UNITED THERAPEUTICS Corp
Form 10-K
February 27, 2019

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2018

OR

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

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

United Therapeutics Corporation

(Exact Name of Registrant as Specified in Its Charter)

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

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

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

Title of each class	**Name of each exchange on which registered**
Common Stock, par value $.01 per share	Nasdaq Global Select Market

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

None
(Title of Class)

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

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ý No o

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

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

Large accelerated filer ý	Accelerated filer o	Non-accelerated filer o	Smaller reporting company o
			Emerging growth company o

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

The aggregate market value of the Common Stock held by non-affiliates of the registrant, based on the closing price on June 30, 2018, as reported by the Nasdaq Global Select Market was approximately $4,302,864,919.

The number of shares outstanding of the issuer's common stock, par value $0.01 per share, as of February 20, 2019, was 43,722,436.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for the registrant's 2019 annual meeting of shareholders scheduled to be held on June 26, 2019, are incorporated by reference in Part III of this Form 10-K.

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PART I

ITEM 1. BUSINESS

Overview

United Therapeutics Corporation focuses on the strength of a balanced, value-creating biotechnology model. We are confident in our future thanks to our fundamental attributes, namely our obsession with quality and innovation, the power of our brands, our entrepreneurial culture and our bioinformatics leadership. We also believe that our determination to be responsible citizens having a positive impact on patients, the environment and society will sustain our success in the long term.

Through our wholly-owned subsidiary, Lung Biotechnology PBC, we are focused on addressing the acute national shortage of transplantable lungs and other organs with a variety of technologies that either delay the need for such organs or expand the supply. Lung Biotechnology is the first public benefit corporation subsidiary of a public biotechnology or pharmaceutical company.

We market and sell four commercial therapies in the United States to treat pulmonary arterial hypertension (PAH): Remodulin® (treprostinil) Injection (Remodulin); Tyvaso® (treprostinil) Inhalation Solution (Tyvaso); Orenitram® (treprostinil) Extended-Release Tablets (Orenitram); and Adcirca® (tadalafil) Tablets (Adcirca). We also market and sell an oncology product in the United States, Unituxin® (dinutuximab) Injection (Unituxin), which is approved for the treatment of high-risk neuroblastoma. Outside the United States, our only significant revenues are derived from the sale of Remodulin, which is approved in Europe and various other countries. We are also engaged in research and development of new indications, formulations and delivery devices for our existing products, as well as new products to treat PAH and other conditions.

We generate revenues from sales of our five commercially approved products noted above. Remodulin was approved by the U.S. Food and Drug Administration (FDA) for subcutaneous and intravenous administration in 2002 and 2004, respectively, and has been sold commercially in the United States since 2002. Tyvaso and Adcirca were both approved by the FDA and launched commercially in the United States in 2009. Orenitram and Unituxin were approved by the FDA in 2013 and 2015, respectively, and were launched commercially in the United States in 2014 and 2015, respectively. Our sales, marketing and other commercial staff supports the availability of our commercial products in the United States, and these efforts are supplemented by our contract distributors. Outside the United States, our contract distributors are primarily responsible for sales and marketing efforts.

United Therapeutics was incorporated in Delaware in June 1996. Our principal executive offices are located at 1040 Spring Street, Silver Spring, Maryland 20910 and 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 (this Report) to "United Therapeutics" and to the "company", "we", "us" or "our" are to United Therapeutics Corporation and its subsidiaries.

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Our Commercial Products

Our commercial product portfolio consists of the following:

Product	Mode of Delivery	Indication	Current Status	Our Territory
Remodulin	Continuous subcutaneous	PAH	Commercial in the U.S., most of Europe*, Argentina, Brazil, Canada, Chile, China, Israel, Japan, Mexico, Peru, Saudi Arabia, South Korea, Taiwan and Venezuela	Worldwide
Remodulin	Continuous intravenous	PAH	Commercial in the U.S., most of Europe*, Argentina, Canada, China, Israel, Japan, Mexico, Peru, Saudi Arabia, South Korea and Switzerland	Worldwide
Tyvaso	Inhaled	PAH	Commercial in the U.S., Argentina and Israel	Worldwide
Adcirca	Oral	PAH	Commercial in the U.S.	United States
Orenitram	Oral	PAH	Commercial in the U.S.	Worldwide
Unituxin	Intravenous	High-risk neuroblastoma	Commercial in the U.S.; Approved in Canada, with launch planned for second quarter 2019.	Worldwide

* We have obtained approval for subcutaneous and intravenous Remodulin in 24 member countries of the European Economic Area (EEA), as well as other non-EEA countries in Europe, and have received pricing approval in most of these countries.

Products to Treat Pulmonary Arterial Hypertension

PAH is a life-threatening disease that affects the blood vessels in the lungs and is characterized by increased pressure in the pulmonary arteries, which are the blood vessels leading from the heart to the lungs. The elevated pressure in the pulmonary arteries strains the right side of the heart as it pumps blood to the lungs. This eventually leads to right heart failure and, ultimately, death. PAH is characterized by structural changes in blood vessel walls, aggregation of platelets and alteration of smooth muscle cell function. We believe that PAH affects about 500,000 individuals worldwide. We have seen increases in the number of people diagnosed with the disease, but due to the rarity of the disease and the complexity of diagnosing it, only a small fraction of patients with PAH are being treated.

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Current FDA-approved therapies for PAH focus on three distinct molecular pathways: the prostacyclin pathway, the nitric oxide (NO) pathway, and the endothelin (ET) pathway. The classes of drugs that target these three pathways are:

Prostacyclin Analogues and IP Prostacyclin Receptor Agonists. Patients with PAH have been shown to have reduced levels of prostacyclin, a naturally occurring substance that relaxes the pulmonary blood vessels, prevents platelet aggregation and inhibits the proliferation of smooth muscle cells in the pulmonary vessels. Therefore, drugs that mimic the action of prostacyclin, known as prostacyclin analogues, are established PAH treatments. Another class of therapy, called IP prostacyclin receptor agonists, has recently been developed to address PAH through the prostacyclin pathway. As compared with prostacyclin analogues, which broadly mimic the effect of prostacyclin, IP prostacyclin receptor agonists bind selectively to the IP receptor, one of several prostacyclin receptors.

Phosphodiesterase Type 5 (PDE-5) Inhibitors and Guanylate Cyclase (sGC) Stimulators. Patients with PAH have also been shown to have reduced levels of the enzyme responsible for producing NO, a naturally occurring substance in the body that causes relaxation of the pulmonary blood vessels. NO produces this effect by increasing intracellular levels of cyclic guanosine monophosphate GMP (cyclic GMP). Therefore, another established therapeutic approach has been to inhibit the degradation of cyclic GMP using drugs known as PDE-5 inhibitors. In addition, sGC is an enzyme found in the endothelial cells and the receptor for NO. When NO binds to sGC, the enzyme enhances production of cyclic GMP. As a result, sGC stimulators are also approved to treat PAH.

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

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

The clinical severity of PAH is classified according to a system originally developed for heart failure by the New York Heart Association and then modified by the World Health Organization (WHO) for patients with PAH, ranging from functional class I (no symptoms) through functional class IV (severe symptoms). Labeled indications for PAH therapies often note that clinical studies for the drug predominantly included patients in one or more functional classes.

PAH is a subset of the condition more broadly known as pulmonary hypertension. WHO has classified pulmonary hypertension into five groups, with PAH being designated WHO Group 1, which includes multiple etiologies such as idiopathic (meaning the cause is unknown) and heritable PAH, as well as PAH associated with connective tissue diseases. While our PAH therapies' labeling is limited to the treatment of WHO Group 1 PAH, we are engaged in research and development efforts to expand the use of Orenitram to treat pulmonary hypertension in certain categories of WHO Group 2, and Tyvaso to treat pulmonary hypertension in certain categories of WHO Group 3. For further details, see *Research and Development* below.

Remodulin

We sell Remodulin to specialty pharmaceutical distributors in the United States and to pharmaceutical distributors internationally. We recognized $599.0 million, $670.9 million and

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$602.3 million in Remodulin net product sales, representing 37 percent, 39 percent and 38 percent of our total revenues for the years ended December 31, 2018, 2017 and 2016, respectively. Remodulin is indicated to treat patients with PAH, to diminish symptoms associated with exercise. Studies establishing effectiveness included patients with functional class II-IV (moderate to severe) symptoms.

Outside of the United States, Remodulin is approved for the treatment of PAH in 38 countries by continuous subcutaneous administration and in 35 countries by continuous intravenous administration, and is sold commercially in most of these countries. In May 2019, our marketing authorization for Remodulin in China will expire, at which point we expect to withdraw Remodulin from the Chinese market in light of the anticipated availability of a generic version of Remodulin. Revenues from sales of Remodulin in China have been immaterial.

We believe Remodulin has many qualities that make it an appealing alternative to competitive therapies. Remodulin is stable at room temperature, so it does not need to be cooled during infusion and patients do not need to use cooling packs or refrigeration to keep it stable. Treprostinil is highly soluble and highly potent, which enables us to manufacture Remodulin in concentrated solutions. This allows therapeutic concentrations of Remodulin to be delivered at very low flow rates via miniaturized infusion pumps for both subcutaneous and intravenous infusion. Remodulin can be continuously infused for up to 48 hours intravenously or 72 hours subcutaneously before refilling the external infusion pump. This profile contrasts favorably with the other continuously infused prostacyclin therapies in the market Flolan®, Veletri® and generic epoprostenol.

Flolan and generic epoprostenol are not stable at room temperature (and therefore require refrigeration or the use of cooling packs), but Veletri may be stable at room temperature depending on its concentration. Flolan, generic epoprostenol, and Veletri have shorter half-lives than Remodulin, requiring mixing prior to pump refills. None of these competitive products may be administered via subcutaneous infusion, and therefore may only be delivered intravenously.

We settled litigation with each of Sandoz, Inc. (Sandoz), Teva Pharmaceuticals USA, Inc. (Teva), Par Sterile Products, LLC (Par) and Dr. Reddy's Laboratories, Inc. (Dr. Reddy's), related to their abbreviated new drug applications (ANDAs) seeking FDA approval to market generic versions of Remodulin before the expiration of certain of our U.S. patents. Under the terms of our settlement agreements, Sandoz was permitted to market its generic version of Remodulin in the United States beginning in June 2018, and Teva, Par and Dr. Reddy's were each permitted to launch their generic versions in the United States beginning in December 2018. To our knowledge, none of these companies has yet launched sales of a generic version of Remodulin. For further detail, see the section below entitled *Patents and Other Proprietary Rights, Strategic Licenses and Market Exclusivity Generic Competition*.

Patients must use external pumps manufactured by third parties to deliver Remodulin. Smiths Medical manufactures the pumps used by most patients in the United States to administer Remodulin, including the Smiths CADD® MS-3 pump used to deliver subcutaneous Remodulin. In 2015, Smiths Medical notified us that it was planning to discontinue the manufacture of the CADD MS-3 pumps and associated cartridges. We entered into an agreement with Smiths Medical to fund the manufacture of a further supply of CADD MS-3 pumps and cartridges for use with branded Remodulin only. We anticipate this supply will be sufficient to ensure continued support of subcutaneous Remodulin for several years, and are working with Smiths Medical to develop a next-generation infusion system called RemoLife prior to the exhaustion of the available CADD MS-3 supply. As noted below under *Research and Development*, we are also working on developing the Trevyent and RemUnity systems for subcutaneous delivery of Remodulin.

There are serious adverse events associated with Remodulin. For example, when infused subcutaneously, Remodulin causes varying degrees of infusion site pain and reaction (redness and swelling) in most patients. Patients who cannot tolerate the infusion site pain related to the use of

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subcutaneous Remodulin may instead use intravenous Remodulin. Intravenous Remodulin is delivered continuously through a surgically implanted central venous catheter, similar to Flolan, Veletri and generic epoprostenol. Patients who receive therapy through implanted venous catheters have a risk of developing blood stream infections and a serious systemic infection known as sepsis. As a result, subcutaneous administration is the preferred method of Remodulin delivery, and is used by a majority of U.S. Remodulin patients. Other common side effects associated with both subcutaneous and intravenous Remodulin include headache, diarrhea, nausea, jaw pain, vasodilation and edema.

Tyvaso

We sell Tyvaso to the same specialty pharmaceutical distributors in the United States that distribute Remodulin. We recognized $415.2 million, $372.9 million and $404.6 million in Tyvaso net product sales, representing 25 percent, 22 percent and 25 percent of our total revenues for the years ended December 31, 2018, 2017 and 2016, respectively. Tyvaso is approved in the United States, Israel and Argentina.

Tyvaso is administered four times a day by inhaling up to nine breaths during each treatment session, which takes approximately three minutes. Tyvaso is required to be administered using our proprietary Tyvaso Inhalation System, which consists of an ultra-sonic nebulizer and related accessories. A single ampule containing Tyvaso is emptied into the Tyvaso Inhalation System once per day, so the Tyvaso Inhalation System only needs to be cleaned once daily. Tyvaso is regulated by the FDA as a drug-device combination product, consisting of Tyvaso drug product and the Tyvaso Inhalation System.

Ventavis® (iloprost) is the only other FDA-approved inhaled prostacyclin analogue. Patients need to inhale Ventavis six to nine times per day via a nebulizer. According to its package insert, each Ventavis inhalation consists of four to ten minutes of continuous inhalation via the nebulizer. We completed an open-label study in the United States to investigate the clinical effects of switching patients from Ventavis to Tyvaso. Patients in this study saved an average of approximately 1.4 hours per day when administering Tyvaso compared to Ventavis.

Studies establishing the effectiveness of Tyvaso included predominately patients with functional class III symptoms (may not have symptoms at rest but activities are greatly limited by shortness of breath, fatigue, or near fainting). Tyvaso was generally well tolerated in our trials. The most common adverse events were transient cough, headache, nausea, dizziness and flushing.

In August 2018, we settled patent litigation with Watson Laboratories, Inc. (Watson) related to its ANDA seeking to market a generic version of Tyvaso in the United States. Under the terms of this settlement, Watson may launch its generic version of Tyvaso in the United States beginning in January 2026, although Watson may be permitted to enter the market earlier under certain circumstances. For further detail, see the section below entitled *Patents and Other Proprietary Rights, Strategic Licenses and Market Exclusivity Generic Competition*.

Orenitram

Orenitram is the only FDA approved, orally administered prostacyclin analogue, and is the only oral PAH prostacyclin class therapy approved in the United States that is titratable to a maximum tolerated dose, without a dose ceiling. We sell Orenitram to the same specialty pharmaceutical distributors in the United States that distribute Remodulin and Tyvaso. We recognized $205.1 million, $185.8 million and $157.2 million in Orenitram net product sales, representing 13 percent, 11 percent and 10 percent of our total revenues for the years ended December 31, 2018, 2017 and 2016, respectively. The primary study that established efficacy included predominately patients with functional class II-III symptoms and etiologies of idiopathic or heritable PAH (75 percent) or PAH associated with connective tissue disease (19 percent). The most common side effects observed in our clinical studies were headache, nausea and diarrhea. Orenitram is not approved outside the United States.

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In February 2018, we settled patent litigation with Actavis Laboratories FL, Inc. (Actavis) related to its ANDA seeking to market a generic version of Orenitram in the United States. Under the terms of this settlement, Actavis may launch its generic version of Orenitram in the United States beginning in June 2027, although Actavis may be permitted to enter the market earlier under certain circumstances. For further detail, see the section below entitled *Patents and Other Proprietary Rights, Strategic Licenses and Market Exclusivity Generic Competition*.

Adcirca

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 Eli Lilly and Company (Lilly) for the treatment of erectile dysfunction. We acquired the commercial rights to Adcirca for the treatment of PAH in the United States from Lilly in 2008. We sell Adcirca at prices established by Lilly, which are at parity with Cialis pricing. We recognized $323.7 million, $419.7 million and $372.2 million in Adcirca net product sales, representing 20 percent, 24 percent and 23 percent of our total revenues for the years ended December 31, 2018, 2017 and 2016, respectively.

In 2009, the FDA approved Adcirca with a recommended dose of 40 mg, making it the only once-daily PDE-5 inhibitor for the treatment of PAH. Adcirca is indicated to improve exercise ability in patients with PAH. Studies establishing effectiveness included predominately patients with functional class II-III symptoms. Headaches were the most commonly reported side effect.

Prior to the approval of Adcirca, Revatio®, which is marketed by Pfizer Inc. (Pfizer), was the only PDE-5 inhibitor approved for the treatment of PAH. Sildenafil citrate, the active ingredient in Revatio, is also the active ingredient in Viagra®, which is marketed by Pfizer for the treatment of erectile dysfunction. In 2012, several companies launched generic formulations of sildenafil citrate. Revatio and generic sildenafil citrate are dosed three times daily.

In September 2014, Gilead Sciences, Inc. (Gilead) announced the results of a study of ambrisentan (an ETRA) and tadalafil in PAH patients as a first-line combination treatment, compared to treating PAH patients with only ambrisentan or tadalafil. In the study, first-line treatment with both therapies reduced the risk of clinical failure (a composite endpoint that incorporates clinical worsening events death, hospitalization and disease worsening and a component of unsatisfactory long-term clinical response) compared to a monotherapy treatment by 50 percent. Based on these results, in October 2015, the FDA approved an update to the new drug application (NDA) for Letairis® (ambrisentan), permitting the use of Letairis in combination with tadalafil for PAH to reduce the risks of disease progression and hospitalization for worsening PAH, and to improve exercise ability.

