause other entities to undertake, or shall otherwise relieve DISTRIBUTOR of its obligations and all costs relating to all PAP Patients, and shall complete such transition or relief with respect to such patients no later than one hundred and eighty (180) days from the termination date. DISTRIBUTOR agrees to use its Best Efforts to cooperate with such transfer.

#### **ARTICLE 16: DISPUTE RESOLUTION**

- Negotiation. The Parties agree to consult and negotiate in good faith to try to resolve any dispute, controversy or claim that arises out of or relates to this Agreement. Except as provided in Section 16.2, no formal dispute resolution shall be used by either Party unless and until senior executive officers of each Party shall have attempted to meet in person to achieve such an amicable resolution.
- 16.2 <u>Reservation for Litigation</u>. Notwithstanding <u>Section 16.3</u> below, each Party expressly reserves the right to seek judicial relief from a court of competent jurisdiction if the other Party is or appears to be in violation of such other Party's obligations of non-use and non-disclosure under <u>Article 10</u> above and each Party expressly reserves the right to seek injunctive or similar equitable relief for any violation or breach hereunder.
- Arbitration. Subject to the reservation of the Parties under Section 16.2 above, any dispute, controversy or claim that arises out of or relates to this Agreement that is not resolved under Section 16.1 shall be settled by final and binding arbitration in accordance with the Commercial Arbitration Rules of the American Arbitration Association ("AAA") in effect on the Effective Date, as modified by Section 16.4 below. Judgment upon the award rendered by the arbitrators may be entered in any court of competent jurisdiction. The place of arbitration shall New York, New York, U.S.A. The arbitration shall be conducted in the English language by three (3) neutral arbitrators selected by mutual agreement of the Parties or, if that is not possible within thirty (30) days of the initial demand for such arbitration, by the AAA.
- 16.4 <u>Special Rules</u>. Notwithstanding any provision to the contrary in the AAA's rules, the Parties hereby stipulate that any arbitration hereunder shall be subject to the following special rules:
  - (a) Each Party shall have the right to request from the arbitrators, and the arbitrators shall order upon good cause shown, reasonable and limited pre-hearing discovery, including (i) exchange of witness lists, (ii) depositions under oath of named witnesses, (iii) written interrogatories, and (iv) document requests;

- (b) Upon conclusion of the pre-hearing discovery, the arbitrators shall promptly hold a hearing upon the evidence to be presented by the Parties and shall promptly render a written opinion and award;
- (c) The arbitrators may not award or assess punitive damages against either Party; and
- (d) Each Party shall bear its own costs and expenses of the arbitration and one-half (1/2) of the fees and costs of the arbitrators, subject to the power of the arbitrators, in their sole discretion, to award all such reasonable costs, expenses and fees to the prevailing Party.

#### ARTICLE 17: RECORDS

During the term hereof and for three (3) years thereafter, or such longer period as may be required by Applicable Laws, DISTRIBUTOR shall maintain accurate records as required to meet Applicable Laws. Except as otherwise required by Applicable Laws, DISTRIBUTOR shall provide UT with access to any reasonably requested documentation related solely to this Agreement during reasonable business hours. UT shall give DISTRIBUTOR seven (7) days' prior written notice of such examinations, which will not occur more than once annually, and such examinations shall be undertaken only to such extent necessary to verify that the DISTRIBUTOR has complied with the terms of this Agreement.

#### **ARTICLE 18: ARTICLE 18 GENERAL PROVISIONS**

- 18.1 <u>Entire Agreement</u>. This Agreement constitutes the entire agreement of the Parties with respect to the subject matter hereof and supersedes all the Parties' previous or contemporaneous correspondence, term sheets, understandings, agreements and representations, oral or written between the Parties.
- Assignment. Neither Party shall assign or otherwise transfer its rights or obligations under this Agreement except with the prior written consent of the other Party, which shall not be unreasonably withheld or delayed; *provided, however*, that no such consent shall be required and either Party may transfer all rights and obligations arising hereunder to an entity if it is: (a) an Affiliate; (b) the successor in interest by reason of sale, merger or operation of law; or (c) has acquired all or substantially all of the assets and business. Any unauthorized attempted assignment or delegation shall be null and void and of no force or effect.
- Subcontracting. DISTRIBUTOR shall not, without the prior written approval of UT, appoint any distributors or agents to act on behalf of DISTRIBUTOR (collectively, "Sub-Distributors") to distribute UT Product within the Territory, other than any of its Affiliates. DISTRIBUTOR shall at all times remain fully liable for the performance of any approved Sub-Distributors and DISTRIBUTOR shall provide UT with a written acknowledgement executed by each Sub-Distributor that it has read this Agreement and agrees to be bound by its terms and conditions, including those contained in the attachments hereto. Notwithstanding the forgoing, DISTRIBUTOR may subcontract portions of certain limited functions and responsibilities of this Agreement, provided that the subcontractor performs in a manner conforming to this Agreement, subcontractor enters into a confidentiality agreement no less extensive than required by this Agreement; and DISTRIBUTOR retains full responsibility and liability for the performance of the subcontracted service. At no time shall DISTRIBUTOR subcontract

all or substantially all of any given function to a third party without the prior written consent of UT.

- 18.4 <u>Amendment</u>. This Agreement may not be modified or amended, in whole or in part, except by a written agreement signed by both Parties, and specifically stating that it modifies or amends this Agreement.
- 18.5 <u>Severability</u>. If one or more of the provisions of this Agreement is subsequently declared invalid or unenforceable, this Agreement shall be treated as though that provision were not in this Agreement, and this shall not affect the validity or enforceability of the remaining provisions of this Agreement (unless those provisions that are invalidated or unenforceable are clearly material and inseparable from the other provisions). The Agreement as modified shall be applied and construed to reflect substantially the good faith intent of the Parties and to achieve the economic effects originally intended by the terms hereof.
- Notices; Language. Except as may be otherwise provided in this Agreement, any notice, demand or request given, made or required to be made shall be in writing and shall be effective, unless otherwise provided herein, either (a) when delivered in person to the other Party, or (b) on the same business day that it is transmitted by facsimile to the facsimile number (s) set forth below, with electronic confirmation of receipt, if transmitted prior to 5:00 p.m. Eastern time on such business day, or on the first business day following such transmission if transmitted after 5:00 p.m. Eastern Time or if transmitted on a day other than a business day; provided a hard copy is deposited within one (1) day after such transmissions in the U.S. mail, postage prepaid, and addressed as set forth below for notices by U.S. mail; or (c) on the third business day following its deposit in the U.S. mail, postage and addressed as follows:

If to UT: United Therapeutics Corporation

1110 Spring Street

Silver Spring, Maryland 20910

Attention: John Ferrari, Chief Financial Officer

Telefax: 301-608-9291

With a copy to:

United Therapeutics Corporation 1735 Connecticut Ave. NW Washington, DC 20009

Attention: Paul Mahon, EVP & General Counsel

Telefax: 202-483-4005

If to DISTRIBUTOR: Accredo Health Group

1640 Century Center Parkway

Memphis, TN 38134

Attention: Michael R. Hess, Chief Counsel Accredo

Telefax: 901-261-6840

18.7 <u>Waiver</u>. Either Party's failure or delay in exercising any remedy for default shall not be deemed a waiver of that or any subsequent defaults of that provision or of any other provision hereof. No waiver shall be effective unless made in writing with specific reference to the relevant provision(s) of this Agreement and signed by a duly authorized representative of the Party granting the waiver.