In May 2017, we amended our Adcirca license agreement with Lilly to clarify and extend the term of the agreement and to amend the economic terms of the agreement following the expiration of a patent covering Adcirca in November 2017. As a result of this amendment, beginning December 1, 2017, our royalty rate on net product sales of Adcirca increased from five percent to ten percent, and we are required to make milestone payments to Lilly equal to $325,000 for each $1,000,000 in net product sales. Adcirca's cost of product sales as a percentage of Adcirca's net product sales has increased significantly since December 1, 2017 due to these cost increases. In August 2018, Mylan N.V. announced the launch of its generic version of Adcirca, which resulted in a material adverse impact on Adcirca net product sales. Additional companies launched generic versions of Adcirca in February 2019. For further detail, see the section below entitled *Patents and Other Proprietary Rights, Strategic Licenses and Market Exclusivity Generic Competition*.

Our license agreement with Lilly related to Adcirca expires on December 31, 2020.

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Product to Treat Cancer Unituxin

In March 2015, the FDA approved our Biologics License Application (BLA) for Unituxin, in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), interleukin-2 (IL-2), and 13-cis-retinoic acid (RA), for the treatment of patients with high-risk neuroblastoma (a rare form of pediatric cancer) who achieve at least a partial response to prior first-line multiagent, multimodality therapy. Unituxin is a chimeric, composed of a combination of mouse and human DNA, monoclonal antibody that induces antibody-dependent cell-mediated cytotoxicity, a mechanism of cell-mediated immunity whereby the immune system actively targets a cell that has been bound by specific antibodies. Unituxin therapy is associated with severe side effects, including infections, infusion reactions, hypokalemia, hypotension, pain, fever, and capillary leak syndrome. In November 2018, we received approval from Health Canada to market Unituxin, and we are preparing to launch commercial sales of the product in Canada during the second quarter of 2019.

We recognized $84.8 million, $76.0 million and $62.5 million in Unituxin net product sales, representing five percent, four percent and four percent of our total revenues for the years ended December 31, 2018, 2017 and 2016, respectively.

Research and Development

We focus most of our research and development efforts on the following near-term pipeline programs (intended to result in product launches in the 2019-2021 timeframe) and medium-term pipeline programs (intended to result in product launches in the 2022-2025 timeframe). We are also engaged in a variety of additional medium- and long-term research and development efforts, including technologies designed to increase the supply of transplantable organs and tissues and improve outcomes for transplant recipients through regenerative medicine, xenotransplantation, biomechanical lungs and ex-vivo lung perfusion.

Near-Term Pipeline Programs (2019-2021)

Product	Mode of Delivery	Indication	Current Status STUDY NAME	Our Territory
Implantable System for Remodulin	Continuous intravenous via implantable pump	PAH	FDA approval received July 30, 2018; U.S. launch pending satisfaction of further regulatory requirements by Medtronic	United States, United Kingdom, Canada, France, Germany, Italy and Japan
RemUnity (treprostinil)	Continuous subcutaneous via pre-filled, semi-disposable system	PAH	510(k) application process ongoing with FDA	Worldwide

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Product	Mode of Delivery	Indication	Current Status STUDY NAME	Our Territory
Orenitram (treprostinil) in combination with approved background therapy	Oral	PAH (decrease morbidity and mortality)	Phase IV *FREEDOM-EV* Study completed, primary endpoint met; NDA supplement submitted to FDA December 2018	Worldwide
Trevyent® (treprostinil)	Continuous subcutaneous via pre-filled, disposable PatchPump® system	PAH	NDA to be resubmitted to FDA	Worldwide, subject to out-licenses granted in Europe, Canada and the Middle East
Tysuberprost (esuberaprost in combination with Tyvaso)	Oral (esuberaprost) Inhaled (Tyvaso)	PAH (decrease morbidity and mortality)	Phase III *BEAT* (fully enrolled)	North America, Europe, Mexico, South America, Egypt, India, Israel, South Africa and Australia
RemoPro (pain-free subcutaneous Remodulin prodrug)	Continuous subcutaneous	PAH	Phase I	Worldwide
Unituxin (dinutuximab)	Intravenous	Small cell lung cancer	Phase II/III *DISTINCT* (fully enrolled)	Worldwide
Tyvaso (treprostinil)	Inhaled	Pulmonary hypertension associated with idiopathic pulmonary fibrosis (WHO Group 3)	Phase III *INCREASE*	Worldwide

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Medium-Term Pipeline Programs (2022-2025)

Product	Mode of Delivery	Indication	Current Status STUDY NAME	Our Territory
Tyvaso (treprostinil)	Inhaled	Pulmonary hypertension associated with chronic obstructive pulmonary disease (WHO Group 3)	Phase III *PERFECT*	Worldwide
Treprostinil Technosphere®	Inhaled dry powder	PAH	Phase III	Worldwide
Orenitram (treprostinil)	Oral	Pulmonary hypertension associated with left ventricular diastolic dysfunction (WHO Group 2)	Phase III *SOUTHPAW*	Worldwide
Ralinepag (IP receptor agonist)	Oral	PAH	Phase III *ADVANCE* studies	Worldwide, excluding the People's Republic of China and certain other Asian territories that have been outlicensed to Everest Medicines
Aurora-GT (eNOS gene therapy)	Intravenous	PAH	Phase II/III *SAPPHIRE*	United States
SM04646 (Wnt pathway inhibitor)	Inhaled	Idiopathic pulmonary fibrosis	Phase I	United States and Canada

Implantable System for Remodulin

On July 30, 2018, we obtained FDA approval of the Implantable System for Remodulin in the United States. We developed this system in collaboration with Medtronic, Inc. (Medtronic). The system incorporates a proprietary Medtronic intravascular infusion catheter with Medtronic's SynchroMed® II implantable infusion pump and related infusion system components (together referred to as the Implantable System for Remodulin) in order to deliver Remodulin for the treatment of PAH. We believe this technology has the potential to reduce many of the patient burdens and other complications associated with the use of external pumps to administer prostacyclin analogues. The FDA approved Medtronic's premarket approval application (PMA) for the device in December 2017, and our NDA for the use of Remodulin in the implantable pump in July 2018. Medtronic must satisfy certain conditions to its PMA approval before we can launch the Implantable System for Remodulin. We have no control over when or whether these conditions will be met.

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In February 2019, we entered into a commercialization agreement under which Medtronic will manufacture and supply the Implantable System for Remodulin, and we will manufacture and supply Remodulin for use in the system. Each party will perform certain additional activities to support the commercialization of the Implantable System for Remodulin, and we will reimburse Medtronic's costs to provide such support. We will pay Medtronic a royalty equal to ten percent of our net sales of Remodulin administered via the Implantable System for Remodulin. We have entered into an agreement with Caremark, L.L.C. (CVS Specialty) to provide for refills of implanted pumps at its infusion centers. Once Medtronic satisfies its remaining PMA conditions, we plan to approach the launch in a careful and deliberate manner to ensure the safety of patients and the long-term success of the program. Medtronic has agreed to produce a supply of pumps for the initial launch that we believe will be sufficient to provide the system to any eligible PAH patient in the United States currently receiving intravenous prostacyclin therapy. We anticipate that the initial pump supply will enable us to launch the Implantable System for Remodulin in 2019 at the ten clinical trial sites that participated in the pivotal *DelIVery* clinical study of the Implantable System for Remodulin, and subsequently commence a broader launch in up to approximately 100 additional sites by the end of the year. These timelines are subject to a number of factors outside our control, including Medtronic's satisfaction of its PMA conditions. We are also working with Medtronic to develop a next-generation system incorporating various enhancements.

Medtronic is entirely responsible for regulatory approvals and all manufacturing and quality systems related to its infusion pump and related components. Medtronic entered into a consent decree with the FDA in April 2015, which required Medtronic to complete certain corrections and enhancements to the SynchroMed II pump and the associated quality system. The consent decree restricted Medtronic's ability to manufacture and distribute the SynchroMed II infusion system, unless specific conditions were met, including retention of a third-party expert to inspect the affected quality system and certify that the quality system complies with the requirements of the consent decree. Medtronic completed the third-party certification audits in January 2017 and successfully completed an FDA inspection in June 2017. After the inspection, FDA lifted the consent decree restrictions on manufacturing, distribution, and design in September 2017. The consent decree remains in effect, with ongoing obligations for annual third-party audits continuing until September 2020. Non-compliance by Medtronic with its consent decree could interrupt the manufacture and sale of the Implantable System for Remodulin.

RemUnity and RemoPro

In December 2014, we entered into an exclusive agreement with DEKA Research & Development Corp. (DEKA) to develop a pre-filled, semi-disposable system for subcutaneous delivery of treprostinil, which we call the RemUnity system. Under the terms of the agreement, we are funding the development costs related to the RemUnity system and will pay product fees and a single-digit royalty to DEKA based on commercial sales of the system and the treprostinil drug product sold for use with the system. The RemUnity system consists of a small, lightweight, durable pump that is intended to have a service life of at least three years. The RemUnity system uses disposable cartridges pre-filled with treprostinil, which can be connected to the pump with less patient manipulation than is typically involved in filling currently-available subcutaneous pumps.

DEKA is working with the FDA to obtain 510(k) clearance of the RemUnity system. Initially, we plan to launch the system with disposable components to be pre-filled with Remodulin by our specialty pharmacy distributors. We are also developing a version of the system that includes disposable components that are pre-filled as part of the manufacturing process.

We are also conducting phase I studies to develop a new prodrug of treprostinil called RemoPro, which is intended to enable subcutaneous delivery without the site pain currently associated with subcutaneous Remodulin. As a prodrug, RemoPro is designed to be inactive in the subcutaneous tissue,

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which should decrease or eliminate site pain, and to metabolize into treprostinil once it is absorbed into the blood.

Trevyent

In August 2018, we acquired SteadyMed Ltd. (SteadyMed), which is developing Trevyent, a post-phase III development-stage drug-device combination product that combines SteadyMed's two-day, single use, disposable PatchPump technology with treprostinil, for the subcutaneous treatment of PAH. In August 2017, SteadyMed received a refuse-to-file letter from the FDA with respect to its 505(b)(2) NDA for Trevyent. SteadyMed met with the FDA in November 2017, and the FDA indicated that SteadyMed does not need to conduct any clinical trials to prove the safety or efficacy of Trevyent. We are completing certain additional non-clinical activities related to Trevyent, and anticipate resubmitting the NDA during the first half of 2019. These activities include design verification testing on the final to-be-marketed Trevyent product, pharmacokinetic modeling and process validation.

Orenitram

In 2013, the FDA approved Orenitram for the treatment of PAH patients to improve exercise capacity. The primary study that supported efficacy of Orenitram was a 12-week monotherapy study (*FREEDOM-M*) in which PAH patients were not on any approved background PAH therapy. In August 2018, we announced that our phase IV study of Orenitram called *FREEDOM-EV* had met its primary endpoint of delayed time to first clinical worsening event. In particular, the preliminary results showed that Orenitram, when taken with an oral PAH background therapy, decreased the risk of a morbidity/mortality event versus placebo by 26 percent (p=0.0391). In December 2018, we submitted a supplement to our NDA to the FDA seeking approval for a label amendment reflecting the *FREEDOM-EV* results, and we are evaluating whether the results could support marketing applications for Orenitram outside the United States. Additional *FREEDOM-EV* data were presented at a medical conference in January 2019, including a 61 percent decrease in the risk of disease progression for patients taking Orenitram, when compared to placebo (p=0.0002). In addition, in participants for which data are available (89 percent), Orenitram was associated with a 37 percent decreased risk of mortality compared with placebo (p=0.0324) at study closure (which includes additional data accrued in the open-label extension study).

Secondary endpoints in the *FREEDOM-EV* study are summarized below:

Change in six-minute walk distance (6MWD) from baseline. The median 6MWD trended toward improvement at week 24 (Hodges-Lehmann treatment estimate: 7 meters; p=0.0913). Median 6MWD improved with Orenitram at weeks 36 (13 meters; p=0.0094) and 48 (21 meters; p=0.0008) compared to placebo.

Change in Borg dyspnea score and WHO functional class from baseline. When classified categorically as 'improved', 'no change', or 'deteriorated', participants in the Orenitram group exhibited a positive shift in Borg dyspnea score and WHO functional class compared to placebo at weeks 24, 36, and 48 ($p<0.05$, all).

Change in N-terminal pro-brain natriuretic peptide (NT-proBNP) levels from baseline. NT-proBNP levels were significantly improved with Orenitram at weeks 24 and 36 ($p<0.0001$, both).

Change in combined 6MWD and Borg dyspnea score from baseline. Combined 6MWD and Borg dyspnea score was significantly improved with Orenitram when assessed at week 24 compared to placebo (p=0.0057).

We expect to discuss the *FREEDOM-EV* results in further detail at upcoming medical conferences.

We are also enrolling patients in a study of Orenitram (*SOUTHPAW*) to treat WHO Group 2 pulmonary hypertension (specifically associated with left ventricular diastolic dysfunction). There are presently no FDA approved therapies indicated for the treatment of WHO Group 2 pulmonary hypertension.

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Tysuberprost

In 2012, we completed a phase I safety study of esuberaprost, a single-isomer orally bioavailable prostacyclin analogue, and the data suggested that dosing esuberaprost four times a day was tolerable. We believe that esuberaprost and treprostinil have differing prostacyclin receptor-binding profiles, and we are studying the potential safety and efficacy benefits for patients when used in combination. We also believe that inhaled treprostinil and oral esuberaprost have complementary pharmacokinetic and pharmacodynamic profiles, which indicate that they should provide greater efficacy in combination. We refer to the use of esuberaprost and Tyvaso therapies in combination with each other as Tysuberprost. In March 2017, we completed enrollment of our phase III registration study called *BEAT* to evaluate the clinical benefit and safety of esuberaprost in combination with Tyvaso for patients with PAH who show signs of deterioration on Tyvaso or have a less than optimal response to Tyvaso treatment. We anticipate announcing the results of the *BEAT* study during the first half of 2019.

Unituxin

Under our BLA approval for Unituxin, the FDA has imposed certain post-marketing requirements and post-marketing commitments on us. We are conducting additional clinical and non-clinical studies to satisfy these requirements and commitments. While we believe we will be able to complete these studies, any failure to satisfy these requirements or commitments could result in penalties, including fines or withdrawal of Unituxin from the market, unless we are able to demonstrate good cause for the failure.

In addition, we are conducting a study (*DISTINCT*) of Unituxin in adult patients with small cell lung cancer, which is another GD2-expressing cancer. During the fourth quarter of 2017, we completed the phase II portion of the study, and commenced the phase III portion of the study following an interim safety review. The phase III portion of the *DISTINCT* study is now fully enrolled with 472 patients, and we expect to announce the results by the first quarter of 2020. We are also conducting preclinical research to determine Unituxin's potential activity against other types of GD2-expressing tumors. These research and development efforts into new indications for Unituxin have been substantially outsourced to a contract research organization called Precision Oncology, LLC.

Unituxin therapy is associated with severe side effects, including infections, infusion reactions, hypokalemia, hypotension, pain, fever, and capillary leak syndrome. In post-approval use of Unituxin, the adverse reactions of prolonged urinary retention, transverse myelitis, and reversible posterior leukoencephalopathy syndrome have been observed. Unituxin's label also includes a boxed warning related to serious infusion reactions and neurotoxicity.

Finally, we are developing a fully humanized (non-chimeric) version of dinutuximab, the active ingredient in Unituxin. We expect this new version to reduce some of the side effects associated with Unituxin, which is a chimeric composed of a combination of mouse and human proteins.

Tyvaso

In October 2017, we received FDA approval of a supplement to our NDA for Tyvaso, covering a new inhalation device as part of the Tyvaso Inhalation System. The new device, called the TD-300/A, was designed based on physician and prescriber feedback, and is intended to aid patient compliance and enhance ease of use. In addition, we are engaged in research and development efforts into new devices to further optimize the delivery of inhaled treprostinil, including a *pro re nata* (as needed) device called Spiresta .

We are enrolling a phase III registration study called *INCREASE*, which is a study of Tyvaso in patients with WHO Group 3 pulmonary hypertension associated with interstitial lung disease (specifically associated with idiopathic pulmonary fibrosis or combined pulmonary fibrosis and

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emphysema). This study is now over 75 percent enrolled. We are also enrolling a phase III registration study called *PERFECT*, which is a study of Tyvaso in patients with WHO Group 3 pulmonary hypertension associated with chronic obstructive pulmonary disease. There are presently no FDA approved therapies indicated for the treatment of WHO Group 3 pulmonary hypertension.

Treprostinil Technosphere

In September 2018, we entered into a worldwide exclusive license and collaboration agreement with MannKind Corporation (MannKind) for the development and commercialization of a dry powder formulation of treprostinil called Treprostinil Technosphere for the treatment of PAH. The agreement became effective on October 15, 2018. Treprostinil Technosphere incorporates the dry powder formulation technology and Dreamboat® inhalation device technology used in MannKind's Afrezza® (insulin human) Inhalation Powder product, which was approved by the FDA in 2014. If the FDA approves Treprostinil Technosphere, we believe this new inhaled treprostinil therapy will provide substantial lifestyle benefits to PAH patients, as compared with Tyvaso therapy, because it will be: (1) less time consuming to administer and easier to maintain as the device and drug will be provided in a pre-filled, single use disposable cassette eliminating the need for cleaning and filling; and (2) mobile and more convenient as the compact design of MannKind's Dreamboat device and drug cassettes used with Treprostinil Technosphere can easily fit into the patient's pocket and do not require electricity. We also have the right to develop a single-use device based on MannKind's Cricket® design. The Cricket device would come pre-loaded with treprostinil and would be discarded immediately after use. In contrast, we envision each Dreamboat device would be used for up to two weeks before it is replaced with a new device.

Under our agreement with MannKind, we are responsible for global development, regulatory and commercial activities related to Treprostinil Technosphere. We plan to commence a clinical study (called *BREEZE*) during the first half of 2019 to evaluate the safety of switching PAH patients from Tyvaso to Treprostinil Technosphere, as well as a pharmacokinetic study in healthy volunteers. The FDA has indicated that these two studies, if successful, will be the only clinical studies necessary to support FDA approval. We and MannKind will share responsibility for manufacturing clinical supplies and initial commercial supplies of Treprostinil Technosphere. We will manufacture long-term commercial supplies. Under the terms of the agreement, we paid MannKind $45.0 million following the effectiveness of the agreement in October 2018, and we are required to make potential milestone payments to MannKind of up to $50.0 million upon the achievement of specific development targets. MannKind is also entitled to receive low double-digit royalties on our net sales of the product. In addition, we have the option, in our sole discretion, to expand the license to include other active ingredients for the treatment of pulmonary hypertension. We will pay MannKind up to $40 million in additional option exercise and development milestone payments for each product (if any) added to the license pursuant to this option, as well as a low double-digit royalty on our net sales of any such product.

We also entered into a research agreement with MannKind under which MannKind will conduct research related to products outside the scope of the licensing and collaboration agreement. We paid MannKind $10.0 million in consideration for its performance under the research agreement.

Aurora-GT

We are enrolling a phase II/III study (called *SAPPHIRE*) of a gene therapy product called Aurora-GT, in which a PAH patient's own endothelial progenitor cells are isolated, transfected with the gene for human endothelial NO-synthase (eNOS), expanded ex-vivo and then delivered to the same patient. This product is intended to rebuild the blood vessels in the lungs that are destroyed by PAH. This study is being conducted in Canada, and is sponsored by Northern Therapeutics, Inc., a Canadian entity in which we have a 49.7 percent voting stake and a 71.8 percent financial stake. We have the

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exclusive right to pursue this technology in the United States, and plan to seek FDA approval of Aurora-GT if *SAPPHIRE* is successful.

SM04646

In September 2018, we entered into a license agreement with Samumed LLC (Samumed) providing us exclusive U.S. and Canadian rights to SM04646, a phase I development-stage Wnt pathway inhibitor being developed for the treatment of idiopathic pulmonary fibrosis (IPF). The Wnt pathway is one of the primary signaling pathways essential for the normal development of all multicellular animals, and for the growth and maintenance of various adult tissues. Recent evidence suggests that aberrant Wnt signaling may be involved in the pathogenesis of chronic lung disease such as IPF. SM04646 is currently undergoing a phase I clinical trial. The FDA has granted orphan drug designation for SM04646 for the treatment of IPF. Under our agreement with Samumed, we paid Samumed $10 million up-front, and we will pay Samumed additional consideration of up to $340 million in developmental milestone payments, plus up to low double-digit royalties on our net sales of the product. Under the terms of the agreement, our subsidiary, Lung Biotechnology PBC, will conduct and fund all development, regulatory and commercialization activities for SM04646 in the United States and Canada. Samumed retains development and commercialization rights for SM04646 for all markets outside of these two countries.

Ralinepag

In November 2018, we entered into a global license agreement with Arena Pharmaceuticals, Inc. (Arena), providing us exclusive rights to ralinepag, a next-generation, oral, selective and potent IP prostacyclin receptor agonist in development for the treatment of PAH. In January 2019, in connection with the closing of the transactions contemplated by the license agreement, (1) Arena granted to us perpetual, irrevocable and exclusive rights throughout the universe to develop, manufacture and commercialize ralinepag; (2) Arena transferred to us certain other assets related to ralinepag, including, among others, related domain names and trademarks, permits, certain contracts, inventory, regulatory documentation, Investigational New Drug (IND) Application No. 109021 (related to ralinepag) and non-clinical, pre-clinical and clinical trial data; and (3) we assumed certain limited liabilities from Arena, including, among others, all obligations arising after the closing under the assumed contracts and the IND described above; and (4) we paid Arena an upfront payment of $800.0 million. We will also pay Arena (1) a one-time payment of $250.0 million for the first, if any, marketing approval we receive in the United States for an inhaled version of ralinepag to treat PAH; (2) a one-time payment of $150.0 million for the first, if any, marketing approval we receive in any of Japan, France, Italy, the UK, Spain or Germany for an oral version of ralinepag to treat any indication; and (3) low double-digit, tiered royalties on net sales of any pharmaceutical product containing ralinepag as an active ingredient, subject to certain adjustments for third party license payments.

In 2017, Arena announced topline results from a 22-week, randomized, double-blind, placebo-controlled phase II trial evaluating the tolerability and safety of ralinepag, and the effectiveness of ralinepag in reducing pulmonary vascular resistance (PVR) and improving exercise capacity. In this trial, 40 patients with PAH received ralinepag and 21 received placebo. Topline results showed statistically significant improvement of both absolute and percentage change from baseline in PVR. Patients on ralinepag also demonstrated numerical improvement in 6MWD, but as the study was not powered to show a difference in 6MWD from placebo, this was a not a statistically-significant finding. The safety and tolerability profiles were in line with other oral prostacyclin-class therapies.

We are continuing the ongoing phase III *ADVANCE OUTCOMES* study initiated by Arena, which is an event-driven study of ralinepag in PAH patients, with a primary endpoint of time to first clinical event. We are also planning two additional phase III studies, called *ADVANCE CAPACITY* and *ADVANCE ENDURANCE*, studying the effect of ralinepag on exercise capacity in PAH patients (with

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primary endpoints of change in peak oxygen uptake via cardiopulmonary exercise test and change in six-minute walk distance, respectively). All three of these studies are global, multi-center, placebo-controlled trials of patients on approved oral background PAH therapies. These studies collectively provide us with multiple potential avenues for FDA approval of ralinepag.

Upon closing, we also assumed Arena's existing outlicense of ralinepag to Everest Medicines in the following territories: the People's Republic of China, Hong Kong, South Korea, Macau and Taiwan.

Organ Manufacturing

Each year, end-stage organ failure kills millions of people. A significant number of these patients could have benefited from an organ transplant. Unfortunately, the number of usable, donated organs available for transplantation has not grown significantly over the past half century while the need has soared. Our long-term goals are aimed at addressing this shortage. With advances in technology, we believe that creating an unlimited supply of tolerable manufactured organs is now principally an engineering challenge, and we are dedicated to finding engineering solutions. Since 2011, we have been engaged in research and development of a variety of technologies designed to increase the supply of transplantable organs and tissues and improve outcomes for transplant recipients. These programs include preclinical research and development of alternative tissue sources through tissue and organ xenotransplantation, regenerative medicine, biomechanical lungs, and other technologies to create engineered organs and organ tissues. Although our primary focus is on engineered lungs, we are also developing technology for other engineered organs, such as kidneys and hearts, and our manufactured lungs, kidneys and hearts have set records for viability in FDA-required animal models. In February 2018 we reached a significant milestone by achieving 30-day survival of our genetically modified porcine lungs in FDA-required animal models. We are also developing technologies to improve outcomes for lung transplant recipients and to increase the supply of donor lungs through ex-vivo lung perfusion. While we continue to develop and commercialize therapies for rare and life-threatening conditions, we view organ manufacturing as the ultimate technology solution for a broad array of diseases, many of which (such as PAH) have proven incurable thus far through more traditional pharmaceutical and biologic therapies. For this reason, in 2015 we created a wholly-owned public benefit corporation called Lung Biotechnology PBC, chartered with the express purpose of "address[ing] the acute national shortage of transplantable lungs and other organs with a variety of technologies that either delay the need for such organs or expand the supply."

Sales and Marketing

Our marketing strategy for our commercial PAH products is to use our sales and marketing teams to reach out to the prescriber community to: (1) increase PAH awareness; (2) increase understanding of the progressive nature of PAH and the importance of early treatment; and (3) increase awareness of our commercial products and how they fit into the various stages of disease progression and treatment.

Distribution of Commercial Products

United States Distribution of Remodulin, Tyvaso, Orenitram, and Unituxin

We distribute Remodulin, Tyvaso and Orenitram throughout the United States through two contracted specialty pharmaceutical distributors: Accredo Health Group, Inc. and its affiliates, including Curascript SD Specialty Distribution (collectively Accredo), and CVS Specialty. These distributors are required to maintain certain minimum inventory levels in order to ensure an uninterrupted supply to patients who are prescribed our therapies. We compensate Accredo and CVS Specialty on a fee-for-service basis for certain ancillary services in connection with the distribution of these products. If any of our distribution agreements expire or terminate, we may, under certain circumstances, be required to repurchase any unsold Remodulin, Tyvaso or Orenitram inventory held by our distributors.

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These specialty pharmaceutical distributors are responsible for assisting patients with obtaining reimbursement for the cost of our treprostinil-based products and providing other support services. Under our distribution agreements, we sell each of our treprostinil-based products to these distributors at a transfer price that we establish. We have also established patient assistance programs in the United States, which provide our treprostinil-based products to eligible uninsured or under-insured patients at no charge. Accredo and CVS Specialty assist us with the administration of these programs.

We distribute Unituxin throughout the United States through an exclusive distribution agreement with ASD Specialty Healthcare, Inc. (ASD), an affiliate of AmerisourceBergen Corporation. Under this agreement, we sell Unituxin to ASD at a transfer price that we establish, and we pay ASD fees for services provided in connection with the distribution and support of Unituxin.

To the extent we increase the price of any of these products, increases are typically in the single-digit percentages per year.

United States Distribution of Adcirca

Under our manufacturing and supply agreement with Lilly, Lilly manufactures and distributes Adcirca on our behalf through its wholesaler network in the same manner that it distributes its own pharmaceutical products. Under the terms of this agreement, we take title to Adcirca upon completion of its manufacture by Lilly. Adcirca is shipped to customers in accordance with purchase orders received by Lilly. Upon shipment, Lilly sends an invoice and collects the amount due from the customer subject to customary discounts and rebates, if any. Although Lilly provides these services on our behalf, we maintain the risk of loss as it pertains to inventory, product returns and non-payment of invoices. The manufacturing and supply agreement will continue in effect until the December 31, 2020 expiration or earlier termination of our license agreement for Adcirca. Lilly retains authority under the license agreement for all regulatory activities with respect to Adcirca, as well as its retail pricing, which has been and is expected to remain at price parity with Cialis. Since receiving FDA approval of Adcirca, Lilly has generally increased the net wholesale price of Adcirca two or three times each year by approximately nine to ten percent each time. We have also established a patient assistance program in the United States, which provides Adcirca to eligible uninsured or under-insured patients at no charge.

International Distribution of Remodulin and Tyvaso

We currently sell Remodulin outside the United States to various distributors, each of which has exclusive distribution rights in one or more countries within Europe, Israel and the Middle East, Asia and South and Central America. We sell Tyvaso commercially to distributors that have exclusive distribution rights in Israel and Argentina. We also distribute Remodulin in Canada through a specialty pharmaceutical wholesaler, and plan to distribute Unituxin in Canada through the same wholesaler upon its commercial launch, which is planned for the first half of 2019. In some of the European markets where we are not licensed to market Remodulin, such as Spain and the United Kingdom, we sell (but do not market) Remodulin on a named-patient basis in which therapies are approved for individual patients by a national medical review board, hospital or health plan on a case-by-case basis. We also maintain similar named-patient programs for Tyvaso in certain countries.

Patents and Other Proprietary Rights, Strategic Licenses and Market Exclusivity

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

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In addition to intellectual property rights, U.S. and international regulatory authorities often provide periods of market exclusivity for manufacturers of biopharmaceutical products.

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

Significant legal questions exist concerning the extent and scope of patent protection for biopharmaceutical products and processes in the United States and elsewhere. Accordingly, there is no certainty that patent applications owned or licensed by us will be issued as patents, or that our issued patents will afford meaningful protection against competitors. Once issued, patents are subject to challenge through both administrative and judicial proceedings in the United States and other countries. Such proceedings include re-examinations, *inter partes* reviews, post-grant reviews and interference proceedings before the U.S. Patent and Trademark Office, as well as opposition proceedings before the European Patent Office. Litigation may be required to enforce, defend or obtain our patent and other intellectual property rights. Any administrative proceeding or litigation could require a significant commitment of our resources and, depending on outcome, could adversely affect the scope, validity or enforceability of certain of our patent or other proprietary rights.

Remodulin, Tyvaso and Orenitram Proprietary Rights

We have a number of issued patents and pending patent applications covering our treprostinil-based products, Remodulin, Tyvaso and Orenitram. We have been granted two patents related to manufacturing treprostinil that expire in 2028 and are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book (see Orange Book below), for Remodulin, Tyvaso and Orenitram.

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

Remodulin. We have been granted three U.S. patents covering an improved diluent for Remodulin, which expire in 2028 and 2029. We have another patent covering intravenous administration of Remodulin with certain diluents, which expires in 2024. We have been granted another patent covering a treprostinil formulation with a citrate buffer, which expires in 2024. All five of these patents are listed in the Orange Book.

Tyvaso. We have been granted two U.S. patents, as well as patents in other countries, for Tyvaso that cover methods of treating PAH by inhaled delivery. These patents expired in the United States in 2018 and will expire in various countries throughout the world in 2020. We have also been granted two patents directed to a method of treating pulmonary hypertension and a kit for treating pulmonary hypertension. These two patents expire in 2028 and are listed in the Orange Book. Counterparts to these two patents are issued in several other countries.

Orenitram. Our patents for Orenitram cover methods of use for treating PAH, orally administered formulations, controlled moisture storage and manufacturing methods, as well as those covering controlled release formulations licensed to us by Supernus Pharmaceuticals Inc. (Supernus). These patents will expire in the United States between 2024 and 2031 and in various countries throughout the world between 2024 and 2030.

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

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Orange Book

In seeking approval of a drug through an NDA or upon issuance of new patents following approval of an NDA, applicants are required to submit to the FDA each patent that has claims covering the applicant's product or a method of using the product. Each of the patents submitted is then published in the Orange Book. See *Governmental Regulation Patent Term and Regulatory Exclusivity* below for further details. Remodulin currently has eight unexpired Orange Book-listed patents with expiration dates ranging from 2024 to 2029. Tyvaso currently has four unexpired Orange Book listed patents expiring in 2028. Orenitram currently has twelve unexpired Orange Book listed patents with expiration dates ranging from 2024 to 2031. Additional patent applications are pending, and if granted, may be eligible for listing in the Orange Book.

Regulatory Exclusivity

Remodulin's regulatory exclusivity in the United States and Europe has expired. In 2010, the FDA granted orphan drug designation for Tyvaso, which resulted in an orphan exclusivity period that expired in July 2016. In 2004, the EMA designated Tyvaso an orphan medicinal product for the treatment of both PAH and chronic thromboembolic pulmonary hypertension, which would confer a ten-year exclusivity period commencing if and when we obtain marketing approval. As a result of FDA approval of our NDA for Orenitram as a new dosage form, Orenitram had three years of market exclusivity for PAH, which expired in December 2016. A request for orphan drug designation for Orenitram was denied by the FDA, and we are currently challenging that denial in litigation pending before the United States District Court for the District of Columbia.

Supernus License

In 2006, we entered into an exclusive license agreement with Supernus to use certain of its technologies in manufacturing Orenitram. Under the agreement, we paid Supernus certain amounts upon the achievement of specified milestones based on the development and commercial launch of Orenitram for PAH, and we would be obligated to make additional milestone payments if we develop Orenitram for a second indication. In addition, the agreement provides that we will pay a single-digit percentage royalty based on net worldwide sales. This royalty will be paid for approximately twelve years commencing with the first product sale, which occurred in the second quarter of 2014.

Generic Competition

We settled litigation with each of Sandoz, Teva, Par and Dr. Reddy's related to their ANDAs seeking FDA approval to market generic versions of Remodulin before the expiration of certain of our U.S. patents. Under the terms of our settlement agreements, Sandoz has been permitted to market its generic version of Remodulin in the United States since June 2018, and Teva, Par and Dr. Reddy's have been permitted to launch their generic versions in the United States since December 2018. To date, both Sandoz and Par have received tentative approval for their ANDAs, but to our knowledge, no generic company has begun to sell its generic version of Remodulin in the United States.

We also settled litigation with Actavis related to its ANDA seeking FDA approval to market a generic version of Orenitram before the expiration of certain of our U.S. patents. Under the settlement agreement, Actavis can market its generic version of Orenitram in the United States beginning in June 2027, although Actavis may be permitted to enter the market earlier under certain circumstances.

We also settled litigation with Watson related to its ANDA seeking FDA approval to market a generic version of Tyvaso before the expiration of certain of our U.S. patents. Under the settlement agreement, Watson can market its generic version of Tyvaso in the United States beginning in January 2026, although Watson may be permitted to enter the market earlier under certain circumstances.

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As a result of our settlements with Sandoz, Teva, Par and Dr. Reddy's, we expect to see generic competition for Remodulin from these companies in the United States beginning sometime in 2019. As a result of our settlements with Watson and Actavis, we expect to see generic competition for Tyvaso and Orenitram in the United States beginning as early as 2026 and 2027, respectively. Competition from these generic companies could reduce our net product sales and profits. In addition, while we intend to vigorously enforce our intellectual property rights related to our products, there can be no assurance that we will prevail in defending our patent rights, or that additional challenges from other ANDA filers or other challengers will not surface with respect to our products. Our patents could be invalidated, found unenforceable or found not to cover one or more generic forms of our products. If any ANDA filer were to receive approval to sell a generic version of our products and/or prevail in any patent litigation, the affected product(s) would become subject to increased competition, which could reduce our net product sales and profits.