- 18.8 <u>Counterparts</u>. This Agreement shall be executed in two (2) or more counterparts in the English language, each of which shall be deemed an original, which taken together shall constitute one and the same instrument.
- 18.9 <u>Governing Law</u>. Except as provided by federal law, this Agreement shall be governed by, and interpreted and construed in accordance with, the laws of the State of New York, excluding (a) any conflict-of-laws rule or principle therein contained under which any other law would be made applicable
- 18.10 <u>Relationship</u>. This Agreement does not make either Party the employee, agent or legal representative of the other Party for any purpose whatsoever. Neither Party is granted any right or authority to assume or to create any obligation or responsibility, express or implied, on behalf of or in the name of the other Party. In fulfilling its obligations pursuant to this Agreement each Party shall be acting as an independent contractor and shall not be deemed to have formed any partnership, joint venture or other relationship
- 18.11 <u>Headings</u>. The headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement.
- 18.12 <u>Signature Authority</u>. Each signatory to this Agreement has signature authority and, is empowered on behalf of his or her respective Party to execute this Agreement.
- 18.13 <u>Cumulative Remedies</u>. Except as expressly provided in this Agreement, and to the extent permitted by Applicable Laws, any remedies described in this Agreement are cumulative and not alternative to any other remedies available at law or equity.
- Anti-Kickback Law Compliance. Each party agrees that it shall not violate the federal anti-kickback statute, set forth at 42 U.S.C § 18.14 1320a-7b(b) ("Anti-Kickback Statute"), the federal "Stark Law," set forth at 42 U.S.C § 1395nn, or the Public Contracts Anti-Kickback Law with respect to the performance of its obligations under this Agreement. The Parties intend to treat all discounts (including, but not limited to, prompt payment discounts) payable by UT hereunder as "discounts or other reductions in price" pursuant to the Anti-Kickback Statute, and to comply with the discount safe harbor set forth at 42 C.F.R. § 1001.952(h). Accordingly, the Parties agree that: (i) DISTRIBUTOR shall, as appropriate, disclose all discounts received hereunder to representatives of Medicare, Medicaid, any governmental authority, and Federal health care programs (as defined under 42 U.S.C. 1320a-7b(f)) (collectively, "governmental entities") upon request in accordance with 42 C.F.R. 1001.952(h); and (ii) UT shall, if required and as appropriate, properly report all discounts paid hereunder to the appropriate governmental entities for purposes of determining "Best Price" under the Medicaid rebate program and for purposes of determining AMP or ASP under Medicare, if applicable. During the Term of this Agreement, each Party shall take all actions necessary and appropriate to ensure that it complies with all Applicable Laws, including, without limitation, the Anti-Kickback Statute, the Stark Law and HIPAA as set forth above; and any laws and regulations relating to the terms of this arrangement as required. In addition, Accredo is subject to Medco Health Solution's Code of Conduct and its policies and procedures relating to compliance with the above-named laws. These polices and procedures, along with the Code of Conduct, are available on Medco's internet site (www.medco.com).
- 18.15 <u>HIPAA Compliance</u>. DISTRIBUTOR shall only provide information to UT in a manner consistent with the Health Insurance Portability and Accountability Act of 1996, as amended, 42 U.S.C. § 1320d, et seq., and the implementing regulations promulgated thereunder (collectively referred to herein as " **HIPAA**"). Accordingly, the Parties agree

that DISTRIBUTOR shall only provide UT with information that is de-identified in accordance with HIPAA's de-identification provision, 45 C.F.R. § 164.514(b)(2), unless DISTRIBUTOR: (i) has on file a valid, HIPAA-compliant authorization for each patient whose protected health information ("PHI") is sought to be disclosed; or (ii) authorization is not required under Applicable Laws in order to disclose the PHI.

- 18.16 Nothing herein shall be construed to limit DISTRIBUTOR from entering into other agreements with other manufacturers or wholesalers that allow DISTRIBUTOR to dispense products that compete with UT's Products. Notwithstanding the preceding sentence, DISTRIBUTOR warrants and represents that it will not disparage UT or UT Product
- 18.17 Each Party shall promptly notify the other Party upon learning of any activity that appears to improperly or inappropriately portray or affect the other Party, its products or Affiliates.
- 18.18 The Parties do not intend for this Agreement to benefit any Third Party and, therefore, there are no third party beneficiaries to this Agreement.

**IN WITNESS WHEREOF** , the Parties have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

UNITED THERAPEUTICS CORPORATION

ACCREDO HEALTH GROUP

By /s/ Jay A. Watson

Jay A, Watson, Pharm.D. Vice President, Strategic Operations and Logistics By /s/ Michael R. Hess
Michael R. Hess
Chief Counsel, Accredo

#### Attachment A

#### **Prices**

#### **UT Product**

UT Product Name	NDC	Strength	Price
Tyvaso Starter Kit	66302-206-01	0.6  mg/ml	TBA
Tyvaso Re-Supply Kit	66302-206-02	0.6 mg/ml	TBA
Tyvaso Supplemental Refill (4ct)	66302-206-03	0.6  mg/ml	TBA

NDC 66302-206-01 Tyvaso Starter Kit includes:

- 28 ampoules of Tyvaso
- 2 Sets of Autoclavable Parts
- 2 Tyvaso Inhalation Devices
- 2 AC Power Adapters
- 1 Rechargeable Battery Pack
- 1 Car Power Cord
- 1 Leather Carrying Case
- 32 Medicine Cups
- 64 Filter Membranes
- 1 Nose Clip
- 1 Measuring Cup
- 1 Safety Box
- 2 Sets of Safety Plugs

NDC 66303-206-02 Tyvaso Re-Supply Kit includes

- 28 ampoules of Tyvaso
- 1 Set of Autoclavable Parts
- 32 Medicine Cups
- 64 Filter Membranes

NDC 66302-206-03 Tyvaso Supplemental Refill includes

• 4 ampoules of Tyvaso

UT shall notify the DISTRIBUTOR in writing of any change (and the amount of the change) in the Price of any respective UT Product during

the term of this Agreement in the same time and manner as it notifies other similarly situated distributors.

UT shall provide DISTRIBUTOR with a current list of Tyvaso prices to Discounted Entities, including FSS prices, Federal Ceiling Prices, and prices to section 340B entities, and shall promptly notify Distributor of any and all changes in such prices as well as the effective dates of such changes.

# Attachment B

# **UT Trademarks Logotypes and Trade Names**

UNITED THERAPEUTICS

UNITED THERAPEUTICS CORPORATION LOGO

REMODULIN

MEDICINES FOR LIFE

# Attachment C Patient Assistance Program Guidelines

The PAP will be administered in accordance with UT SOPs that will require at a minimum the activities described in this Agreement and this Attachment C . DISTRIBUTOR is responsible for collecting the necessary patient demographics, financial, and clinical information and the oversight of the completion of the PAP enrollment form application. In addition, the DISTRIBUTOR will follow these guidelines and associated SOPs (as developed by UT) and will make the necessary decisions for patient acceptance into the PAP. DISTRIBUTOR will maintain a detailed and retrievable record of all communications, correspondence, and activities related to the PAP including dispensing of UT Product, supplies, and equipment without charge to the PAP Included Patient, and will use reasonable attempts to aid in securing third party payer benefits for each PAP Included Patient where applicable. In addition, DISTRIBUTOR shall take all necessary steps to preserve the confidentiality of Included Patient information gathered under the PAP in accordance with all federal, state and local laws relating to patient privacy, except as such confidentiality may otherwise be expressly waived by Included Patients. If and when Included Patients are presented to DISTRIBUTOR who do not meet the designated UT criteria, then DISTRIBUTOR will consult with UT prior to any decision regarding PAP acceptance.

## **Indigent Patients**

Included Patients who meet the UT PAP criteria for indigent patients will qualify for the PAP for a period up to one (1) year from the date of acceptance into the PAP. DISTRIBUTOR will reevaluate Included Patient household income information, health insurance status, and out-of-pocket medication and supply expenses each quarter to assure continued eligibility. At the end of the one (1) year period, the PAP Included Patient will be required to re-enroll (as they did with the initial application) and provide proof of income or lack of third party payer information eligibility.

# <u>Under-Insured/"GAP" Coverage Patients</u>

Included Patients who meet the under-insured/GAP coverage patient criteria will qualify for the PAP for a period up to a maximum of six (6) months or until he/she is able to obtain third party payer or similar reimbursement capabilities (whichever comes first). DISTRIBUTOR will reevaluate Included Patient household income information, health insurance status, and out-of-pocket medication and supply expenses each quarter to assure continued eligibility.