A U.S. patent for Adcirca for the treatment of pulmonary hypertension expired in November 2017, and two remaining patents have been invalidated. In May 2017, we amended our Adcirca license agreement with Lilly to extend the term of the agreement through December 2020 and to amend the economic terms of the agreement following the expiration of a patent covering Adcirca in November 2017. As a result of this amendment, beginning December 1, 2017, our royalty rate on net product sales of Adcirca increased from five percent to ten percent, and we are required to make milestone payments to Lilly equal to $325,000 for each $1,000,000 in net product sales. Adcirca's cost of product sales as a percentage of Adcirca's net product sales has increased significantly since December 1, 2017 due to these cost increases. In August 2018, Mylan N.V. announced the launch of its generic version of Adcirca, which resulted in a material adverse impact on Adcirca net product sales, driven by a greater than 40 percent reduction in the number of bottles of Adcirca sold to distributors during the first full month following the availability of the generic version. This reduction has increased each month, resulting in a greater than 55 percent decrease in the average number of bottles sold per month during the period from generic launch in August 2018 through December 2018, compared to the average number of bottles sold per month in 2018 prior to generic launch. Additional companies announced the launch of generic versions of Adcirca in February 2019. In addition, we expect declines in patient demand will increase the amount of Adcirca inventory held by distributors and other downstream customers that expires unsold. Our allowance for product returns was $22.4 million and $7.2 million as of December 31, 2018 and December 31, 2017, respectively.

Generic versions of Remodulin have been approved in Austria, Germany, Italy, France and Spain. The launch of generic versions in these countries, which occurred in January 2019 in Austria and is pending in the other countries, will likely lead to a decline in our international Remodulin revenues in 2019 due to increased competition and a contractual reduction in our transfer price for Remodulin sold by an international distributor for sales in countries in which the pricing of Remodulin is impacted by the launch of a generic version of Remodulin. The approval and launch of a generic version of Remodulin in other countries may follow. Our non-U.S. net product sales for Remodulin were $95.4 million for the year ended December 31, 2018.

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

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Adcirca License Agreement

In 2008, Lilly granted us an exclusive license to develop, market, promote and commercialize Adcirca for the treatment of pulmonary hypertension in the United States. We agreed to pay Lilly royalties based on our net product sales of Adcirca. 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 for the treatment of other diseases worldwide. Lilly retained authority for all regulatory activities with respect to Adcirca and for setting the wholesale price of Adcirca, which has been and is expected to continue to be at price parity with Cialis. In May 2017, we amended our Adcirca license agreement with Lilly in order to clarify and extend the term of the agreement and to amend the economic terms of the agreement following a patent expiry in November 2017. As amended, our license agreement expires on December 31, 2020. For additional discussion, refer to our *Adcirca* product description contained in *Part I, Item 1 Business Overview Products to Treat Pulmonary Arterial Hypertension.*

We also agreed to purchase Adcirca at a fixed manufacturing cost. The agreement provides a mechanism, generally related to the increase in the national cost of pharmaceutical manufacturing, pursuant to which Lilly may raise the manufacturing cost of Adcirca.

Unituxin Proprietary Rights and Regulatory Exclusivity

We have orphan drug exclusivity in the United States for Unituxin, expiring March 2022, which precludes the FDA from approving any application to market the same drug for the same indication, except in limited circumstances. In addition, approval of our BLA conferred a 12-year data exclusivity period through March 2027, during which the FDA may not approve a biosimilar for Unituxin. Under a non-exclusive license agreement with The Scripps Research Institute, we pay a royalty of one percent of Unituxin net sales. We have no patents covering Unituxin.

Medtronic Agreements

As noted above, we are collaborating with Medtronic to develop and commercialize the Implantable System for Remodulin. Following FDA approval of the Implantable System for Remodulin, we entered into a commercialization agreement with Medtronic in February 2019, under which we will collaborate with Medtronic to commercialize the Implantable System for Remodulin in the United States. This agreement provides that the Implantable System for Remodulin will be exclusive to Remodulin, and further provides that we will not work with any third party to develop a competing implantable system to deliver Remodulin in the United States. The commercialization agreement has an initial term of five years, which may be extended for additional one-year terms if mutually agreed by the parties. Either party may terminate the commercialization agreement immediately for safety, quality or regulatory concerns, in the event of the other party's bankruptcy or insolvency, or in the case of a material breach by the other party that remains uncured following the relevant cure period. In addition, Medtronic may terminate the commercialization agreement upon 180 days' notice if Medtronic elects to discontinue its drug delivery business, and either party may terminate the commercialization agreement without cause on 180 days' notice to the other party, after the initial five-year term. For further details, see the section above entitled *Research and Development Implantable System for Remodulin*.

The Implantable System for Remodulin was developed under a development agreement with Medtronic that covers the treatment of PAH in the United States, United Kingdom, Canada, France, Germany, Italy and Japan. The development agreement provides that the system will be exclusive to Remodulin in these countries, subject to certain conditions. We continue to work with Medtronic under the development agreement to fund further enhancements to the system. The development agreement has similar termination rights to the commercialization agreement described above.

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Esuberaprost and the Toray Amended License Agreement

In 2000, we licensed from Toray Industries, Inc. (Toray) the exclusive right to develop and market beraprost for cardiovascular indications. Beraprost is a chemically stable oral prostacyclin analogue in a sustained release formulation, which is approved to treat PAH in Japan and certain other countries. This license gives us exclusive rights to develop beraprost and its variants (including esuberaprost) throughout North America, Europe, and certain other territories. We are currently developing esuberaprost under this license agreement in combination with Tyvaso.

Pursuant to a 2007 amendment to our license agreement with Toray, we issued 200,000 shares of our common stock to Toray. Toray has the right to request that we repurchase these shares (which have since split into 400,000 shares) upon 30 days prior written notice at the price of $27.21 per share. The 2007 amendment also provided for certain milestone payments during the development period and upon receipt of regulatory approval for beraprost in the United States or the EU.

In 2011, we amended our license agreement with Toray to reduce the royalty rates in exchange for a total of $50.0 million in equal, non-refundable payments to Toray over the five-year period ending in 2015. As of December 31, 2015, this obligation was fully satisfied. Toray has the right to terminate the license agreement in the event of a change of control of our company under certain circumstances.

In March 2017, we amended our license agreement with Toray to further reduce the royalty rate to single digits in exchange for contingent milestone payments in the event that we do not achieve certain clinical and regulatory events by certain dates. In addition, Toray granted us sole manufacturing rights for commercial esuberaprost.

The FDA has granted orphan drug designation for esuberaprost, which we expect would provide seven years of regulatory exclusivity if the FDA approves an NDA for esuberaprost following successful study results. We have one U.S. patent, which expires in 2031, covering a method of treating pulmonary hypertension using oral and inhaled prostacyclin therapies in combination, which we expect should be eligible for listing in the Orange Book if the FDA approves esuberaprost.

DEKA Agreement

In December 2014, we entered into an exclusive agreement with DEKA to develop a pre-filled, semi-disposable system for subcutaneous delivery of Remodulin, which we refer to as RemUnity. Under the terms of the agreement, we are funding the development costs related to the semi-disposable system and will pay product fees and a single-digit royalty to DEKA based on commercial sales of the system and the Remodulin sold for use with the system. Our agreement with DEKA expires on the last to occur of twenty-five years from the first product launch under the agreement, or upon the expiration of the last valid claim of a patent licensed from DEKA under the agreement that covers the RemUnity system. Either party may terminate the agreement immediately upon a material breach by the other party that is uncured following the relevant cure period, or in the event of the other party's bankruptcy or insolvency. The RemUnity system is covered by issued patents and pending patent applications both in the U.S. and other countries. The expiration dates of currently issued U.S. patents range from 2027 through 2033.

Trevyent

In 2016, the FDA granted orphan designation for Trevyent for the treatment of PAH. Thus, the FDA should grant orphan drug exclusivity if an NDA for Trevyent is approved; such exclusivity would extend for seven years from approval. Trevyent is protected by a variety of issued patents expiring at various dates ranging from 2024 to the early 2030s. Additional patent applications for Trevyent are pending.

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Treprostinil Technosphere and the MannKind Agreement

Under our license agreement with MannKind, we have an exclusive license to a variety of granted and pending patents and patent applications related to treprostinil inhalation powder and the Dreamboat® and Cricket® devices, including multiple patent families covering the U.S. and other major market countries. These patents cover drug formulation, devices and device components, and manufacturing processes and intermediates. Expiration dates for issued patents range from the mid-2020s to the mid-2030s. Additional patents subject to pending patent applications, if issued, would have expiration dates in the late 2030s. Many of these patents would be eligible for listing in the Orange Book. For a description of the license agreement, please refer to the section above entitled *Research and Development Treprostinil Technosphere.*

Ralinepag and the Arena Agreement

Under our license agreement with Arena, we have an exclusive license to a variety of granted and pending patents and applications related to ralinepag covering drug formulation, manufacturing and dosage, among others. Many of these patents and patent applications would be eligible for listing in the Orange Book. Based on potential patent term extensions and additional patent filings, we believe U.S. patent protection for ralinepag will likely last through at least the mid-2030s. For a description of the license agreement, please refer to the section above entitled *Research and Development Ralinepag.*

Other

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

Manufacturing and Supply

We manufacture our primary supply of Remodulin, Tyvaso, Orenitram and Unituxin at our own facilities. In particular, we synthesize treprostinil, the active ingredient in Remodulin and Tyvaso, and treprostinil diolamine, the active ingredient in Orenitram, at our facility in Silver Spring, Maryland. We also produce dinutuximab, the active ingredient in Unituxin, at our Silver Spring facility. We also manufacture finished Tyvaso, Remodulin, and Unituxin at our Silver Spring facility. We manufacture Orenitram and we package, warehouse and distribute Remodulin, Tyvaso, Orenitram and Unituxin at our facility in Research Triangle Park, North Carolina.

We maintain a two-year inventory of Remodulin, Tyvaso and Orenitram based on expected demand, and we contract with third-party contract manufacturers to supplement our capacity, in order to mitigate the risk that we might not be able to manufacture sufficient quantities to meet patient demand. For example, Baxter Pharmaceutical Solutions, LLC is approved by the FDA, the EMA and various other international regulatory agencies to manufacture Remodulin for us. We rely on Catalent Pharma Solutions, Inc. to serve as an additional manufacturer of Tyvaso, and we rely entirely on Minnetronix Inc. to manufacture the nebulizer used in our Tyvaso Inhalation System. We obtained FDA approval of a third-party contract manufacturer to serve as an additional manufacturer of finished Unituxin drug product, and are constructing an additional facility to increase our manufacturing capacity for dinutuximab, the active ingredient in Unituxin. We have no plans to develop a redundant manufacturing source for finished Orenitram drug product.

Although we believe that additional third parties could provide similar products, services and materials, there are few companies that could replace our existing third-party manufacturers and suppliers. A change in supplier or manufacturer could cause a delay in the manufacturing, distribution

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and research efforts associated with our respective products or result in increased costs. See also *Item 1A Risk Factors* included in this Report.

Competition

Many drug companies engage in research and development to commercialize products to treat cardiovascular 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, Veletri and generic epoprostenol. Flolan (epoprostenol) is a prostacyclin that is delivered by intravenous infusion. Glaxo began marketing Flolan in the United States in 1996. In 2008, the FDA approved Teva's version of generic epoprostenol for the treatment of PAH. In 2010, Actelion (which was acquired by Johnson & Johnson in 2017) commenced sales of Veletri, which is another version of intravenous epoprostenol;

Ventavis and Ilomedin®. Approved in 2004 in the United States and in 2003 in Europe, Ventavis (iloprost) is an inhaled prostacyclin analogue. Ventavis is currently marketed by Actelion in the United States and by Bayer Schering Pharma AG (Bayer) in Europe. Iloprost is also marketed by Bayer in certain countries outside the United States in an intravenous form known as Ilomedin;

Tracleer®. Tracleer (bosentan), an oral ETRA therapy for the treatment of PAH, was approved in 2001 in the United States and in 2002 in Europe. Tracleer is marketed worldwide by Actelion. We anticipate generic bosentan could be launched in the United States in the near term. Generic bosentan is already available in other countries;

Letairis. Approved in 2007 in the United States, Letairis (ambrisentan) is an oral ETRA therapy marketed by Gilead for the treatment of PAH. In 2008, Glaxo received marketing authorization from the EMA for Letairis in Europe, where it is known as Volibris®. In 2015, Gilead announced the positive results of the *AMBITION* study of ambrisentan and tadalafil as an up-front combination therapy for PAH, which we believe has driven increased use of Letairis and Adcirca. We expect generic ambrisentan could be launched in the United States in the near term;

Revatio and generic sildenafil citrate. Approved in 2005 in the United States, Revatio (sildenafil citrate) is an oral PDE-5 inhibitor therapy manufactured by Pfizer. Revatio contains sildenafil citrate, the same active ingredient as Viagra. In 2012, several companies began marketing generic formulations of sildenafil citrate;

Opsumit®. Approved in 2013 in both the United States and in the EU, Opsumit (macitentan) is an oral ETRA therapy marketed by Actelion for the treatment of PAH;

Adempas®. Approved in 2013 in the United States and 2014 in the EU, Adempas (riociguat) is an sGC stimulator, which targets a similar vasodilatory pathway as PDE-5 inhibitors and is approved for chronic thromboembolic pulmonary hypertension and PAH. Adempas is an oral therapy marketed by Bayer; and

Uptravi®. Approved in the United States in December 2015 and by the EMA in May 2016, Uptravi (selexipag) is an oral IP prostacyclin receptor agonist marketed by Actelion. Actelion also has applications pending in various other jurisdictions. Uptravi is also marketed in Japan by Nippon Shinyaku Co., Ltd.

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

Bardoxolone, an oral therapy being developed by Reata Pharmaceuticals, Inc. for treatment of PAH associated with connective tissue disease. Reata is enrolling patients in a phase III clinical trial;

LIQ861, a dry powder formulation of treprostinil designed for deep-lung delivery using a disposable inhaler being developed by Liquidia Technologies Inc. (Liquidia), which announced commencement of a phase III study in PAH patients in January 2018;

Sotatercept, an injected TGF-beta modulator being developed by Acceleron Pharma, Inc., which announced the commencement of a phase II study in PAH patients in May 2018;

CXA-10, an oral nitrated fatty acid compound being developed by Complexa Inc., which is currently enrolling PAH patients in a phase II study;

Tacrolimus, an oral therapy being developed by VIVUS Inc., which is currently enrolling PAH patients in a phase II study;

PB1046, a subcutaneously-injected, sustained release analogue of the native human vasoactive intestinal peptide, which is being developed by PhaseBio Pharmaceuticals, Inc., and is currently undergoing a phase II study in PAH patients;

CAM2043, a liquid crystal gel formulation of treprostinil being developed as a once-weekly subcutaneous depot injection for PAH by Camurus AB. Camurus announced the positive results from a phase I clinical study in May 2018;

INS1009, an inhaled nanoparticle formulation of a treprostinil prodrug being developed by Insmed Incorporated for PAH. Insmed announced the completion of a phase I study in September 2016; and

RVT-1201 (rodatristat ethyl), a tryptophan hydroxylase inhibitor being developed by Altavant Sciences, Inc. to treat PAH. Altavant announced it expects to commence phase II clinical studies in PAH patients in 2019.

Oral non-prostacyclin therapies (such as PDE-5 inhibitors and ETRAs) are commonly prescribed as first-line treatments for the least severely ill PAH patients (functional class II patients). As patients progress in their disease severity (functional classes III and IV), less convenient approved therapies, such as inhaled prostacyclin analogues (such as Tyvaso) or infused prostacyclin analogues (such as Remodulin) are commonly added. Orenitram was the first approved oral prostacyclin-class therapy for PAH in the United States, and offers a less invasive and more convenient alternative therapy to Remodulin and Tyvaso. The use of available oral therapies could delay many patients' need for inhaled or infused prostacyclin therapy. As a result, the availability of oral therapies affects demand for our inhaled and infused products.

Orenitram faces direct competition from Uptravi, which is indicated to delay disease progression and reduce the risk of hospitalization for PAH. As a result, many physicians may choose to prescribe Uptravi instead of Orenitram, which is indicated to improve exercise capacity. As noted above, however, Uptravi is an oral IP prostacyclin receptor agonist. While prostacyclin analogues such as Orenitram broadly mimic the effect of prostacyclin, IP prostacyclin receptor agonists bind selectively to the IP receptor, one of several prostacyclin receptors. In addition, Orenitram's label allows physicians flexibility to titrate each patient's dosing up to a level according to tolerability, without any stated maximum. By contrast, Uptravi's label limits uptitration to a specific maximum dose. Given the progressive nature of PAH, we believe many patients will initiate Orenitram or another one of our treprostinil-based therapies after their disease progresses on Uptravi. Furthermore, we believe the

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results of our *FREEDOM-EV* clinical study, which demonstrated that Orenitram delays time to clinical worsening and at study closure indicated a positive impact on survival, will result in increased use of Orenitram.