# Potential Exhaustion of Insurance Coverage

Included Patients who meet the PAP criteria for potential exhaustion of insurance coverage will qualify for the PAP program for a period up to one (1) year from the date of acceptance into the PAP, except that eligibility will terminate at any earlier time that the Included Patient obtains a new source of insurance coverage (including supplemental coverage) and no longer meets the applicable criteria. DISTRIBUTOR will reevaluate Included Patient household income information, health insurance status, and out-of-pocket medication and supply expenses each quarter to assure continued eligibility.

# Further DISTRIBUTOR Responsibilities:

DISTRIBUTOR will use Best Efforts to secure all information to support eligibility of PAP Included Patients PRIOR to any commitments for start of care. However, it may not always be possible to secure all information in the event of a medical need which could cause delays with the start of care. Therefore, DISTRIBUTOR may obtain at the very minimum a completed and

signed enrollment form and use its best judgment as to the Included Patient's eligibility for acceptance prior to receiving all required supporting documentation. This will constitute a 28-30 day grace period for which the DISTRIBUTOR will not be liable for UT Product, pumps/devices, and supporting pump/device supplies from the initial start of care for a PAP Included Patient. At the end of the grace period, UT will not provide or reimburse for additional UT Product (or related supplies) unless DISTRIBUTOR obtains the required supporting documentation and determines that the PAP Included Patient is eligible for the PAP.

# Attachment D UT Warranty

UT warrants that all of its Product shall as of the date such Product arrives at DISTRIBUTOR's Designated Shipment Location: (i) be free from defects in design, material and workmanship; (ii) be in compliance with all applicable law and regulation, including without limitation all regulatory requirements of the FDA, including those related to the adulteration or misbranding of Product within the meaning of Section 501 and 502 of the Food Drug and Cosmetics Act; (iii) not be articles which may not be introduced into interstate commerce pursuant to the requirements of Sections 505, 514, 515, 516 or 520 thereof; (iv) be manufactured in accordance with current FDA Good Manufacturing Practice as required by 21 C.F.R. 210 and 820; (v) are fit for the ordinary purposes for which such Products are intended; and (vi) are not infringing upon the patents or trademarks of any third party.

#### Attachment E

# **Designated Shipment Locations and Designated Storage Locations**

Name/Address/Phone/Fax	Name/Address/Phone/Fax	Name/Address/Phone/Fax
Accredo Health Group, Inc.	Accredo Health Group, Inc.	Accredo Health Group, Inc.
2100 Riverchase Center, Suite 405	12900 Foster, Suite 120	45 Route, 46 East, Suite 609
Hoover, AL 35244	Overland Park, KS 66213	Pine Brook, NJ 07058
205-987-0778	913-339-7100	973-276-0794
800-442-7202	800-569-5451	800-549-2654
205-987-0332 (Fax)	913-339-7440 (Fax)	973-276-0998 (Fax)
Accredo Health Group, Inc.	Accredo Health Group, Inc.	Accredo Health Group, Inc.
10400 North 25 <sup>th</sup> Avenue, Suite 120	2115 Stanley Gault Parkway, #150	11A Commerce Way
Phoenix, AZ 85021	Louisville, KY 40223	Totowa, NJ 07512
602-944-1199	502-244-2400	973-256-1870
800-232-1199	800-553-8832	800-526-5113
602-944-1787 (Fax)	502-244-5590 (Fax)	973-256-5346 (Fax)
Accredo Health Group, Inc.	Accredo Health Group, Inc.	Accredo Health Group, Inc.
1831 Commerce Street, Suite 104	520 Elmwood Park Blvd. Suite 145	505 East Capovilla, Suite 103
Corona, CA 92880	Jefferson, LA 70123-6827	Las Vegas, NV 89119
951-737-2355	504-731-6113	702-895-8990
800-622-1820	800-250-5278	800-234-7044
951-737-2553 (Fax)	504-731-6112 (Fax)	702-895-8992 (Fax)
Accredo Health Group, Inc.	Accredo Health Group, Inc.	AHG of New York, Inc.
1660 Riverside Drive, Suite 101	261 Cedar Hill Street, Bldg. C	500 Executive Blvd.
Los Angeles, CA 90031	Marlboro, MA 01752	Elmsford, NY 10523-1109
323-953-4500	508-460-9813	914-592-0333
888-709-6004	800-343-9813	800-680-6843
323-665-5123 (Fax)	508-460-0072 (Fax)	914-592-5859 (Fax)
Accredo Health Group, Inc.	Accredo Health Group, Inc.	Accredo Health Group, Inc.
3069 Research Drive	39625 Lewis Drive, Suite 800	4901 West Reno Rd, Ste 950
Richmond, CA 94806	Novi, MI 48377	Oklahoma City, OK 73127
510-223-1360	248-489-0300	405-942-3961
800-842-3399	800-688-2024	800-999-9376
510-758-1235 (Fax)	248-489-1126 (Fax)	405-949-2689 (Fax)
Accredo Health Group, Inc.	Accredo Health Group, Inc.	Home HealthCare Resources, Inc.
361 Iverness Drive South, Suite F	2915 Waters Road, Suite 109	800 Clarmont Avenue
Englewood, CO 80112	Eagan, MN 55121-1562	Bensalem, PA 19020
303-799-6550	651-681-0885	215-245-7003
800-488-0290	800-955-3121	800-626-4427
303-799-6551 (Fax)	651-681—0977 (Fax)	215-245-9038 (Fax)
Accredo Health Group, Inc.	Accredo Health Group, Inc.	Accredo Health Group, Inc.
5249 N.W. 33 <sup>rd</sup> Avenue, Bldg. 6	749 Goddard Avenue	3000 Ericsson Drive, Ste 100
Ft. Lauderdale, FL 33309-6301	Chesterfield, MO 63005	Warrendale, PA 15086 -7502
954-777-1685	636-530-1514	724-772-6000
800-955-5909	800-285-7384	888-200-2811
954-730-0129 (Fax)	636-530-1508 (Fax)	724-742-2450 (Fax)
Accredo Health Group, Inc. 5300 Oakbrook Parkway, Suite 320	Accredo Health Group, Inc. 4000-E Spring Garden Street	Accredo Health Group, Inc. 1620 Century Center Parkway, Ste 109

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Norcross, GA 30093	Greensboro, NC 27407	Memphis, TN 38134
770-935-2510	336-854-3128	901-385-3600
800-310-7995	800-887-9253	800-235-8498
800-554-5545 (Fax)	336-854-3147 (Fax)	901-385-3780 (Fax)
Accredo Health Group, Inc. 2415 Heinz Road Iowa City, IA 52240-2661 319-354-7844 800-288-3752	Accredo Health Group, Inc. 7866 Thorndike Road Greensboro, NC 27409 336-393-0555 800-866-0566	Accredo Health Group, Inc. 201 Great Circle Road Nashville, TN 37228 615-352-2500 800-800-6606
319-354-6808 (Fax)	866-832-3709 (Fax)	615-850-5100 (Fax)
Accredo Health Group, Inc. 650 West Grand Avenue, Suite 102 Elmhurst, IL 60126 630-249-7390 800-753-5554 630-279-8464 (Fax)	Hemophilia Resources of America, Inc. 4000-E Spring Garden Street Greensboro, NC 27407 336-854-3128 800-887-9253 336-854-6033 (Fax)	Accredo Health Group, Inc. 9307 Kirby Drive Houston, TX 77054 713-791-1552 800-878-7690 713-791-9411 (Fax)
BioPartners in Care, Inc. 11411 Strangline Road Lenexa, KS 66215 913-451-2919 800-662-2922 913-451-2939 (Fax)	Accredo Health Group, Inc. 422 E. Gallimore Dairy Road Suite A Greensboro, NC 27409-9725 336-393-0555 866-832-3709 (Fax)	Accredo Health Group, Inc. 4343 West Royal Lane, Suite 124 Irving, TX 75063 972-929-6800 800-878-1254 972-929-6945 (Fax)
Accredo Health Group, Inc. 14111 Strang Line, Suite A Lenexa, KS 66215 913-451-2919 913-451-2939 (Fax)	Accredo Health Group, Inc. 11329 — P Street, Suite 118 & 119 Omaha, NE 68137 402-597-2330 800-569-5451 402-597-2333 (Fax)	Accredo Health Group, Inc. 3488 South Main Street Salt Lake City, UT 84115 801-832-0222 800-729-5984 801-832-0333 (Fax)