We have faced generic competition for Adcirca since the launch of generic tadalafil in the U.S. in August 2018, which has significantly reduced our Adcirca revenues. We will also face competition from generic pharmaceutical companies in the future. For example, we entered into settlement agreements with four generic drug companies permitting them to launch generic versions of Remodulin beginning in 2018. Although these companies have not yet launched generic versions of Remodulin, we anticipate generic competition in the U.S. for Remodulin in 2019. A generic version of Remodulin was launched in Austria in January 2019, and we anticipate generic competition for Remodulin in additional countries in Europe beginning in 2019. Finally, we have entered into settlement agreements with Actavis and Watson, permitting them to launch generic versions of Orenitram and Tyvaso in June 2027 and January 2026, respectively, or earlier under certain circumstances. For details regarding these and other potential generic competitors, see the section above entitled *Patents and Other Proprietary Rights, Strategic Licenses and Market Exclusivity Generic Competition*.

Tyvaso may face competition from Liquidia if it obtains approval of LIQ861, a dry powder inhaled version of treprostinil. In addition, we expect Liquidia's products would compete directly with Treprostinil Technosphere, if approved.

Unituxin may face competition from Qarziba® (dinutuximab beta), a similar antibody product developed by Apeiron Biologics AG that is already approved in Europe to treat high-risk neuroblastoma. In October 2016, EUSA Pharma (UK) Ltd. announced it had acquired global commercialization rights to Qarziba, and plans to file for FDA approval.

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

Governmental Regulation

Pharmaceutical Product Approval Process

The research, development, testing, manufacture, promotion, marketing, distribution, sampling, storage, approval, labeling, record keeping, post-approval monitoring and reporting, and import and export of pharmaceutical products are extensively regulated by governmental agencies in the United States and in other countries. In the United States, failure to comply with requirements under the Federal Food, Drug, and Cosmetic Act (FDC Act), the Public Health Service Act (PHSA), and other federal statutes and regulations, may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending NDAs or BLAs, warning letters, product recalls, product seizures, total or partial suspension of manufacturing or distribution, injunctions, fines, civil penalties, and criminal prosecution.

Satisfaction of FDA pre-market approval requirements is extremely costly and typically takes many years. The actual cost and time required may vary substantially based upon the type, complexity and novelty of the product or disease. Drugs are subject to rigorous regulation by the FDA in the United States, the EMA in the EU and similar regulatory authorities in other countries. The steps ordinarily required before a new drug may be marketed in the United States, which are similar to steps required in most other countries, include: (1) preclinical testing; (2) submission to the FDA of an investigational new drug application (IND); (3) clinical studies, including well-controlled clinical trials, in healthy

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volunteers and patients to establish safety, efficacy and dose-response characteristics for each drug indication; (4) submission of an NDA to the FDA; and (5) FDA review and approval of the NDA.

Preclinical Testing

Preclinical tests include laboratory evaluation of product chemistry and formulation, as well as animal studies to explore toxicity and for proof-of-concept. The conduct of the preclinical tests must comply with federal regulations and requirements including good laboratory practices.

Submission of IND

The results of preclinical testing are submitted to the FDA as part of an IND, along with other information including information about product chemistry, manufacturing and controls and a proposed clinical trial protocol. Absent FDA objection within 30 days after submission of an IND, the IND becomes effective and the clinical trial proposed in the IND may begin.

Clinical Studies

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (1) in compliance with federal regulations; (2) in compliance with good clinical practices (GCP), an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; and (3) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

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

Clinical trials in support of an NDA typically are conducted in sequential phases, but the phases may overlap.

Phase I involves the initial introduction of the drug into healthy human subjects or patients to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness.

Phase II usually involves studies in a limited patient population to assess the efficacy of the drug in specific, targeted indications, explore tolerance and optimal dosage, and identify possible adverse effects and safety risks.

Phase III trials, also called pivotal studies, major studies or advanced clinical trials, demonstrate clinical efficacy and safety in a larger number of patients, typically at geographically diverse clinical study sites, and permit the FDA to evaluate the overall benefit-risk relationship of the drug and provide adequate information for drug labeling.

Phase IV studies are often conducted following marketing approval, in order to meet regulatory requirements or to provide additional data related to drug use.

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FDA Approval Process

After successful completion of the required clinical testing, an NDA is typically submitted to the FDA in the United States, and an MAA is typically submitted to the EMA in the EU. FDA approval of the NDA is required before the product may be marketed in the United States. The NDA must include the results of all preclinical, clinical and other testing and a compilation of data related to the product's pharmacology, chemistry, manufacture, and controls.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing. If the FDA determines that the application is not sufficiently complete to permit substantive review, it may request additional information and decline to accept the application for filing until the information is provided. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs. Most applications for non-priority drugs are reviewed within ten to twelve months. Special pathways, including "accelerated approval," "fast track" status, "breakthrough therapy" status and "priority review" status are granted for certain drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. These special pathways can significantly reduce the time it takes for the FDA to review a NDA, but do not guarantee that a product will receive FDA approval. In May 2018, the Right to Try Act established a new regulatory pathway to increase access to unapproved, investigational treatments for patients diagnosed with life-threatening diseases or conditions who have exhausted approved treatment options and who are unable to participate in a clinical trial.

The FDA may refer applications for novel pharmaceutical products or pharmaceutical products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. During the review process, the FDA also reviews the drug's product labeling to ensure that appropriate information is communicated to health care professionals and consumers. In addition, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP and the facility or the facilities at which the drug is manufactured to ensure they are in compliance with the FDA's current Good Manufacturing Practices (cGMP).

After the FDA evaluates the NDA and the manufacturing facilities, the FDA may issue either an approval letter or a complete response letter, which generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those conditions have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even after a resubmission, the FDA may decide that the application does not satisfy the regulatory criteria for approval.

Post-Approval Regulatory Requirements

Once an NDA is approved, the product is subject to continuing regulation. For instance, pharmaceutical products may be marketed only for their approved indications and in accordance with the provisions of their approved labeling. The FDA closely regulates the post-approval marketing, labeling and advertising of prescription drugs, including direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet.

Adverse event reporting and submission of periodic reports continue to be required following FDA approval of an NDA. In addition, as a condition of NDA approval, the FDA may require

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post-marketing testing, including phase IV clinical studies, and/or a risk evaluation and mitigation strategy (REMS) to help ensure that the benefits of the drug outweigh the potential risks. A REMS can include medication guides, communication plans for healthcare professionals, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. Additionally, quality control as well as drug manufacture, packaging, and labeling procedures must continue to conform to cGMP requirements. Manufacturing facilities are subject to continual review and periodic inspections by the FDA and certain state agencies.

Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards or if previously unrecognized problems are subsequently discovered. Discovery of previously unknown problems with a product, including adverse events or problems with manufacturing processes of unanticipated severity or frequency, or failure to comply with regulatory requirements, may also result in (1) revisions to the approved labeling; (2) imposition of post-market studies or clinical trials to assess new safety risks; or (3) imposition of distribution or other restrictions under a REMS program. Other potential consequences include: (1) restrictions on the marketing or manufacturing of the product; (2) fines, warning letters or holds on post-approval clinical trials; (3) refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals; (4) product seizure or detention, or refusal to permit the import or export of products; or (5) injunctions or the imposition of civil or criminal penalties.

Approval of Changes to an Approved Product

Certain changes to the conditions established in an approved application, including changes in indications, labeling, equipment, or manufacturing processes or facilities, require submission and FDA approval of an NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing supplements as it does in reviewing NDAs.

Orphan Drugs

Under the Orphan Drug Act, an applicant can request the FDA to designate a product as an "orphan drug" in the United States if the drug is intended to treat a rare disease or condition affecting fewer than 200,000 people in the United States. Orphan drug designation must be requested before submitting an NDA or BLA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA or BLA applicant to receive orphan drug designation and FDA approval for a particular active ingredient to treat a particular disease via a particular delivery method is entitled to a seven-year exclusive marketing period in the United States. During the seven-year period, the FDA may not approve any other application to market the same drug for the same disease, except in limited circumstances such as a showing of clinical superiority to the product with orphan drug exclusivity, meaning that it has greater effectiveness or safety, or provides a major contribution to patient care (such as a change in delivery system). Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. The 21st Century Cures Act (Cures Act), which became law in December 2016, expanded the types of studies that qualify for orphan drug grants. Orphan drug designation also may qualify an applicant for federal tax credits related to research and development costs.

Patent Term and Regulatory Exclusivity

In 1984, the Hatch-Waxman Act created a faster approval process for generic drugs, called the ANDA. Generally, an ANDA provides for marketing of a drug product that has the same active ingredients in the same strength(s), route of administration, and dosage form as an approved drug and

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has been shown through bioequivalence testing to be therapeutically equivalent to the approved drug. ANDA applicants are not required to conduct or submit results of preclinical or clinical tests to prove the safety or effectiveness of their drug product, other than the requirement for bioequivalence testing. Drugs approved in this way are commonly referred to as "generic equivalents" to the approved drug, and can often be substituted by pharmacists under prescriptions written for the original approved drug. In 2018, the FDA advanced policies aimed at promoting drug competition and patient access to generic drugs, such as issuing guidance about making complex generic drugs and the circumstances in which approval of a generic product application may be delayed.

NDA applicants are required to identify each patent whose claims cover the product or FDA-approved method of using the product. Upon product approval, these patents are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Every ANDA applicant must certify to the FDA that (1) the required information for the original product was not filed or (2) every patent listed for the approved product in the Orange Book is either (a) expired or will expire on a particular date and approval is sought after patent expiration or (b) invalid or will not be infringed by the new product. A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid is called a Paragraph IV certification. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired. Alternatively, for a patent covering an approved indication, an ANDA applicant may submit a statement to the FDA that the company is not seeking approval for the covered indication.

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

The Hatch-Waxman Act also 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 is generally one-half of 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.

An ANDA application also will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of an NDA for a new chemical entity, has expired. Federal law provides a period of five years following approval of a drug containing no previously approved active ingredient, during which ANDAs for generic versions of those drugs cannot be submitted unless the submission contains a Paragraph IV certification, in which case the submission may be made four years following the original product approval. Following approval of an application to market a drug that contains previously approved active ingredients in a new dosage form, route of administration or combination, or for a new condition of use that was required to be supported by new clinical trials conducted by or for the sponsor, the FDC Act provides three years of exclusivity during which the FDA cannot grant effective approval of an ANDA for such new condition of use, dosage form or strength that meets certain statutory requirements.

Section 505(b)(2) New Drug Applications

Most drug products (other than biological products) obtain FDA marketing approval pursuant to an NDA submitted under Section 505(b)(1) of the FDC Act, or an ANDA. A third alternative is a special type of NDA submitted under Section 505(b)(2) of the FDC Act, commonly referred to as a Section 505(b)(2) NDA, which enables the applicant to rely, in part, on the FDA's finding of safety and efficacy data for an existing product, or published literature, in support of its application.

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Section 505(b)(2) NDAs may provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Section 505(b)(2) permits the filing of an NDA in which the applicant relies, at least in part, on information from studies made to show whether a drug is safe or effective that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use. A Section 505(b)(2) applicant may eliminate the need to conduct certain preclinical or clinical studies, if it can establish that reliance on studies conducted for a previously-approved product is scientifically appropriate. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all or some of the labeled indications for which the referenced product has been approved, as well as for any new indication for which the Section 505(b)(2) NDA applicant has submitted data.

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

Marketing Pharmaceutical Products Outside the United States

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

Biologics

Biological products used for the prevention, treatment, or cure of a disease, or condition, of a human being are subject to regulation under the FDC Act and the PHSA. Biological products are approved for marketing via a BLA that follows an application process and carries approval requirements that are very similar to those for NDAs. To help reduce the increased risk of the introduction of adventitious agents, the PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend licenses in situations where there is a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction, or spread, of communicable diseases in the United States.

After a BLA is approved, the product may also be subject to official lot release, meaning the manufacturer must submit samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. As with drugs, after approval of biologics, manufacturers must address any safety issues that arise, are subject to recalls or a halt in manufacturing, and are subject to periodic inspection after approval.

The Biologics Price Competition and Innovation Act of 2009, or BPCI Act, created an abbreviated approval pathway for biological products shown to be "biosimilar" to an FDA-licensed reference

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biological product to minimize duplicative testing. Biosimilarity requires the absence of clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, which, absent a waiver, must be shown through analytical studies, animal studies, and at least one clinical study. Intricacies associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation that are still being addressed by the FDA. In July 2018, the FDA announced an action plan to encourage the development and efficient review of biosimilars, including the establishment of a new office within the agency that will focus on therapeutic biologics and biosimilars.

A reference biologic is granted twelve years of exclusivity from the time of first licensure of the reference product. The first biologic product submitted under the abbreviated approval pathway that is approved as a biosimilar and also meets additional standards for interchangeability with the reference product, has exclusivity against other biologics submitted under the abbreviated approval pathway for a set period. Starting in March 2020, certain products currently approved as drugs under the FDC Act, such as insulin and human growth hormone, will be deemed to be biologics under the PHSA, which means they may face competition through the biosimilars pathway and they will not be eligible for the twelve-year period of exclusivity granted to new BLAs.

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

Cell-and Tissue-Based Products

Manufacturers of cell- and tissue-based products must comply with the FDA's current good tissue practices (cGTP), which are FDA regulations that govern the methods used in, and the facilities and controls used for, the manufacture of such products. The primary intent of the cGTP requirements is to ensure that cell and tissue-based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable diseases. Cell and tissue-based products may also be subject to the same approval standards, including demonstration of safety and efficacy, as other biologic and drug products, if they meet certain criteria such as if the cells or tissues are more than minimally manipulated or if they are intended for a non-homologous use (a use different from the cell's origin).

The Cures Act established a new FDA Office of Tissues and Advanced Therapies and Regenerative Advanced Therapy (RAT) designation, which makes a product eligible for FDA priority review and accelerated approval. Therapies that are eligible for RAT designation include cell therapies, therapeutic tissue engineering products, human cell and tissue products, or any combination product using these therapies, with certain exceptions. For RAT designation, the product also must be intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition, and the preliminary clinical evidence must indicate that the product has the potential to address unmet medical needs for the disease or condition.

U.S. Regulation of Medical Devices

Medical devices may also be subject to FDA approval and extensive regulation under the FDC Act. Medical devices are classified into one of three classes: Class I, Class II, or Class III. A higher class indicates a greater degree of risk associated with the device and a greater amount of control needed to ensure safety and effectiveness.

All devices, unless exempt by FDA regulation, must adhere to a set of general controls, including compliance with the applicable portions of the FDA's Quality System Regulation (QSR), which sets forth good manufacturing practice requirements; facility registration and product listing; reporting of adverse medical events; truthful and non-misleading labeling; and promotion of the device consistent

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with its cleared or approved intended uses. Class II and III devices are subject to additional special controls and may require FDA clearance of a premarket notification (510(k)) or approval of a premarket approval application.

Most Class I devices are exempt from FDA premarket review or approval. Class II devices, with some exceptions, must be "cleared" by the FDA through the 510(k) process, which requires a company to show that the device is "substantially equivalent" to certain "predicate" devices already on the market. In November 2018, the FDA announced plans to significantly revise the 510(k) program to encourage reliance on modern predicates (e.g., predicates that are less than 10 years old). In January 2019, the FDA also finalized guidance on the alternative 510(k) pathway for well-known device types, the "Safety and Performance Based Pathway," which relies on modern performance-based criteria and current technological principles to demonstrate substantial equivalence. Class III devices, again with some exceptions, must be approved through a PMA. A PMA generally requires data from clinical trials that establish the safety and effectiveness of the device. A 510(k) application also sometimes requires clinical data.

The Cures Act requires the FDA to establish a program that would expedite access to devices that provide more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions, for which no approved or cleared treatment exists or which offer significant advantages over existing approved or cleared alternatives. In December 2018, the FDA published final guidance on this "breakthrough" devices pathway and announced plans to establish the Safer Technologies Program (STeP) to encourage the innovation and market entry of device technologies that are safer than current alternatives but that do not otherwise satisfy the breakthrough device criteria.

Clinical trials for medical devices are subject to similar requirements as clinical trials with respect to drugs or biologics. Clinical trials involving significant risk devices (e.g., devices that present a potential for serious risk to the health, safety, or welfare of human subjects) are required to obtain both FDA approval of an investigational device exemption (IDE) application and IRB approval before study initiation. Clinical trials involving non-significant risk devices are not required to submit an IDE for FDA approval but must obtain IRB approval before study initiation.

The FDA has broad regulatory and enforcement powers with respect to medical devices, similar to those for drugs and biologics. The FDA requires medical device manufacturers to comply with detailed requirements regarding the design and manufacturing practices, labeling and promotion, record keeping, and adverse event reporting.

States also impose regulatory requirements on medical device manufacturers and distributors. Failure to comply with the applicable federal or state requirements could result in, among other things: (1) fines, injunctions, and civil penalties; (2) recall or seizure of products; (3) operating restrictions, partial suspension or total shutdown of manufacturing; (4) refusing requests for approval of new products; (5) withdrawing approvals already granted; and (6) criminal prosecution.

The FDA also administers certain controls over the import and export of medical devices to and from the United States. Additionally, each foreign country subjects medical devices to its own regulatory requirements. In the EU, a single regulatory approval process has been created, and approval is represented by the CE Mark.

Combination Products

A combination product is a product composed of a combination of two or more FDA-regulated product components or products, e.g., drug-device or device-biologic. A combination product can take a variety of forms, such as a single entity made by physically or chemically combining components, or a single unit made of separately packaged products. Each combination product is assigned a lead FDA Center, which has jurisdiction for the premarket review and regulation, based on which constituent part

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of the combination product provides the primary mode of action, i.e., the mode of action expected to make the greatest contribution to the overall intended therapeutic effect of the product. If the classification as a combination product or the lead Center assignment is unclear or in dispute, a sponsor may request a meeting, submit a Request for Designation (RFD), and the FDA will issue a designation letter within 60 calendar days of the filing of the RFD. Depending on the type of combination product, the FDA may require a single application for approval, clearance, or licensure of the combination product, or separate applications for the constituent parts. During the review of marketing applications, the lead Center may consult or collaborate with other FDA Centers. In 2017, the FDA released final documents addressing the application of cGMP requirements and classification issues related to combination products.