Name/Address/Phone/Fax	Name/Address/Phone/Fax	Name/Address/Phone/Fax
Accredo Health Group, Inc. 4125 Lafayette Drive, Suite 400 Chantilly, VA 20151	Critical Care Systems, Inc. 2985 Gateway Drive, Suite 150 Norcross, GA 30071	Critical Care Systems, Inc. 3631 44 <sup>th</sup> Street, Suite C Grand Rapids, MI 49512
703-817-7707 800-366-1824 888-445-4581 (Fax)	(Atlanta) 770.209.9728 770.209.9695 (Fax)	616.458.1400 616.458.1481 (Fax)
Accredo Health Group, Inc. 22623 — 68 <sup>th</sup> Avenue South Kent, WA 98032 253-872-2121 800-647-2448	Critical Care Systems, Inc. 12301 W. Explorer Drive, Suite 126 Boise, ID 83713 208.322.8868 208.322.3330 (Fax)	Critical Care Systems, Inc. 46998 Magellan Drive, Suite 300 Wixom, MI 48393 (Detroit) 248.960.8095
253-872-5663 (Fax)		248.960.9172 (Fax)
Critical Care Systems, Inc. 4100 Colonnade Parkway, Suite 175 Birmingham, AL 35243 205.969.1006 205.969.1107 (Fax)	Critical Care Systems, Inc. 655 W. Grand Ave Elmhurst, IL 60126 (Chicago) 630.833.3427 630.833.8020 (Fax)	Critical Care Systems, Inc. 1850 Lackland Hill Parkway St. Louis, MO 63146 314.991.2400 314.991.2401 (Fax)
Critical Care Systems, Inc. 820 S. University Boulevard Suite D-E, Building 1 Mobile, AL 36609 251.344.4452 251.344.4451 (Fax)	Critical Care Systems, Inc. 3700 Vanguard Drive, Suite D Fort Wayne, IN 46809 260.747.0552 260.747.2126 (Fax)	Critical Care Systems, Inc. 505 East Capovilla Ave, Suite 103 Las Vegas, NV 89119 702.992.4007 702.992.4015 (fax)
Critical Care Systems, Inc. 4645 S. Ash Avenue, Suite 1-6 Fempe, AZ 85282 480.897.2927 480.897.8533 (Fax)	Critical Care Systems, Inc. 5648 West 74 th Street Indianapolis, IN 46278 317.291.1700 317.291.1777 (Fax)	Critical Care Systems, Inc. 5401 Longley Lane Building B, Suite 34 Reno, NV 89511 775.829.2100 775.829.2151 (Fax)
Critical Care Systems, Inc. 5880 North La Cholla Blvd, Suite 126 Tucson, AZ 85741 520.297.1351 520.297.5760 (Fax)	Critical Care Systems, Inc. 11382 Aurora Avenue Urbandale, IA 50322 (Des Moines) 515.276.1660 515.276.1933 (Fax)	Critical Care Systems, Inc. 10 Commerce Park North, # 4 Bedford, NH 03110 603.625.8880 603.625.8881 (Fax)
Critical Care Systems, Inc. 1326 W. Winton Avenue Hayward, CA 94545 (San Francisco) 510.670.1384 510.670.0879 (Fax)	Critical Care Systems, Inc. 8053 Bond Street Lenexa, KS 66214 (Kansas City) 913.894.0090 913.894.0095 (Fax)	Critical Care Systems, Inc. 20 World's Fair Drive, Unit D Somerset, NJ 08873 732.748.4690 732.748.4695 (Fax)
Critical Care Systems, Inc. 1950 Rosaline Avenue, Suite C Redding, CA 96001 530.241.4727 530.241.4600 (Fax)	Critical Care Systems, Inc. 10 Donald B. Dean Drive S. Portland, ME 04106 207.775.3600 207.775.3636 (Fax)	Critical Care Systems, Inc. 15 Technology Place, Suite 2 East Syracuse, NY 13057 315.434.1980 315.434.1985 (Fax)
Critical Care Systems, Inc. 14661 Myford Road, Suite B Fustin, CA 92780 (LA/Orange County) 714.508.2990 714.508.2992 (Fax)	Critical Care Systems, Inc. 806 Cromwell Park Drive, Suite N Glen Burnie, MD 21061 (Baltimore) 410.768.0711 410.768.0712 (Fax)	Critical Care Systems, Inc. 215J Industrial Avenue Greensboro, NC 27406 336.273.2993 336.273.2994 (Fax)
Critical Care Systems, Inc. 176 Bolton Road Vernon, CT 06066	Critical Care Systems, Inc. 191 Bay State Drive Braintree, MA 02184	Critical Care Systems, Inc. 6185 Shamrock Court Dublin, OH 43016

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(Hartford) 860.872.9337 860.872.9155 (Fax)	(Boston South) 781.843.6688 781.843.4719 (Fax)	(Columbus) 614.791.8700 614.791.0754 (Fax)
Critical Care Systems, Inc. 4854 Woodbine Road, Suite 5 Pace, FL 32571 (Pensacola) 850.994.2333 850.994.0650 (Fax)	Critical Care Systems, Inc. 1 North Avenue Burlington, MA 01803 (Boston North) 781.270.5565 781.270.5575 (Fax)	Critical Care Systems, Inc. 6380 Flank Drive, Suite 600 Harrisburg, PA 17112 717.540.6800 717.540.6805 (Fax)
Critical Care Systems, Inc. 3901 Columbia Avenue, Suite 100 Linwood, PA 19061 (Philadelphia) 610.485.9900 610.485.9903 (Fax)	Critical Care Systems, Inc. 246 Boston Turnpike Shrewsbury, MA 01545 (Boston West) 508.363.3665 508.363.3666 (Fax)	Critical Care Systems, Inc. 3243 Old Frankstown Road Pittsburgh, PA 15239 724.325.9977 724.325.9949 (Fax)

Name/Address/Phone/Fax	Name/Address/Phone/Fax	Name/Address/Phone/Fax
Critical Care Systems, Inc. 253 Benner Pike, Suite D State College, PA 16801 814.867.4100 814.867.4004 (Fax)	Critical Care Systems, Inc. 1801 Royal Lane, Suite 1006 Dallas, TX 75229 214.574.4700 214.574.8700 (Fax)	Critical Care Systems, Inc. 2233 S. Presidents Drive, Suite B Salt Lake City, UT 84120 801.978.9600 801.978.0020 (Fax)
Critical Care Systems, Inc. 70 Catamore Boulevard E. Providence, RI 02914 401.435.4030 401.435.4035 (Fax)	Critical Care Systems, Inc. 900 S. Loop West, Suite 170 Houston, TX 77054 713.440.0200 713.440.0400 (Fax)	Critical Care Systems, Inc. 527B Branchway Road Richmond, VA 23236 804.378.8005 804.378.8043 (Fax)

# Attachment F

# **Inventory Data Reports**

The following reports will be completed timely as indicated herein and provided to UT Management via electronic mail in Microsoft Word  $^{\circ}$  or Excel  $^{\circ}$  file formats or comma delimited (" CSV") files and without cost or fee charges to UT.

#### **DEFINITIONS**

#### Reports

Written reports as described in this Attachment F.

#### **Patient Starts**

The initiation of commercial Product on an Included Patient for treatment.

## Patient Discontinuations

When UT Product is no longer required by the Included Patient for any variety of medical or physical reasons.

## Patient Assistance Program (PAP)

A US based program for Included Patients receiving UT Product who are either indigent, under insured, or in jeopardy of losing insurance due to therapy costs. The program allows for access to Product at no charge and demonstration of financial hardships through an enrollment process is required prior coverage. US Distributors are designated administrators of the program on behalf of UT in accordance with this Agreement.

#### **Product Forecasts**

Non-binding detailed reports by product size with reasonable estimates of use over a period of no less than 12 calendar months spanning January through December. Forecasts are updated each quarter during the year with revised 12 month calendar forecasts occurring annually. Forecasts may also include planned purchases of equipment or supplies to support the UT Product, where applicable and requested by UT.

#### **Purchase Orders**

An official and binding document, generated by the Distributor, to guarantee a request to purchase and pay at a contractual rate for the UT Products.