The Cures Act sets forth a number of provisions pertaining to combination products, such as procedures for negotiating disagreements between sponsors and FDA and requirements intended to streamline FDA premarket reviews of combination products that contain an already-approved component. For drug-device combination products, comprised of an FDA-approved drug and device primary mode of action, the Cures Act applies Hatch Waxman requirements to the premarket review process such that a patent dispute regarding the listed drug may result in the delay of the 510(k) clearance or PMA approval of the combination product. Furthermore, the Cures Act applies exclusivity provisions (e.g., new chemical entity and orphan drug exclusivities) to the device clearance and approval process for combination products with a device primary mode of action.

Government Reimbursement of Pharmaceutical Products

In the United States, many independent third-party health plans, and government health care programs, pay for patient use of our commercial products. Medicare is the federal program that provides health care benefits to senior citizens and certain disabled and chronically ill persons. Medicaid is the federal program jointly funded and administered by the states to provide health care benefits to participants who qualify based on income. Unituxin is administered entirely as an in-patient therapy and would typically be reimbursed under Medicare Part A, which covers inpatient hospital benefits. However, because Unituxin is indicated for the treatment of a pediatric cancer, Medicare beneficiaries are unlikely to receive this treatment. Remodulin and Tyvaso are reimbursed by the Medicare Part B program, which covers physician services and outpatient care. The Medicare Part B contractors who administer the program provide reimbursement for Remodulin and Tyvaso according to statutory guidelines. As a condition of the inclusion of Adcirca and Orenitram in the Medicare Part D program, which provides a voluntary outpatient prescription drug benefit, we pay rebates to Medicare Part D plan sponsors that reimburse these products. State Medicaid programs also reimburse the cost of our commercial products at rates established by statutory guidelines. Because Remodulin, Tyvaso, Adcirca, Orenitram and Unituxin are reimbursed by state Medicaid programs, we must pay a rebate to those state Medicaid programs. We are required by government contract to sell our commercial products under contracts with the Department of Veterans Affairs, Department of Defense, Public Health Service and numerous other federal agencies as well as certain hospitals that are designated as 340B covered entities (entities designated by federal programs to receive drugs at discounted prices) at prices that are significantly below the price we charge to our specialty distributors. These programs and contracts are highly regulated, are subject to regulatory changes and amendments that we cannot control, and impose restrictions on our business. Failure to comply with these regulations and restrictions could result in a loss of our ability to continue receiving reimbursement for our drugs, exclusion of our products from reimbursement under the federal healthcare programs, or debarment, and expose us to liability under federal and state false claims laws. The availability of adequate government reimbursement for our products may also be subject to regulatory changes and controls. We estimate that between 40-50 percent of Remodulin, Tyvaso, Adcirca and Orenitram sales are reimbursed under the Medicare and Medicaid programs.

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

The federal Anti-Kickback Statute (AKS) prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of, or referring an individual for the furnishing of, any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted broadly to apply to arrangements between pharmaceutical manufacturers and prescribers, purchasers, formulary managers and others. The term "remuneration" has been broadly interpreted to apply to anything of value including, for example, gifts, cash payments, donations, waivers of payment, ownership interests, and providing any item, service, or compensation for something other than fair market value. Violations of the AKS are punishable by imprisonment, criminal fines, civil monetary penalties, exclusion from participation in federal healthcare programs and liability under the False Claims Act (FCA).

The FCA prohibits any person from, among other things, presenting, or causing to be presented, a false or fraudulent claim for payment to the federal government, or making, or causing to be made, a false statement material to a false or fraudulent claim. Many pharmaceutical and other healthcare companies have been prosecuted under the FCA for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates; for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product; for violating the AKS; for materially deviating from statutorily required manufacturing standards; and on the basis of allegations related to certain marketing practices, including off-label promotion. Many states also have statutes or regulations similar to the AKS and the FCA, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. Sanctions under these federal and state laws may include treble damages, civil penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment.

We are also subject to numerous other anti-bribery and anti-fraud laws, including the U.S. Foreign Corrupt Practices Act (FCPA), the UK Bribery Act and the federal Civil Monetary Penalties Law.

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

The Patient Protection and Affordable Care Act of 2010 (PPACA)

The PPACA is intended to expand healthcare coverage within the United States. Several provisions of the law, which have varying effective dates, have impacted us and have increased certain of our costs. The PPACA imposes an annual fee on pharmaceutical manufacturers, based on the manufacturer's sale of branded pharmaceuticals and biologics (excluding orphan drugs) to certain U.S. government programs during the preceding year; expands the 340B drug discount program (excluding orphan drugs) including the creation of new penalties for non-compliance; includes a 50 percent discount on brand name drugs for Medicare Part D participants in the coverage gap, or "donut hole"; and revised the definition of "average manufacturer price" for reporting purposes, which could increase the amount of the Medicaid drug rebates paid to states.

In addition, the PPACA imposes new annual reporting requirements for pharmaceutical, biological and device manufacturers with regard to payments or other transfers of value made to physicians and

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teaching hospitals. In addition, pharmaceutical, biological and device manufacturers are required to report annually investment interests held by physicians and their immediate family members during the preceding calendar year. Many of these laws and regulations contain ambiguous requirements that have not yet been clarified. Further, the PPACA amends the intent requirement of the AKS and the federal criminal health care fraud statute. A person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them. In addition, the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

In December 2017, Congress repealed a PPACA requirement that individuals obtain healthcare insurance coverage or face a penalty, which could decrease the number of patients who have coverage under health plans that pay for patient use of our products.

21st Century Cures Act

The Cures Act, which was signed into law on December 13, 2016, contains a wide range of provisions designed to promote clinical research and streamline and expedite the FDA review and approval process. For example, the law clarifies the FDA's authority regarding drugs that target rare diseases, and broadens the type of data and information that may be used to support a drug or biologic application for a genetically targeted drug or variant protein targeted drug. The law requires the FDA to facilitate development programs for, and provides expedited review of, regenerative advanced therapies. The law further requires the FDA to establish a program to evaluate the use of real-world evidence, i.e., evidence from sources other than randomized clinical trials, to support the approval of certain drug and biological product applications and to satisfy post-approval requirements; in 2018, the FDA published a framework for evaluating real-world evidence. Other key provisions related to orphan drugs, combination products, and medical devices, are discussed separately above.

State Pharmaceutical and Medical Device Marketing Laws

If not preempted by the PPACA, several jurisdictions require pharmaceutical companies to report expenses related to the marketing and promotion of pharmaceutical products and to report gifts and payments to healthcare practitioners in those jurisdictions, or to obtain licenses for sales representatives and require them to satisfy educational and other requirements. Some of these jurisdictions also prohibit various marketing related activities. Still other states require the posting of information related to clinical studies and their outcomes. In addition, certain states require pharmaceutical companies to implement compliance programs or marketing codes and several other states are considering similar proposals. Compliance with these laws is difficult and time consuming, and companies that do not comply with these state laws face civil penalties or other civil enforcement action.

Other Laws and Regulations

Numerous other statutory and regulatory regimes affect our business and operations. For example, our research and development efforts may be subject to laws, regulations and recommendations related to data privacy and protection, safe working conditions, laboratory practices, use of animals in research and development activities, and the purchase, storage, movement, import, export and use and disposal of hazardous or potentially hazardous substances. Antitrust and competition laws may restrict our ability to enter into certain agreements involving exclusive license rights. Future legislation and administrative action will continue to affect our business, the extent and degree of which we cannot accurately predict.

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Employees

We had approximately 860 employees as of December 31, 2018. The success of our business is highly dependent on attracting and retaining highly talented and qualified personnel.

Corporate Website

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

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EXECUTIVE OFFICERS OF THE REGISTRANT

The following is a list, as of February 27, 2019, 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.

Name	Age	Position
Martine A. Rothblatt, Ph.D., J.D., M.B.A.	64	Chairman, Chief Executive Officer and Director
Michael Benkowitz	47	President and Chief Operating Officer
James C. Edgemond	51	Chief Financial Officer and Treasurer
Paul A. Mahon, J.D.	55	Executive Vice President, General Counsel and Corporate Secretary

Martine A. Rothblatt, Ph.D., J.D., M.B.A., founded United Therapeutics in 1996 and served as Chairman and Chief Executive Officer since its inception through January 2015, when she became Chairman and Co-Chief Executive Officer. She was promoted to her current role as Chairman and *soul* CEO in June 2016. Prior to United Therapeutics, she founded and served as Chairman and Chief Executive Officer of SiriusXM Satellite Radio. She is a co-inventor on six of our patents pertaining to treprostinil.

Michael Benkowitz joined United Therapeutics in 2011 as our Executive Vice President, Organizational Development. In this role, he was responsible for most companywide administrative functions, including human resources, information technology, corporate real estate and risk management, and was also responsible for many of our business development efforts and oversight of several of our key collaborations. He was promoted to President and Chief Operating Officer in June 2016, when he also became responsible for all of our commercial and medical affairs activities.

James C. Edgemond joined United Therapeutics in January 2013 as Treasurer and Vice President, Strategic Financial Planning. Mr. Edgemond was promoted to Chief Financial Officer and Treasurer in March 2015. Prior to joining United Therapeutics, he was Vice President, Corporate Controller and Treasurer of Clark Construction Group from 2008 through January 2013. He also served in a variety of roles at The Corporate Executive Board Company from 1998 to 2008, serving as Executive Director, Finance from 2005 to 2008. He began his career as a public accountant at KPMG Peat Marwick LLP, from 1990 through 1998, where he served in a variety of roles, including as a Senior Manager prior to his departure.

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

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ITEM 1A. RISK FACTORS

Forward-Looking Statements

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

- Expectations of revenues, expenses, profitability, and cash flows, including our expectation that revenue growth will recommence over the long term;
- The sufficiency of current and future working capital to support operations;
- Our ability to obtain financing on terms favorable to us or at all;
- The maintenance of domestic and international regulatory approvals;
- Our ability to maintain attractive pricing for our products, in light of increasing competition, including from generic entries and pressure from government and other payers to decrease the costs associated with healthcare;
- The expected volume and timing of sales of our existing commercial products Remodulin, Tyvaso, Orenitram, Adcirca and Unituxin and potential future commercial products, including the anticipated effect of various research and development efforts (including the *FREEDOM-EV* study) on sales of these products;
- The timing and outcome of clinical studies, other research and development efforts, and related regulatory filings and approvals, including (among others) those described in this Report related to our *BEAT* study of esuberaprost, our collaboration with DEKA to develop the RemUnity system, our efforts to obtain FDA approval of Trevyent, our *DISTINCT* study of dinutuximab in patients with small cell lung cancer, and our plan to develop a pain-free subcutaneous formulation of treprostinil called RemoPro;
- The timing and success of our anticipated launch of the Implantable System for Remodulin;
- The outcome of pending and potential future legal and regulatory actions by the FDA and other regulatory and government enforcement agencies, and the anticipated duration of regulatory exclusivity for our products;
- The impact of competing therapies on sales of our commercial products and the amount of inventory of our products that will expire unsold, including the impact of generic versions of Adcirca (which launched in August 2018) and Remodulin (which launched in Austria in January 2019 and which we expect will launch in the United States and other countries during 2019); established therapies such as Uptravi; and newly-developed therapies;
- The expectation that we will be able to manufacture sufficient quantities and maintain adequate inventories of our commercial products, through both our in-house manufacturing capabilities and third-party manufacturing sites, and our ability to obtain and maintain related approvals by the FDA and other regulatory agencies;

The adequacy of our intellectual property protection and the validity and expiration dates of the patents we own or license, as well as the regulatory exclusivity periods for our products;

The expected eligibility of patents for inclusion in the Orange Book;

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

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Other statements contained or incorporated by reference in this Report that are not historical facts.

These statements are subject to risks and uncertainties and our actual results may differ materially from anticipated results. Factors that may cause such differences include, but are not limited to, those discussed below. We undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise.

Risks Related to Our Business

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

Sales of our current treprostinil-based PAH therapies (Remodulin, Tyvaso and Orenitram) comprise the vast majority of our revenues. Decreased sales of any one of these products could have a material adverse impact on our operations. A wide variety of events, such as withdrawal of regulatory approvals or substantial changes in prescribing practices or dosing patterns, many of which are described in other risk factors below, could cause sales of these products to decline, or to grow more slowly than expected. Generic competition due to the current commercial availability of generic versions of Remodulin, which launched in Austria in January 2019, and which we expect will be launched in the United States and certain other countries in Europe during 2019, as well as generic versions of Tyvaso and Orenitram, which could be launched in the United States by Watson and Actavis as early as January 2026 and June 2027, respectively (or earlier under certain circumstances), may decrease our revenues. In addition, the inability of any third party that manufactures, markets, distributes or sells any of our commercial products to perform these functions satisfactorily, or our inability to manage our internal manufacturing processes, could result in an inability to meet patient demand and decrease sales. Finally, our strategy involves the development and successful launch of next-generation delivery systems (such as the Implantable System for Remodulin, RemUnity and Trevyent) and expanded indications for our existing treprostinil-based products. RemUnity and Trevyent may not be approved by the FDA, and the demand for our products following launch of the Implantable System for Remodulin or the RemUnity system may not meet our expectations. Without this increased demand, the revenue opportunity for our treprostinil products could be significantly lower than we expect.

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 to sell new products, or to expand the product labeling for our existing products to new indications, we must conduct clinical trials demonstrating that our products are safe and effective. These regulators have substantial discretion over the approval process for our products, and may not agree that we have demonstrated the requisite level of product safety and efficacy to grant approval.

The FDA and other regulatory agencies may require us to amend ongoing trials or perform additional trials beyond those we planned, which could result in significant delays and additional costs or may be unsuccessful. For example, approval of an NDA or a BLA could be delayed if the FDA determines that it cannot review or approve the application as submitted. In such a case, the FDA may require substantial additional studies, testing or information in order to complete its review of the application. If our clinical trials are not successful, or we fail to address any identified deficiencies adequately, we will not obtain required approvals to market the new product or new indication.

We cannot predict with certainty the length of time it will take to complete necessary clinical trials or obtain regulatory approvals related to our current or future products. The length of time we need to complete clinical trials and obtain regulatory approvals varies by product, indication and country.

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Our clinical trials may be discontinued, delayed, canceled or disqualified for various reasons, including:

- The drug is ineffective, or physicians and/or patients believe that the drug is ineffective, or that other therapies are more effective or convenient;
- We fail to reach agreement with the applicable regulatory agencies regarding the scope or design of our clinical trials;
- Patients do not enroll, patients drop out, or we do not observe worsening events, at the rate we expect;
- Ongoing or new clinical trials conducted by drug companies in addition to our own clinical trials reduce the availability of patients for our trials;
- Our clinical trial sites, contracted clinical trial administrators or clinical studies conducted entirely by third parties do not adhere to trial protocols and required quality controls under good clinical practices (GCP) regulations and similar regulations outside the United States;
- Patients experience severe side effects during treatment or die during our trials because of adverse events related to the trial drug, advanced disease, or other medical complications; and
- The results of our clinical trials conducted in a particular country are not acceptable to regulators in other countries.

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

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

Numerous treatments currently compete with our commercial therapies, and others are under development. For example, for the treatment of PAH, we compete with Adempas®, Flolan®, Ilomedin®, Letairis®, Opsumit®, Revatio®, Tracleer®, Uptravi®, Veletri®, Volibris®, Ventavis®, generic tadalafil, generic epoprostenol and generic sildenafil citrate. Our competitors may introduce new products that render all or some of our technologies and products obsolete or noncompetitive. For example, Uptravi was approved by the FDA in December 2015 for the treatment of PAH and competes directly with Orenitram. In addition, we may not compete successfully against generic competitors. Sales of a generic version of Adcirca launched in August 2018 and have already had a material adverse impact on demand for Adcirca. A generic version of Remodulin was launched in Austria in January 2019. We anticipate generic versions of Remodulin may be launched in the United States and certain additional countries in Europe in 2019, as described elsewhere in this Report, which could materially impact our revenues. Furthermore, we have limited visibility into the level of Adcirca inventory held by wholesale distributors and pharmacies, and rapid generic penetration could cause substantial amounts of Adcirca to expire unsold, causing us to incur increased liabilities for product returns. Any change in our estimated allowance for returns could result in a material impact on our revenues during the quarter in which the change is made.

Legislation such as the 21st Century Cures Act, which was enacted in December 2016 and designed to encourage innovation and bring pharmaceutical products to market more quickly, may enable our competitors to bring competing products to market on an expedited basis. In addition, alternative approaches to treating chronic diseases, such as gene therapy, cell therapy or transplantation

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technologies, may make our products obsolete or noncompetitive. Patients and doctors may discontinue use of our products if they perceive competing products as safer, more effective, less invasive, more convenient and/or less expensive than ours. Alternatively, doctors may reduce the prescribed doses of our products if they prescribe them in combination with competing products. In addition, many competing therapies are less invasive or more convenient than Tyvaso and Remodulin, and the use of these products may delay or prevent initiation of Tyvaso or Remodulin therapy. Any of these circumstances could negatively impact our operating results.

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

The commercial success of our products depends, in part, on the availability of reimbursements by governmental payers such as Medicare and Medicaid, and private insurance companies. A significant portion of Remodulin, Tyvaso, Adcirca and Orenitram sales in the United States are reimbursed under the Medicare and Medicaid programs. A reduction in the availability or extent of reimbursement from domestic or foreign government health care programs could have a material adverse effect on our business and results of our operations. In the United States, the European Union and other potentially significant markets for our products, government payers and/or third-party payers are increasingly attempting to limit or regulate the price of medicinal products and frequently challenge the pricing of new and expensive drugs. Financial pressures may cause United States government payers to seek cost containment more aggressively through mandatory discounts or rebates on our products, policies requiring the automatic substitution of generic products, more rigorous requirements for initial reimbursement approvals for new products or other similar measures. For example, there have been proposals to reduce reimbursement rates and/or adopt mandatory rebates under Medicare Part B, which covers Remodulin and Tyvaso. In January 2017, the Medicare Prescription Drug Price Negotiation Act was proposed in Congress; this act would require the federal government to negotiate the price of Medicare prescription drugs with pharmaceutical companies. In October 2017, the Medicare Drug Price Negotiation Act of 2017 was proposed in Congress, with similar requirements. More recently, in November 2017, the Centers for Medicare and Medicaid Services (CMS) announced a Final Rule that would adjust the applicable payment rate as necessary for certain separately payable drugs and biologicals acquired under the 340B Program from average sales price (ASP) plus 6 percent to ASP minus 22.5 percent. In many markets outside the United States, governments control the prices of prescription pharmaceuticals through the implementation of reference pricing, price cuts, rebates, revenue-related taxes and profit control.

Our prostacyclin analogue products (Remodulin, Tyvaso and Orenitram) and our oncology product (Unituxin) are expensive therapies. Consequently, it may be difficult for our distributors to obtain adequate reimbursement for our products from commercial and government payers to motivate such distributors to support our products. Alternatively, third-party payers may reduce the amount of reimbursement for our products based on changes in pricing of other therapies for the same disease. In addition, third-party payers may encourage the use of less-expensive generic alternative therapies following the launch of generic forms of Remodulin and Adcirca. If commercial and/or government payers do not approve our products for reimbursement, or limit reimbursements, patients and physicians could choose competing products that are approved for reimbursement or provide lower out-of-pocket costs.

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Patient assistance programs for pharmaceutical products have come under increasing scrutiny by governments, legislative bodies and enforcement agencies. These activities may result in actions that have the effect of reducing prices or demand for our products, harming our business or reputation, or subjecting us to fines or penalties.

Recently, there has been enhanced scrutiny of company-sponsored patient assistance programs, including insurance premium and co-pay assistance programs and manufacturers' donations to third-party charities that provide such assistance. If we, our vendors or donation recipients, are deemed to have failed to comply with relevant laws, regulations or government guidance in any of these areas, we could be subject to criminal and civil sanctions, including significant fines, civil monetary penalties and exclusion from participation in government healthcare programs, including Medicare and Medicaid, and burdensome remediation measures. Actions could also be brought against executives overseeing our business or other employees.

It is possible that any actions taken by the Department of Justice (DOJ) as a result of this industry-wide inquiry could reduce demand for our products and/or reduce coverage of our products, including by federal health care programs such as Medicare and Medicaid and state health care programs. If any or all of these events occur, our business, prospects and stock price could be materially and adversely affected.

Our manufacturing strategy exposes us to significant risks.

We must be able to manufacture sufficient quantities of our commercial products to satisfy growing demand. We manufacture Remodulin, Orenitram, Tyvaso and Unituxin, including the active ingredient in each of these products, at our own facilities and rely on third parties for additional manufacturing capacity for Remodulin, Tyvaso and finished Unituxin drug product. We rely on Minnetronix, Inc. as the sole manufacturer of the Tyvaso Inhalation System, and on Lilly as the sole manufacturer of Adcirca. If and when we launch the Implantable System for Remodulin, we will rely on Medtronic as the sole manufacturer of the SynchroMed II infusion system and related components used in the Implantable System for Remodulin. We rely on MannKind to perform manufacturing activities related to Treprostinil Technosphere, and we rely on a limited number of sole-source suppliers for manufacturing activities related to ralinepag and Trevyent.

If any of our internal or third-party manufacturing and supply arrangements are interrupted for compliance issues or other reasons, we may not have sufficient inventory to meet future demand. In addition, any change in suppliers and/or service providers could interrupt the manufacturing of our commercial products and impede the progress of our commercial launch plans and clinical trials.

In addition, our internal manufacturing process subjects us to risks as we engage in increasingly complex manufacturing processes. For example, Remodulin, Tyvaso and Unituxin are sterile solutions that must be prepared under highly-controlled environmental conditions, which are challenging to maintain on a commercial scale. In addition, Unituxin is a monoclonal antibody. As with all biologic products, monoclonal antibodies are inherently more difficult to manufacture than our treprostinil-based products and involve increased risk of viral and other contaminants. We manufacture our entire supply of Orenitram and dinutuximab, the active ingredient in Unituxin, without an FDA-approved back-up manufacturing site. We are constructing a new facility to expand our manufacturing capacity for dinutuximab, but this process will take several years and may not be successful at all. We presently have no plans to engage a third-party contract manufacturer to manufacture Orenitram or dinutuximab. Our long-term organ manufacturing programs will involve exceptionally complicated manufacturing processes, many of which have never been attempted on a clinical or commercial scale. It will take substantial time and resources to develop and implement such manufacturing processes, or we may never be able to do so successfully.

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

- We and our third-party manufacturers are subject to the FDA's current good manufacturing practices regulations, current good tissue practices, and similar international regulatory standards. Our ability to exercise control over regulatory compliance by our third-party manufacturers is limited;

- We may experience difficulty designing and implementing processes and procedures to ensure compliance with applicable regulations as we develop manufacturing operations for new products;

- Natural and man-made disasters (such as fires, contamination, power loss, hurricanes, earthquakes, flooding, terrorist attacks and acts of war) impacting our internal and third-party manufacturing sites could cause a supply disruption for example, Medtronic manufactures the Implantable System for Remodulin at its facilities in Puerto Rico, which is vulnerable to hurricanes;

- Even if we and our third-party manufacturers comply with applicable drug manufacturing regulations, the sterility and quality of our products could be substandard and such products could not be sold or used or subject to recalls;

- If we had to replace our own manufacturing operations or a third-party manufacturer, the FDA and its international counterparts would require new testing and compliance inspections. Furthermore, a new manufacturer would have to be familiarized with the processes necessary to manufacture and commercially validate our products, as producing our treprostinil-based and biologic 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 products may become scarce or unavailable, which could delay the manufacturing and subsequent sale of such products. Products manufactured with substituted materials or components must be approved by the FDA and applicable international regulatory agencies before they could be sold.

Any of these factors could disrupt sales of our commercial products, delay clinical trials or commercialization of new products, result in product liability claims and product recalls, and entail higher costs. Interruptions in our manufacturing process could be significant given the length of time and complexity involved in obtaining necessary regulatory approvals for alternative arrangements, through either third parties or internal manufacturing processes.

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

Third parties assist us in activities critical to our operations, such as: (1) manufacturing our clinical and commercial products; (2) conducting clinical trials, preclinical studies and other research and development activities; (3) obtaining regulatory approvals; (4) conducting pharmacovigilance-related and product complaint activities, including drug safety, reporting adverse events and product complaints; and (5) marketing and distributing our products. For risks related to the involvement of third parties in our manufacturing process, see the risk factor above, entitled *Our manufacturing strategy exposes us to significant risks*.

We rely on various distributors to market, distribute and sell Remodulin, Tyvaso, Orenitram and Unituxin. From time-to-time, we increase the price of products sold to our U.S.-based and international distributors. Our price increases may not be fully reimbursed by third-party payers. If our distributors do not achieve acceptable profit margins on our products, they may reduce or discontinue the sale of

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our products. Furthermore, if our distributors devote fewer resources to sell our products or are unsuccessful in their sales efforts, our revenues may decline materially. Outside the United States, we rely substantially on our international distributors to obtain and maintain regulatory approvals for our products and to market and sell our products in compliance with applicable laws and regulations.

We rely on Lilly to manufacture and supply Adcirca for us, and we use Lilly's pharmaceutical wholesaler network to distribute Adcirca. 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. In addition, Lilly has the right to determine the price of Adcirca. Changes in the price of Adcirca set by Lilly could adversely impact demand or reimbursement for Adcirca.

Any change in service providers could interrupt the distribution of our commercial products and our other products and services, and impede the progress of our clinical trials, commercial launch plans and related revenues.

We rely heavily on third-party contract research organizations, contract laboratories, clinical investigative sites and other third-parties to conduct our clinical trials, preclinical studies and other research and development activities. In particular, our research and development efforts into new indications for Unituxin are substantially outsourced to a contract research organization called Precision Oncology, LLC. In addition, the success of certain products we are developing will depend on clinical trials sponsored by third parties. Failure by any third party to conduct or assist us in conducting clinical trials in accordance with study protocols, quality controls and GCP, or other applicable U.S. or international requirements or to submit associated regulatory filings, could limit or prevent our ability to rely on results of those trials in seeking regulatory approvals.

We rely on third parties to supply pumps and other supplies necessary to deliver Remodulin. There are a limited number of pumps available in the market, and the discontinuation of any particular pump could have a material, adverse impact on our Remodulin revenues if a viable supply of an alternate pump is not available.

We rely heavily on Medtronic for the success of our program to develop an implantable pump to deliver intravenous Remodulin (the Implantable System for Remodulin). In particular, Medtronic is entirely responsible for regulatory approvals and all manufacturing and quality systems related to its infusion pump and related components. This includes satisfying FDA-imposed PMA conditions prior to launching the Implantable System for Remodulin. Medtronic entered into a consent decree related to the SynchroMed II implantable infusion pump systems. Medtronic's failure to comply with the ongoing obligations under the consent decree could adversely impact Medtronic's ability to manufacture and supply the Implantable System for Remodulin. In the event Medtronic is unwilling or unable to supply the system for any reason, our ability to meet patient demand and generate additional revenues will be materially adversely impacted; any delays in supply could also adversely impact our ability to meet patient demand and generate revenues.

We rely heavily on MannKind for various manufacturing activities related to Treprostinil Technosphere. MannKind has announced that its currently available cash and financing sources are not sufficient to continue to meet its current and anticipated cash requirements, raising substantial doubt about its ability to continue as a going concern. If MannKind is unable to supply us with devices and other components necessary to develop and manufacture Treprostinil Technosphere, the timing and success of this program could be materially adversely impacted.

Finally, we rely heavily on DEKA for the development of RemUnity, our pre-filled, semi-disposable system for subcutaneous treprostinil.

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Our operations must comply with extensive laws and regulations in the United States and other countries, including FDA regulations. Failure to obtain approvals on a timely basis or to achieve continued compliance with these requirements could delay, disrupt or prevent the commercialization of our products.

The products we develop must be approved for marketing and sale by regulatory agencies. Our research and development efforts must comply with extensive regulations, including those promulgated by the FDA and the U.S. Department of Agriculture. The process of obtaining and maintaining regulatory approvals for new drugs is lengthy, expensive and uncertain. The regulatory approval process is particularly uncertain for our transplantation programs, which include the development of xenotransplantation, regenerative medicine, biomechanical lungs and cell-based products. Once approved, the manufacture, distribution, advertising and marketing of our products are subject to extensive regulation, including product labeling, strict pharmacovigilance and adverse event and medical device reporting, complaint processing, storage, distribution and record-keeping requirements. Our product candidates may fail to receive regulatory approval on a timely basis, or at all. If granted, product approvals can be conditioned on the completion of post-marketing clinical studies, accompanied by significant restrictions on the use or marketing of a given product and withdrawn for failure to comply with regulatory requirements, such as post-marketing requirements and post-marketing commitments, or upon the occurrence of adverse events subsequent to commercial introduction. If data from post-marketing studies suggest that an approved product presents an unacceptable safety risk, regulatory authorities could withdraw the product's approval, suspend production or place other marketing restrictions on that product.

In December 2017, we entered into a Corporate Integrity Agreement (the CIA) with the Office of Inspector General of the Department of Health and Human Services (OIG), which requires us to maintain our corporate compliance program and to undertake a set of defined corporate integrity obligations for a period of five years from the date the agreement was signed. We may be required to incur significant future costs to comply with the CIA. The CIA was entered into in connection with a civil Settlement Agreement with the DOJ and the OIG. The Settlement Agreement relates to a May 2016 subpoena from the DOJ requesting documents regarding our support of 501(c)(3) organizations that provide financial assistance to patients. Other companies received similar inquiries as part of a DOJ investigation regarding whether that support may violate the Federal Anti-Kickback Statute and the Federal False Claims Act.

If we fail to comply with applicable regulatory requirements or the CIA, we could be subject to penalties including fines, suspension of regulatory approvals that cause us to suspend production, distribution or marketing activities, product recalls, seizure of our products and/or criminal prosecution. If regulatory sanctions are applied or regulatory approval is delayed or withdrawn, our operating results and the value of our company may be adversely affected. In addition, our reputation could be harmed as a result of any such regulatory restrictions or actions, and patients and physicians may avoid the use of our products even after we have resolved the issues that led to such regulatory action.

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

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

While physicians may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those approved by regulatory authorities (called "off-label" uses), our ability to promote our products is limited to those indications that are specifically approved by the FDA. If our promotional activities fail to comply with regulations or guidelines related to off-label

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promotion, we may be subject to warnings from, or enforcement action by, these authorities. In addition, failure to follow FDA rules and guidelines related to promotion and advertising can result in the FDA's refusal to approve a product, suspension or withdrawal of an approved product from the market, product recalls, fines, disgorgement of money, operating restrictions, civil lawsuits, injunctions or criminal prosecution.

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

Our business activities may be subject to challenge under laws in jurisdictions around the world restricting particular marketing practices such as anti-kickback and false claim statutes, the Foreign Corrupt Practices Act and the UK Bribery Act. Any penalties imposed upon us for failure to comply could have a material adverse effect on our business and financial condition.

In the United States, the Federal Anti-Kickback Statute prohibits, among other activities, knowingly and willfully offering, paying, soliciting, or receiving compensation to induce, or in return for, the purchase, lease, order or arranging the purchase, lease or order of any health care product or service reimbursable under any federally financed health-care program. This statute has been interpreted broadly to apply to arrangements between pharmaceutical manufacturers and prescribers, purchasers, formulary managers, patients, and others. The exemptions and safe harbors under this statute may be narrow, and practices that involve compensation may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices do not always qualify for safe harbor protection. The discount safe harbor is currently the subject of possible reform. Any changes to the discount safe harbor may cause us to review our arrangements and pricing strategies with payers.

The Federal False Claims Act, as amended by the Patient Protection and Affordable Care Act of 2010 (PPACA), prohibits any person from presenting or causing to be presented a false or fraudulent claim or making or causing a false statement material to a false or fraudulent claim. Several pharmaceutical and health care companies have been investigated under this law for allegedly providing free product to customers with the expectation that the customers would bill federal health care programs for the free product. Other companies have been prosecuted for causing false claims to be submitted because of these companies' marketing of a product for unapproved and non-reimbursable uses. Potential liability under the Federal False Claims Act includes mandatory treble damages and significant per-claim penalties. The majority of states also have statutes similar to the Federal Anti-Kickback Statute and the Federal False Claims Act. Sanctions under these federal and state laws may include treble civil monetary penalties, exclusion of a manufacturer's product from reimbursement under state government programs, debarment, criminal fines, and imprisonment.

Any investigation, inquiry or other legal proceeding under these laws and related to our operations may adversely affect our business, results of operations or reputation.

The PPACA also imposed reporting requirements for pharmaceutical, biologic and device manufacturers regarding payments or other transfers of value made to physicians and teaching hospitals, including investment interests in such manufacturers held by physicians and their immediate family members during the preceding calendar year. Failure to submit required information may result in civil monetary penalties, which may increase significantly for "knowing failures." Compliance with these and similar laws on a state-by-state basis is difficult and time consuming.

Government healthcare reform could adversely affect our revenue, costs and results of operations.

Our industry is highly regulated and changes in law may adversely impact our business, operations or financial results. The PPACA is a broad measure intended to expand health care coverage within the United States, primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. The reforms imposed by the law will significantly

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impact the pharmaceutical industry; however, the full effects of the PPACA will be unknown until all of these provisions are implemented and CMS and other federal and state agencies issue applicable regulations or guidance. Moreover, in the coming years, additional changes could be made to governmental health care programs that could significantly impact the success of our products or product candidates. We may face uncertainties as a result of federal and administrative efforts to repeal, substantially modify or invalidate some or all of the provisions of the PPACA. There is no assurance that the PPACA, as currently enacted or as amended in the future, will not adversely affect our business and financial results, and we cannot predict how future federal or state legislative or administrative changes related to healthcare reform will affect our business.

Since the November 2016 U.S. election, President Trump and the U.S. Congress have made numerous efforts to repeal or amend the Affordable Care Act in whole or in part. In May 2017, the U.S. House of Representatives voted to pass the American Health Care Act (the AHCA), which would repeal many provisions of the Affordable Care Act. Although the U.S. Senate considered but failed to pass the AHCA and other comparable measures, the U.S. Congress may consider further legislation to repeal or replace elements of the Affordable Care Act. In addition, the Tax Cuts and Jobs Act, which President Trump signed into law in December 2017, repeals the Affordable Care Act's individual health insurance mandate, which is considered a key component of the Affordable Care Act. The future stability of the Affordable Care Act and the resulting impact on our business is thus uncertain and could be material.