# PROCEDURES: REPORTS

Reports will be provided to UT on a monthly and quarterly basis based on the type of the Report and data collected. These Reports are outlined below and are referenced as Attachments elsewhere in Attachment F (listed as Exhibits 1-4). Reports will consist of:

Report Name	Frequency	Due Following Reporting Period	Exhibits
Product Utilization Report	Monthly	10 th of each month	1
Medicaid Utilization Report 340B Covered Entity Reconciliation Report Product Forecast	Monthly Monthly Quarterly	10 <sup>th</sup> of each month 10 <sup>th</sup> of each month 10 <sup>th</sup> of month after each quarter	2 3 4
1 Todaet 1 official	Quartorry	To of monar after each quarter	

#### **Product Utilization Report**

The *monthly* Product Utilization Report provides details of Product dispensing activities to commercial (reimbursable) and PAP Included Patients for the Territory. **Exhibit 1** contains a sample Report form.

The Product Utilization Reports will be provided to UT by the DISTRIBUTOR no later than the 10 th of each month using only the UT approved electronic form.

The Report contains the following three sections:

## Product Utilization Data (by size) & Ordering Patients / Month

- Total Number of Tyvaso Starter Kits, Tyvaso Re-Supply Kits, Tyvaso Supplemental Refill dispensed/sold during the reporting period.
- Total number of orders for the package sizes dispensed/sold accessing the UT Product.

## Commercial Inventory On Hand Summary values:

- An Inventory count of UT Product by package size at the end (last day) of the reporting period month.
- A realistic average dispensing/sold quantity of UT Product (a previous 3 month average is recommended).
- Actual Inventory days on hand which is automatically calculated by the Inventory count and average dispensing/sold quantities. The Inventory days on hand are measured based on a 28 day period.
- Purchase Order (PO) Requests for quantities expected to be purchased in order to meet both regular commercial activity and maintain a contractual on hand Inventory balance. (Note: An actual Purchase Order should accompany the Report)
- An Adjusted Inventory quantity is automatically calculated as the sum of the physical Inventory count plus the expected purchases from the PO.
- The Adjusted Inventory Days on Hand. This automatically calculated field is based on the previous data entries and will confirm if the new purchases plus actual Inventory, divided by the average dispensing/sold product will maintain the contractually required Inventory levels.

## Patient Assistance Program for consigned inventory to support PAP Included Patients:

- The total Included Patient census on PAP at the beginning of the reporting period.
- The total Included Patient census on PAP at the end of the reporting period.
- Consignment PAP Inventory count of UT Product by package size at the end (last day) of the reporting period month.

- A realistic average estimate of Consigned PAP Inventory dispensed of UT Product (a previous 3 month average is recommended).
- Actual PAP Consigned Inventory days on hand which is automatically calculated by the PAP Consigned Inventory count and average dispensing/sold quantities. The PAP Consignment Inventory days on hand are measured based on a 28 day period.
- PAP Consignment Purchase Order (PO) Requests (if needed for the next period). It is recommended to request a PO for approximately of a 3 to 4 months worth of Consigned Product based on current use. (Note: An actual PO for Consigned Product should accompany the report).
- An Adjusted PAP Consigned Inventory quantity is automatically calculated as the sum of the PAP Consigned physical inventory count plus any expected Consigned Products from the PO.
- The Adjusted PAP Consignment Inventory Days on Hand. This automatically calculated field is based on the previous data entries and will confirm if the new purchases plus actual Inventory, divided by the average dispensing of PAP Consignment product levels.

# Medicaid Utilization Report

The *monthly* Medicaid Utilization Report provides the information necessary for UT to manage its Medicaid-related programs. UT is a participant in the Federal Fee Schedule ("FFS") and for the Centers of Medicare and Medicaid Services ("CMS"). Participation requirements are for provisions of rebates to CMS for those patients receiving UT Products who are covered by individual State Medicaid programs. Exhibit 2 contains a sample Report form.

The Medicaid Utilization Report will be provided to UT by the DISTRIBUTOR no later than the 10 th of each month using only the UT approved electronic form.

The Report includes summary of activity for the reporting period (month) that includes a unique patient identifier number (HIPAA compliant), the UT Product size), the quantity dispensed during the reporting period, the Distributor's internal State Medicaid identification number/description, the State of the Program (abbreviated), and any other descriptions or comments to support the data.

# 340B Covered Entity Reconciliation Report

The *monthly* 340B Covered Entity Reconciliation Report provides the records that are required in order for the Distributor to recover the loss on Product cost incurred due to UT's participation in the FFS and CMS. **Exhibit 3** contains a sample Report form.

The 340B Covered Entity Reconciliation Report will be provided to UT by the DISTRIBUTOR no later than the <u>10 th</u> <u>of each month IF any</u> <u>transactions to 340B Covered Entities occurred</u>. Any Reports filed for previous months not reported to UT will be denied for refund. If no activity of 340B sales occurs during the month, no Report submission will be required.

Public Health Services ("PHS") pricing programs as part of FFS participation requires discounted pricing to be offered under the FFS program title known as 340B with whom 340B eligible hospitals or clinics (known as 340B covered entities) are entitled to receive products from FFS/PHS Participating manufactures at reduced price.

In order to facilitate 340B covered entities to obtain the reduced prices, DISTRIBUTOR will offer 340B prices at rates regularly updated and provided by UT when a 340B covered entity identifies itself and requests such prices. If the DISTRIBUTOR purchased UT Product from UT at transfer prices higher than the 340B price, UT will provide payment to the DISTRIBUTOR for the difference between the DISTRIBUTOR's transfer price and the 340B price sold to a 340B covered entity.

The Report must include the following elements:

- 340B Covered Entity Name
- 340B Identification Number
- Date of UT Product Sale
- Quantity of UT Product Sold
- 340B Ceiling Price (per product NDC /sold) provided by UT
- Total 340B Sales (unit 340B Ceiling price times quantity sold)
- Distributor Transfer price (per product NDC/ sold)
- Transfer price extension (Transfer price time the unit quantity sold)
- Refund due

## **PROCEDURES: FORECASTS**

#### **Forecasts**

The non-binding forecasts will be based on reasonable estimates of expected purchases and be presented in Excel Spreadsheet or similar electronic format listed by month and totaled for the calendar year. The forecasts will list each UT Product size for a particular drug category and may include medical devices (such as Infusion Pumps) or supplies needed from UT contracted equipment distributors to support the Product.

At the end of each Calendar quarter, DISTRIBUTOR will revise and update its twelve (12) month rolling non-binding forecasts for future quarters for that twelve (12) month period based on changes in demand and the market. These revised non-binding Forecasts will be provided to UT no later than the 10 <sup>th</sup> day of first month in the new calendar quarter unless otherwise specified in this Agreement using the UT approved electronic format (refer to Exhibit 4).

# Exhibit 1

# Monthly Product Utilization Report

TYVASO		i y vaso	iiii® Mont	my Otmza	ион кероп
treprostinil sodium	-//		Distributor Name:		
Того сопциения эмплину тиров и	Distrogram in un		For Month Endin	g: (specify MM(YYY)	3
documentation is due to United The	rapeutics Corp. r	10	Report Date:	(spedfy mm/dd/yy)	
later then the 10th of each month					
				For Calendar Year:	
Section I: Utilization Data	(running tot	als) & Ordering	Patients/Mor	<u>ith</u>	
	Tyvaso Packa	age Size			
Month	Starter Kit	Re-supply Kit	4Ct package		
Jan-06	- S				
Feb-06					
Mar-06					
Apr-06					
May-06					
Jun-06					
Jul-06					
Aug-06					
Sep-06					
Oct-06					
Nov-06					
Dec-06					
2006 Totals	(	0	0		
Active Patient Census Valu	es:				
Start of Reporting Period					
End of Reporting Period			I		
Gain/Loss		0			
Comments:					
	N =53713	0 100000			
Section II: Commercial In	ventory On H	and Summary			
Tyvaso	Starter Kit	Re-Supply Kit	4 CT Package		
Inventory Count (end of Reporting Period):					
3 Month Avg of Total sizes Shipped/Month:					
Actual Inventory Days On Hand:	#DIV/0!	#DIV/0!	#DIV/0!		
		(U.SASANCIA)	Charles de Colonia.		
Expected Purchase Order Request					
Adjusted Inventory Qty (Invent count + new PO):	C	) 0	0	·	
Adjusted Inventory Days On Hand:	#DIV/0!	#DIV/0!	#DIV/0!		
		_			

Section III: Patient Assistance Program (PAP) • Patients & Inventory Summary

#### **Active PAP Patient Census** Start of Reporting Period: End of Reporting Period: Gain/Loss 0 Consigned PAP Tyvaso Re-Supply Kit 4CT Package Starter Kit PAP Inventory Count (end of Reporting Period): 3 Month Avg of Total PAP Vials Shipped/Month: Projected PAP Inventory #DIV/0! #DIV/0! #DIV/01 Days On Hand: PAP Consignment PO Request (if applicable) Adjusted PAP Inventory Qty

#DIV/01

#DIV/0!

#DIV/01

Exhibit 2

# Monthly Medicaid Utilization Report

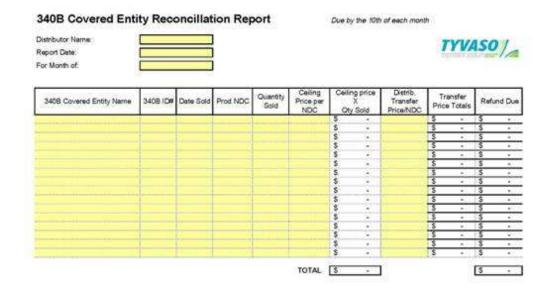
			TY	(ASO)
			Mposh	SOUTHER
Product by NDC	Quantity Dispensed	State Medicald Description	Medicaid State	DEA Code
	Product by NDC:	Product by NDG Quantity Dispensed		Product by NDC Quantity Dispensed   State Medicald Description   Medicald State

(Invent count + new PO): Adjusted PAP Inventory

Days On Hand:

## Exhibit 3

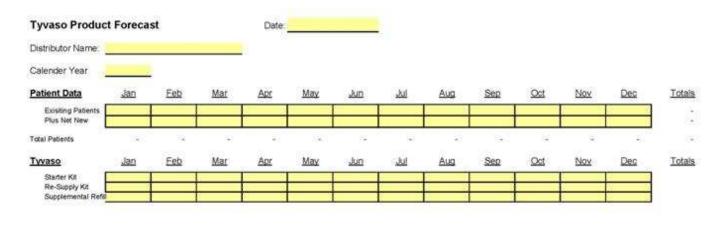
# 340B Covered Entity Reconciliation Report





#### Exhibit 4

# Product Forecast (example):



\*Update every Quarter - Highlight Changes to originial 12 month Forecast

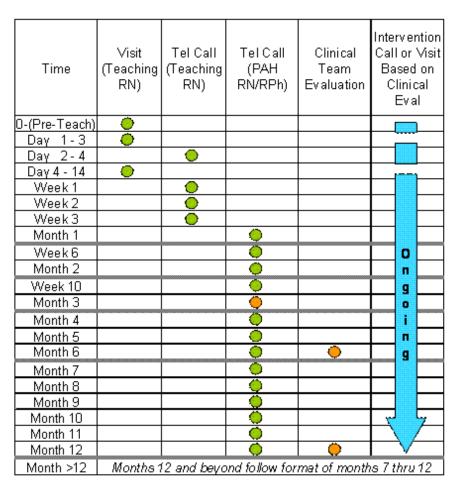
# **Attachment G**

**Tyvaso Education & Compliance Program** 

THIS CHART NEEDS TO BE UPDATED TO MATCH TEXT



# Continuing Patient Compliance, Support & Education Program



# The Tyvaso™ Continuing Patient Compliance, Support and Education Program

TIME	ACTIVITY
Day Zero	• Pre — teach (as needed)*
Day 1 – 3	• Teaching RN initiation visit*
Day 2 – 3	• RN post start telephonic status check/assessment*
Day 4 – 14	• RN visit within first 3 to 14 days post-start. Evaluation and review.
Week 1,2,3	• RN telephonic status check/assessment minimum of weekly contact.
Week 4/Month 1	• Telephonic status check/assessment with transfer to PAH RN/RPh** as required. (Reorder Call)
Week 6/Month 1.5	PAH RN/RPh telephonic status check/assessment
Week 8/Month 2	• Telephonic status check/assessment with transfer to PAH RN/RPh** (Reorder Call)
Week 10/Month 2.5	PAH RN/RPh telephonic status check/assessment

Week 12/Month 3	<ul> <li>Telephonic status check/assessment with transfer to PAH/RNRPh** (Reorder Call)</li> <li>90 day Risk Stratification Review</li> </ul>
Month 4,5	Telephonic status check/assessment with transfer to PAH RN/RPh** (Reorder Call)
Month 6	<ul> <li>Telephonic status check/assessment PAH RN/RPh** (Reorder Call)</li> <li>Clinical Team Evaluation and Treatment Goal Planning</li> </ul>
Months 7 thru 11	• Telephonic status check/assessment with transfer to PAH RN/RPh** (Reorder Call)
Month 12	<ul> <li>Telephonic status check/assessment PAH RN/RPh** (Reorder Call)</li> <li>Clinical Team Evaluation and Treatment Goal Planning</li> </ul>
Months 13 plus	• Follows format of months 7 through 12

# The Tyvaso™ Continuing Patient Compliance, Support and Education Program Description of Activities

Subject to patient's consent, the Teaching RN will complete a minimum of two (2 teaching sessions within the first fourteen (14) days of therapy. Additionally, a clinicianwill contact the patient telephonically in weeks one, two, and three of therapy. During these teaching visits and telephonic touch points, the clinician will review with the patient in detail:

#### • TYVASO

- Education Tools (Example 1 of Exhibit A to this Attachment G). Includes UT/Lung Rx materials that can be used to supplement DISTRIBUTOR-developed educational materials. Exhibit A will be updated as needed.
  - Disease information
  - Dosing and Administration
    - Use of one ampule per day
    - Daily documentation in Patient Diary
    - Daily disposal of unused drug
    - Titration schedule (prescribed per breath)
    - Missed Doses
  - Managing Side Effects
  - Establish treatment goals
  - Storage/Handling/Cleaning

# • TYVASO Inhalation System

- Education Tools Information For Use Manual, Patient DVD, Patient Breath Counter, Patient Diary and Quick Start Mat
  - Preparing for treatment
  - Using the TYVASO Inhalation System
    - Assembly
      - Use of distilled water only
    - Inhaling Technique
    - Audiovisual prompts
    - Cleaning and maintenance
      - Use of distilled water only
    - Alarms/Troubleshooting
    - Recording number of breaths per treatment sessions
    - Use of Breath Counter/Patient Diary
    - Fitting 4 treatment sessions into your day

#### • DISTRIBUTOR Services

- Refills services
- Monthly Touch points (Clinical Risk/Assessments & Medication Resupply)
- Emergency/After Hours Support

<sup>\*</sup> These activities are considered standard activities for a specialty pharmacy and should be included under this Agreement at no additional charge.

<sup>\*\*</sup>In each case throughout this <u>Exhibit G</u>, the reference to "PAH RN/RPh" means that such activity requires a Registered Nurse or Registered Pharmacist with the required expertise and training in PAH.

• Reimbursement Services

After the first month of therapy, the patient should be competent in the administration of TYVASO and use of the TYVASO Inhalation System. From this point in the Continuing Patient Compliance, Support and Education Program, Accredo will continue to monitor the patient telephonically on a bi-weekly basis in the second and third month of the program, and monthly there after. These ongoing telephonic touch points will include a *Risk Stratification Review*.

A typical *Risk Stratification Review* call should cover the following topics:

- **Disease:** Assess changes in signs and symptoms of disease
- **Dose:** Confirm the current dose
  - Confirm use of one ampule per day and discard of any remaining solution
  - Confirm proper breath tracking per treatment session
  - Review titration schedule, if applicable
- **Side effects:** Assess extent and duration of side effects.

Develop solution to minimize side effects.

Consult with prescribing physician if necessary.

• **Device:** Confirm proper use of the TYVASO Inhalation System.

Confirm use of distilled water only

- Goals: Measure attainment for treatment goals
- **Support:** Encourage patient to use educational/support tools provided by the manufacturer (PEER/Integrated Persistency Program). Increase patient awareness of PAH support groups.

Based on information received from the *Risk Stratification Review* the patient will be identified as one of the following:

- 1) Compliant
- 2) Compliant risk requires clinical intervention
- 3) Non-compliant requires clinical intervention
- Compliant: With minimal side effects, the patient is showing benefit from TYVASO and taking treatments 4x a day, between 3 9 breaths per session, discarding any remaining solution at the end of each day.
- Compliant Risk: The PAH RN/RPh has documented interventions for device management issues, non-compliant, side effect management, or lack of efficacy.
- Non-compliant: The PAH RN/RPh has multiple documented interventions for non-compliance in addition to lack of efficacy.

If it is determined that a patient is in the *compliant risk or non-compliant* category, the PAH RN/RPh will intervene appropriately. Intervention may require a home visit and include the following:

- Additional disease education
- Continued education on the use of the TYVASO Inhalation Device
- Review proper Inhalation technique
- Side effect management
- Dose escalation/titration
- Strategies to fit four inhalation sessions into a day

- Reassessment of treatment goals
- Consultation with the prescribing physician

Upon reaching the 180 <sup>th</sup> day of therapy, DISTRIBUTOR's clinical team will perform a *Clinical Team Evaluation and Treatment Goal Plan* for the patient. This will include a clinical contact (either PAH RN or RPh) contacting the patient for assessment. After the assessment, the physician will be contacted to review the patients progress to date and therapeutic goals for the next six months.

In addition to the clinical support outlined above, DISTRIBUTOR will contact the patient telephonically on a monthly basis to process refills, ensure the patient is using one ampule per day, confirm the patient is properly tracking number of breaths per treatment session, using distilled water only and resolve reimbursement issues.

#### **Service Fees**

Description of CPCSEP Service	Service Fee
Teaching RN visit within 4 to 14 days post-start	\$250 per visit
Teaching RN telephonic status check/assessment weeks 1, 2 and 3	\$52 per completed call
PAH RN/RPh telephonic status check/assessment	\$52 per completed call
Clinical Team Evaluation and Treatment Goal Planning	\$150 per session (including completed communication
	with physician)

The Parties agree that the activities described in <u>Attachment G</u> occurring from Day Zero through Day 3 (including the initial visit from the Teaching RN and the post start telephonic status check/assessments) are considered standard activities for a specialty pharmacy and should be included under this Agreement at no additional charge.

Note: The CPCSEP Services and corresponding Service Fees will be evaluated by UT on an annual basis and UT may terminate all or a portion of the CPCSEP Services at any time upon thirty (30) days prior written notice to DISTRIBUTOR without any additional fee or expense.

# Attachment G "Exhibit A"

Education Theme	<b>Education Tool Description</b>	Item #
The welcome letter provides on overview of the TYVASO Patient Tool Kit components.	TYVASO Patient Tool Kit Welcome Letter (Tool kit contains: Patient Video, Patient Brochure, Treatment Tracker, Breath Counter & Quick Start Mat)	TBD
Educational video designed to:		
<ol> <li>Teach the patient how to clean, assemble and store the inhalation system.</li> <li>Proper inhalation technique and use of the inhalation system.</li> </ol>	TYVASO Patient Video	TBD
Disease overview: what is PAH, causes and symptoms of PAH, and treatment options. TYVASO overview: what is TYVASO, how does TYVASO help, and how do I take TYVASO.	TYVASO Patient Brochure	TBD
A daily diary to assist the patient with tracking breathes and cycles.	TYVASO Treatment Tracker	TBD
A table top tool to assist the patient with tracking breaths and cycles.	TYVASO Breath Counter	TBD
Reinforce important information such as: inhalation technique, treatment sessions and how to operate the inhalation system.	TYVASO Inhalation System Quick Start Mat	TBD

# UNITED THERAPEUTICS CORPORATION SHARE TRACKING AWARDS PLAN TERMS & CONDITIONS

(applicable to Awards granted to employees on or after January 1, 2010)

- Non-Transferability. This Award may not be transferred in any manner other than by will or the laws of descent and distribution, and once vested may be exercised prior to expiration only by the Participant. If the Participant dies prior to exercising a vested Award, the Award may be exercised by the person or persons entitled to do so under Section 9.1 of the Plan. The terms of this Award shall be binding upon the executors, administrators, heirs, successors, and assigns of the Participant.
- 2. <u>Vesting</u>. For employees, this Award shall vest in accordance with the vesting schedule set forth in Section 5.4 of the Plan so long as Participant remains employed with the Company or its subsidiaries. For members of the Board of Directors of United Therapeutics, this Award shall vest in accordance with the vesting schedule set forth in Section 5.4 of the Plan so long as the Participant serves as a member of the Board of Directors of the Company and meets the requirements for the period specified.
- 3 <u>Form of Payment</u>. The Appreciation (as that term is defined in Section 2.2 of the Plan) shall generally be paid to the Participant by Company check in the next payroll cycle for employees and next accounts payable cycle for the Board of Directors following the Exercise Date.
- 4. <u>Withholding</u>. As a condition to this Award, the Company will withhold in accordance with applicable law from any cash compensation payable to Participant any taxes required to be withheld by the Company under federal, state or local law as a result of Participant's exercise of this Award.
- 5. Special Exercise Rights. Notwithstanding any other provision in the Plan or this Agreement to the contrary, upon (a) a Change of Control of the Company (as defined in Section 2.6 of the Plan) if the Award is not assumed by, or a substitute award granted, in connection with such Change of Control, (b) a Qualifying Termination of the employment of an employee within twelve months following a Change of Control of the Company (as defined in Section 2.6 of the Plan) if the Award is assumed, or a new award substituted, in connection with a Change in Control,, or (c) the Participant's death or Total Disability (as defined in Section 2.19 of the Plan), or (d) as required by an employee's employment agreement, this Award shall become fully exercisable. If so determined by the Compensation Committee of the Board of Directors, all or a portion of the Award shall be automatically exercised upon the occurrence of a Change of Control to the extent the Award vests in connection with the Change of Control.

#### 6. Method of Exercise

- a. Once vested, this Award may only be exercisable by a Participant who is an employee of the Company or its subsidiaries either (i) at any time that Participant remains fully employed with United Therapeutics or its subsidiaries, or (ii) for a period of ninety (90) days following the date of termination of Participant's employment with the Company or its subsidiaries. For members of the Board of Directors of United Therapeutics, this Award, once vested, shall be exercisable at any time prior to its expiration.
- b. This Award shall be exercisable upon delivery to the Company of an executed Award Exercise Form (a copy of which is attached hereto). This Award shall lapse and shall be without further force and effect if it remains unexercised by the Participant who is an employee of the Company or its subsidiaries ninety (90) days following the date of termination of Participant's employment with the Company and its subsidiaries.

#### 7. Qualifying Termination Definitions.

- a. For purposes of Section 5 above, a "Qualifying Termination" means termination of the employee's employment by the Company without "Cause" or resignation by the employee for "Good Reason".
- b. "Cause" has the meaning specified in an employee's employment agreement with the Company or, if there is no such agreement or definition, termination of the employee's employment by the Company due to (i) employment- or profession-related misconduct or other employment- or profession-related similar action on the part of the employee; (ii) conviction of the employee of a crime involving a felony, fraud, embezzlement or the like; or (iii) misappropriation of Company funds or misuse of Company assets by the employee.
- c. "Good Reason" means the employee's resignation from employment with the Company within 30 days following (i) a reduction in the employee's base compensation by 10% or more, or (ii) a required relocation of the employee's principal place of employment by more than 50 miles.
- 8. <u>Miscellaneous</u>. The Participant acknowledges receipt of a copy of the Plan which is attached hereto, and Participant represents that he or she is familiar with the terms and provisions thereof. The Participant hereby accepts this Award subject to all the terms and provisions of the Plan. The Participant hereby agrees to accept as binding, conclusive, and final all decisions and interpretations of the Board of Directors and, where applicable, the Compensation Committee of the Board of Directors, upon any

questions arising under the Plan. In the event of any conflict between the provisions of the Plan and these Terms & Conditions, the provisions of the Plan shall govern.

# United Therapeutics Corporation Ratio of Earnings to Fixed Charges (Unaudited)

	Year Ended December 31,									
		2009		2008		2007		2006		2005
				As adjusted (	1) i	n thousand:	s, ex	cept ratio		
Earnings:										
Earnings (losses) from continuing										
operations before income taxes	\$	18,767	\$	(83,721)	\$	4,477	\$	37,973	\$	47,522
Add:										
Loss from equity investee		141		226		321		491		754
Fixed charges		18,326		17,357		16,855		3,589		29
Less: Capitalized interest		(5,154)		(4,757)		(689)				
Earnings, as adjusted	\$	32,080	\$	(70,895)	\$	20,964	\$	42,053	\$	48,305
Fixed charges:				<del></del>				<del></del> !	-	
Interest expense(2)	\$	12,875	\$	11,439	\$	14,281	\$	2,417	\$	29
Capitalized interest		5,154		4,757		689		_		_
Portion of rentals representative of										
interest factor		297		1,161		1,885		1,172		_
Fixed charges	\$	18,326	\$	17,357	\$	16,855	\$	3,589	\$	29
Ratio of earnings to fixed charges		1.75		(4.08)		1.24		11.72		1,665.69
Excess of fixed charges over earnings	\$		\$	88,252	\$	_	\$		\$	

- (1) Years ended December 31, 2006 through 2008 have been adjusted for the retrospective adoption of Financial Accounting Standards Board Accounting Standards Codification<sup>TM</sup> 470-20, *Debt with Conversion Options and Other Options*, formerly provided under FASB Staff Position No. APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash Upon Conversion (Including Partial Cash Settlement* (FSP APB 14-1).
- (2) Includes amortization of debt discount and issue costs.

NOTE: The Ratio of Earnings to Fixed Charges should be read in conjunction with the Consolidated Financial Statements and related Notes and Management's Discussion and Analysis of Financial Condition and Results of Operations contained in United Therapeutics Corporation's Annual Report on Form 10-K for the year ended December 31, 2009.

	Lin	

United Therapeutics Corporation Ratio of Earnings to Fixed Charges (Unaudited)

# SUBSIDIARIES OF THE REGISTRANT

Lung Rx, LLC, a Delaware Corporation
Unither Telmed, Ltd, a Delaware Corporation
Unither Pharmaceuticals, LLC, a Delaware Corporation
United Therapeutics Europe, Ltd., a United Kingdom Company
Unither Therapeutik GmbH, a German Company
Unither Pharma, LLC, a Delaware Corporation
Medicomp, Inc., a Delaware Corporation
Unither Neurosciences, Inc., a Delaware Corporation
Unither.com, Inc., a Delaware Corporation
Unither.com, Inc., a Delaware Corporation
LungRx Limited, a United Kingdom Company
Unither Biotech Inc., a Canadian Company
Unither Virology, LLC, a Delaware Corporation

# **Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the following Registration Statements:

- (1) Registration Statement (Form S-3 No. 333-118699) of United Therapeutics Corporation,
- (2) Registration Statement (Form S-8 No. 333-108169) pertaining to the United Therapeutics Corporation Equity Incentive Plan,
- (3) Registration Statement (Form S-8 No. 333-56922) pertaining to the United Therapeutics Corporation Equity Incentive Plan,
- (4) Registration Statement (Form S-8 No. 333-95419) pertaining to the United Therapeutics Corporation Equity Incentive Plan,
- (5) Registration Statement (Form S-8 No. 333-153695) pertaining to the United Therapeutics Corporation Share Tracking Awards Plan; and
- (6) Registration Statement (Form S-8 No. 333-161995) pertaining to the United Therapeutics Corporation Share Tracking Awards Plan.

of our reports dated February 26, 2010, with respect to the consolidated financial statements and schedule of United Therapeutics Corporation and the effectiveness of United Therapeutics Corporation's internal control over financial reporting included in this Annual Report (Form 10-K) for the year ended December 31, 2009.

/s/ Ernst & Young LLP

McLean, Virginia February 26, 2010 QuickLinks

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

# CERTIFICATION PURSUANT TO RULE 13a-14 (a) OF THE SECURITIES EXCHANGE ACT OF 1934

## I, Martine A. Rothblatt, certify that:

- 1. I have reviewed this annual report on Form 10-K of United Therapeutics Corporation;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 26, 2010

/s/ MARTINE A. ROTHBLATT

By: Martine A. Rothblatt, Ph.D.

Title: Chairman and Chief Executive Officer

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CERTIFICATION PURSUANT TO RULE 13a-14 (a) OF THE SECURITIES EXCHANGE ACT OF 1934

# CERTIFICATION PURSUANT TO RULE 13a-14 (a) OF THE SECURITIES EXCHANGE ACT OF 1934

#### I, John M. Ferrari, certify that:

- 1. I have reviewed this annual report on Form 10-K of United Therapeutics Corporation:
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 26, 2010

/s/ JOHN M. FERRARI

By: John M. Ferrari

Title: Chief Financial Officer and Treasurer

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CERTIFICATION PURSUANT TO RULE 13a-14 (a) OF THE SECURITIES EXCHANGE ACT OF 1934

# CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report of United Therapeutics Corporation (the "Company") on Form 10-K for the period ended December 31, 2009 as filed with the Securities and Exchange Commission (the "Report"), I, Martine A. Rothblatt, Chief Executive Officer of the Company, certify, to the best of my knowledge, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ MARTINE A. ROTHBLATT

Martine A. Rothblatt

Chairman and Chief Executive Officer

United Therapeutics Corporation
February 26, 2010

THE FOREGOING CERTIFICATION IS BEING FURNISHED SOLELY PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002 AND IS NOT BEING FILED AS PART OF THE FORM 10-K OR AS A SEPARATE DISCLOSURE DOCUMENT.

A SIGNED ORIGINAL OF THIS WRITTEN STATEMENT REQUIRED BY SECTION 906, OR OTHER DOCUMENT AUTHENTICATING, ACKNOWLEDGING, OR OTHERWISE ADOPTING THE SIGNATURE THAT APPEARS IN TYPED FORM WITHIN THE ELECTRONIC VERSION OF THIS WRITTEN STATEMENT REQUIRED BY SECTION 906, HAS BEEN PROVIDED TO UNITED THERAPEUTICS CORPORATION AND WILL BE RETAINED BY UNITED THERAPEUTICS CORPORATION AND FURNISHED TO THE SECURITIES AND EXCHANGE COMMISSION OR ITS STAFF UPON REQUEST.

Exhibit 32.1
CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

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# CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report of United Therapeutics Corporation (the "Company") on Form 10-K for the period ended December 31, 2009 as filed with the Securities and Exchange Commission (the "Report"), I, John M. Ferrari, Chief Financial Officer of the Company, certify, to the best of my knowledge, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ JOHN M. FERRARI

John M. Ferrari

Chief Financial Officer and Treasurer
United Therapeutics Corporation
February 26, 2010

THE FOREGOING CERTIFICATION IS BEING FURNISHED SOLELY PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002 AND IS NOT BEING FILED AS PART OF THE FORM 10-K OR AS A SEPARATE DISCLOSURE DOCUMENT.

A SIGNED ORIGINAL OF THIS WRITTEN STATEMENT REQUIRED BY SECTION 906, OR OTHER DOCUMENT AUTHENTICATING, ACKNOWLEDGING, OR OTHERWISE ADOPTING THE SIGNATURE THAT APPEARS IN TYPED FORM WITHIN THE ELECTRONIC VERSION OF THIS WRITTEN STATEMENT REQUIRED BY SECTION 906, HAS BEEN PROVIDED TO UNITED THERAPEUTICS CORPORATION AND WILL BE RETAINED BY UNITED THERAPEUTICS CORPORATION AND FURNISHED TO THE SECURITIES AND EXCHANGE COMMISSION OR ITS STAFF UPON REQUEST.

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Exhibit 32.2