In addition, many states have proposed legislation that seeks to indirectly or directly regulate pharmaceutical drug pricing by requiring biopharmaceutical manufacturers to publicly report proprietary pricing information or to place a maximum price ceiling on pharmaceutical products purchased by state agencies. If such proposed legislation is passed, we may experience additional pricing pressures on our products. For example, in October 2017, California's governor signed a prescription drug price transparency state bill into law, requiring prescription drug manufacturers to provide advance notice and explanation for price increases of certain drugs that exceed a specified threshold. Similar bills have been previously introduced at the federal level, and the Trump administration has focused attention on proposed efforts to curb prescription drug prices. In May 2018, President Trump and the Health and Human Services (HHS) Secretary released the American Patients First blueprint, which included measures to increase generic drug and biosimilar competition, the ability of the Medicare program to negotiate drug prices, public transparency regarding drug prices and information available to beneficiaries regarding ways to lower out-of-pocket costs. The Trump administration has begun implementing many of these measures, and in October 2018, President Trump proposed a demonstration project to establish an "international pricing index" that would be used as a benchmark in deciding how much to pay for Medicare Part B drugs. The potential effect of health insurance market destabilization during ongoing repeal and replace discussions, as well as the impact of potential changes to the way the Medicaid program is financed, will likely affect patients' sources of insurance and resultant drug coverage. In addition to the Trump administration's proposals, discussions continue at the federal level regarding policies that would require manufacturers to pay higher rebates in Medicare Part D, give states more flexibility on drugs that are covered under the Medicaid program, permit the re-importation of prescription medications from Canada or other countries and other policy proposals that could impact reimbursement for our products. It is difficult to predict the impact, if any, of any such legislation, executive actions or Medicaid flexibility on the use and reimbursement of our products in the United States, including the potential for the importation of generic versions of our products.

On January 31, 2019, the U.S. Department of Health and Human Services released a proposal to revise the federal Anti-Kickback Statute safe harbor regulations to exclude from safe harbor protection certain rebates and other forms of remuneration paid by a manufacturer of prescription drugs to Medicaid managed care organizations or plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers.

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In addition, state Medicaid programs could request additional supplemental rebates on our products as a result of the increase in the federal base Medicaid rebate. Private insurers could also use the enactment of these increased rebates to exert pricing pressure on our products, and to the extent that private insurers or managed care programs follow Medicaid coverage and payment developments, the adverse effects may be magnified by private insurers adopting lower payment schedules.

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

Reports of side effects and adverse events associated with our products could have a significant adverse impact on the sale of our products. An example of a known risk associated with intravenous Remodulin is sepsis, which is a serious and potentially life-threatening infection of the bloodstream caused by a wide variety of bacteria. Intravenous Remodulin is infused continuously through a catheter placed in a large vein in the patient's chest, and sepsis is a known risk associated with this type of delivery. In addition, Unituxin is associated with severe side effects, and its label contains a boxed warning related to potential infusion reactions and neurotoxicity. Development of new products, and new formulations and indications for existing products, could result in new side effects and adverse events which may be serious in nature. Concerns about side effects may affect a physician's decision to prescribe or a patient's willingness to use our products.

Negative attention from special interest groups may impair our business.

As is common with pharmaceutical and biotechnology companies, our early-stage research and development involves animal testing required by regulatory authorities, which we conduct both directly and through contracts with third parties. Our xenotransplantation and regenerative medicine programs rely heavily on the use of animals to manufacture and test our products. Certain special interest groups categorically object to the use of animals for research purposes. Any negative attention, threats or acts of vandalism directed against our animal research activities in the future could impede the operation of our business.

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

Our business depends upon our continuing ability to exploit our intellectual property rights acquired from third parties under product license and purchase agreements. Under each of our purchase agreements, we have rights to certain intellectual property covering a drug or other product or technology. We may be required to license additional intellectual property owned by third parties to continue to develop and commercialize our products.

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

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

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

Our rights to develop and market products to which the intellectual property relates are frequently limited to specific territories and fields of use (such as treatment of particular diseases); and

If a licensor of intellectual property fails to maintain the intellectual property licensed, we may lose any ability to prevent others from developing or marketing similar products covered by such

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intellectual property. In addition, we may be forced to incur substantial costs to maintain the intellectual property ourselves or take legal action seeking to force the licensor to do so.

Our intellectual property rights may not effectively deter competitors from developing competing products that, if successful, could have a material adverse effect on our revenues and profits.

The period under which our commercial and developmental therapies are protected by our patent rights is limited. Three of our U.S. patents covering our current methods of synthesizing and producing treprostinil, the active ingredient in Remodulin, Tyvaso and Orenitram, expired in October 2017, and three more will expire in 2028. Our patents related to our individual treprostinil-based products expire at various times between 2018 and 2031. We settled patent litigation with Sandoz, Teva, Par and Dr. Reddy's, and entered into settlement agreements permitting them to launch generic versions of Remodulin in the United States in June 2018 (Sandoz) and December 2018 (Teva, Par and Dr. Reddy's). We anticipate one or more of these companies will launch their generic versions of Remodulin in the United States in 2019. We also settled patent litigation with Actavis and Watson, and entered into settlement agreements permitting them to launch generic versions of Orenitram and Tyvaso in the United States in June 2027 and January 2026, respectively, although each may be permitted to enter the market earlier under certain circumstances.

A U.S. patent for Adcirca for the treatment of pulmonary hypertension expired in November 2017, and FDA-conferred regulatory exclusivity expired in May 2018, leading to the launch of a generic version of Adcirca in August 2018. We have no issued patents or pending patent applications covering Unituxin. For further details, please see *Part I, Item 1. Business Patents and Other Proprietary Rights, Strategic Licenses and Market Exclusivity Generic Competition.*

We continue to conduct research into new methods to synthesize treprostinil and have pending U.S. and international patent applications and patents related to such methods. We also have additional issued and pending patents covering the use of our existing commercial products in new indications and with new devices. However, we cannot be sure that our existing or any new patents will effectively deter or delay competitors' efforts to bring new products to market, or that additional patent applications will result in new patents. Upon the expiration of any of our patents, competitors may develop generic versions of our products and may market those generic versions at a lower price to compete with our products. Competitors may also seek to design around our patents or exclude patented methods of treatment, such as patent-protected indications, from the label for generic versions of our products in an effort to develop competing products that do not infringe our patents. In addition, patent laws of foreign jurisdictions may not protect our patent rights to the same extent as the patent laws of the United States.

Third parties have challenged, and may in the future challenge, the validity of our patents, through patent litigation and/or initiating proceedings, including re-examinations, IPRs, post-grant reviews and interference proceedings, before the USPTO or other applicable patent filing office, or other means.

Patent litigation can be time consuming, distracting to our operations, costly and may conclude unfavorably for us. In addition, the outcome of patent infringement litigation often is difficult to predict. If we are unsuccessful with respect to any future legal action in the defense of our patents and our patents are invalidated or determined to be unenforceable, our business could be negatively impacted. Even if our patents are determined to be valid or enforceable, it is possible that a competitor could circumvent our patents by effectively designing around the claims of our patents. Accordingly, our patents may not provide us with any competitive advantage.

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

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and expensive to enforce or may not provide an adequate remedy in the event of unauthorized disclosure. In addition, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our business and competitive position could be harmed.

Third parties may allege that our products or services infringe their patents and other intellectual property rights, which could result in the payment of royalties. Payment of royalties would negatively affect our profits; furthermore, if we chose to contest these allegations, we could be subject to costly and time-consuming litigation or could lose the ability to continue to sell the related products.

To the extent third-party patents to which we currently do not hold licenses are necessary for us to manufacture, use or sell our products, we would need to obtain necessary licenses to prevent infringement. In the case of products or services that utilize intellectual property of strategic collaborators or other suppliers, such suppliers may have an obligation to secure the needed license to these patents at their cost. Otherwise, we would be responsible for the cost of these licenses. Royalty payments and other fees under these licenses would erode our profits from the sale of related products and services. Moreover, we may be unable to obtain these licenses on acceptable terms or at all. If we fail to obtain a required license or are unable to alter the design of the product to avoid infringing a third-party patent, we would be unable to continue to manufacture or sell related products.

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

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

The testing, manufacturing, marketing, and sale of drugs and diagnostics involve product liability risks. We may not be able to maintain our current product liability insurance at an acceptable cost, if at all. In addition, our insurance coverage may not be adequate for all potential claims. If claims or losses significantly exceed our liability insurance coverage, we may experience financial hardship or potentially be forced out of business. While we historically have had a limited number of product liability claims, the clinical testing and eventual marketing and sale of new products, reformulated versions of existing products, or existing products in new indications, could expose us to new product liability risks. The launch of new products will raise new product liability risks, and in many cases the quality of these products will depend on the performance of third parties that we do not control (such as Medtronic, in the case of the Implantable System for Remodulin).

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

Members of our management team, including our founder, Chairman and Chief Executive Officer, Dr. Martine Rothblatt, play a critical role in defining our business strategy and maintaining our corporate culture. The loss of the services and leadership of Dr. Rothblatt or any other members of our senior management team could have an adverse effect on our business. We do not maintain key person life insurance on our senior management team members. In addition, effective succession planning is important to our long-term success. Failure to identify, hire and retain suitable successors for members of our senior management team and to transfer knowledge effectively could impede the achievement of our business objectives. Our future success also depends on our ability to attract and

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retain qualified scientific and technical personnel. Competition for skilled scientific and technical personnel in the biotechnology and pharmaceutical industries is intense. Furthermore, our compensation arrangements may not be sufficient to attract new qualified scientific and technical employees or retain such core employees. If we fail to attract and retain such employees, we may not be successful in developing and commercializing new therapies for PAH and other diseases.

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

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

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

If we experience substantial sales growth, we may have difficulty managing inventory levels as marketing new therapies is complicated and gauging future demand can be difficult and uncertain until we possess sufficient post-launch sales experience. In addition, we have spent considerable resources building and expanding our offices, laboratories and manufacturing facilities. However, our facilities could be insufficient to meet future demand for our products. Conversely, we may have excess capacity at our facilities if future demand falls short of our projections, or if we do not receive regulatory approvals for the products we intend to manufacture at our facilities. Our ability to satisfactorily recover our investments in our facilities will depend on sales of the products manufactured at these facilities in sufficient volume.

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

We may be required to seek additional sources of financing to meet unplanned or planned expenditures. Unplanned expenditures could be significant and may result from necessary modifications to product development plans or product offerings in response to difficulties encountered with clinical trials. We may also face unexpected costs in preparing products for commercial sale, or in maintaining sales levels of our currently marketed therapeutic products. In addition, our 2018 Credit Agreement contains affirmative and negative covenants that, among other things, limit our ability to incur additional indebtedness. If we are unable to obtain additional funding on commercially reasonable terms or at all, we may be compelled to delay clinical studies, curtail operations or obtain funds through collaborative arrangements that may require us to relinquish rights to certain products or potential markets.

We may require additional financing to meet significant future obligations. For example, our Share Tracking Awards Plan (STAP) awards entitle participants to receive in cash an amount equal to the appreciation in the price of our common stock, which is calculated as the positive difference between the closing price of our common stock on the date of exercise and the date of grant. Consequently, our STAP may require significant future cash payments to participants to the extent the price of our common stock appreciates and the number of vested STAP awards increases over time. If we do not

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have sufficient funds to meet such obligations or the ability to secure alternative sources of financing, we could be in default, face litigation and/or lose key employees, which could have a material adverse effect on our business.

We may not be able to generate sufficient cash to service our indebtedness, which may have a material adverse effect on our financial position, results of operations and cash flows. In addition, we may be forced to take other actions to satisfy our obligations in connection with our indebtedness, which actions may not be successful.

We may borrow up to $1.5 billion under the 2018 Credit Agreement, which matures in June 2023. Currently, our outstanding principal balance is $1.05 billion. Our ability to make payments on or refinance our debt obligations, including any outstanding balance under the 2018 Credit Agreement, and any future debt that we may incur, will depend on our financial condition and operating performance, which are subject to prevailing economic and competitive conditions and to certain financial, business, legislative, regulatory and other factors beyond our control. We may be unable to maintain a level of cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our indebtedness. Our inability to generate sufficient cash flows to satisfy our debt obligations would materially and adversely affect our financial position and results of operations.

If we cannot repay or refinance our debt as it becomes due, we could be forced to take disadvantageous actions, including reducing or delaying investments and capital expenditures, disposing of material assets or operations, seeking additional debt or equity capital or restructuring or refinancing our indebtedness. We may not be able to effect any such alternative measures, if necessary, on commercially reasonable terms or at all and, even if successful, such actions may not be sufficient for us to meet any such debt service obligations. In addition, our ability to withstand competitive pressures and to react to changes in our industry could be impaired.

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

We are increasingly dependent on information technology systems and infrastructure, much of which is outsourced to third parties including in "cloud" based platforms. In the ordinary course of our business, we collect, store and use sensitive or confidential data, including intellectual property, our proprietary business information and that of our suppliers, customers and business partners, and personally identifiable information. The secure maintenance of this information is critical to our operations and business strategy. We are subject to laws and regulations in the United States and abroad, such as the Health Insurance Portability and Accountability Act of 1996 and European Union regulations related to data privacy, which require us to protect the privacy and security of certain types of information. Our information technology and infrastructure may be vulnerable to attacks by hackers, breached due to employee error, malfeasance or other disruptions, or subject to system failures. We must continuously monitor and enhance our information security controls to prevent, detect, and/or contain unauthorized activity and malicious software. Because the techniques used to obtain unauthorized access, disable or degrade service, or sabotage systems change frequently and may be difficult to detect for long periods of time, we may be unable to anticipate these techniques or implement adequate preventive measures. Any breaches or failures could compromise sensitive and confidential information stored on our networks or those of third parties and expose such information to public disclosure, loss or theft. Any actual or alleged unauthorized access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, disruption of our operations, and damage to our reputation which could adversely affect our business, financial condition, or results of operations. In addition, remediation, repair and other costs we may incur as a result of any of the foregoing, including increased costs to

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protect our information technology systems and infrastructure, and increased insurance premiums, could adversely affect our business, financial condition, or results of operations.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate information about our products and the diseases that our therapies are designed to treat. Social media practices in our industry continue to evolve and regulations related to such use are not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients and others may use social media channels to comment on the effectiveness of a product or to report an alleged adverse event. When such disclosures occur, we may fail to monitor and comply with applicable adverse event reporting obligations or we may not be able to defend against political and market pressures generated by social media due to restrictions on what we may say about our products. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate comments about us on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face overly restrictive regulatory actions or incur other harm to our business.

Tax legislation may materially adversely affect us.

Tax laws are dynamic and continually changing as new laws are passed and new interpretations of existing laws are issued or applied. Governmental tax authorities are increasingly scrutinizing the tax positions of companies. If federal, state or foreign tax authorities change applicable tax laws or issue new guidance, our overall taxes could increase, and our business, financial condition or results of operations may be adversely impacted.

If we are not able to successfully identify, finance, consummate and/or integrate acquisitions, our business operations and financial position could be adversely affected.

In August 2018 we acquired SteadyMed. We also entered into several in-licenses related to ongoing development programs in 2018, including our license with Arena related to ralinepag and our license with MannKind related to Treprostinil Technosphere. We may continue to seek to expand in part through acquisitions of complementary businesses, products and technologies, through business combinations or in-licenses. The success of this strategy will depend on our ability to identify, and the availability of, suitable acquisition candidates. We may incur costs in the preliminary stages of an acquisition, but may ultimately be unable or unwilling to consummate the proposed transaction for various reasons. In addition, acquisitions involve numerous risks, including the ability to realize or capitalize on anticipated synergies; managing the integration of personnel, products and acquired infrastructure and controls; potential increases in operating costs; managing geographically remote operations; the diversion of management's attention from other business concerns and potential disruptions in ongoing operations during integration; the inherent risks in entering markets and sectors in which we have either limited or no direct experience; and the potential loss of key employees, clients or vendors and other business partners of the acquired companies. External factors, such as compliance with laws and regulations, may also impact the successful integration of an acquired business. Acquisitions could result in dilutive issuances of equity securities, the incurrence of debt, one-time write-offs of goodwill and substantial amortization expenses of other intangible assets. We may be unable to obtain financing on favorable terms, or at all, if necessary to finance future acquisitions, which may make acquisitions impossible or more costly. If we are able to obtain financing, the terms may be onerous and restrict our operations. Further, certain acquisitions may be subject to regulatory approval, which can be time consuming and costly to obtain or may be denied, and if obtained, the terms of such regulatory approvals may impose limitations on our ongoing operations or require us to divest assets.

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Risks Related to Our Common Stock

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

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

	High	Low
January 1, 2018 - December 31, 2018	$ 151.94	$ 101.14
January 1, 2017 - December 31, 2017	$ 168.42	$ 114.60
January 1, 2016 - December 31, 2016	$ 155.54	$ 98.33

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

Failure to meet our estimates or expectations, or those of securities analysts;

Quarterly and annual financial results;

Timing of enrollment and results of our clinical trials, including the anticipated announcement of our *BEAT* and *DISTINCT* phase III clinical studies;

Announcements regarding generic or other challenges to the intellectual property related to our products, the launch of generic versions of our products, and the impact of generic competition on our revenues;

Announcements regarding our efforts to obtain FDA approval of new products, such as RemUnity and Trevyent, and the timing and success of our launch of new products, such as the Implantable System for Remodulin;

Physician, patient, investor or public concerns regarding the efficacy and/or safety of products marketed or being developed by us or by others;

Changes in, or new legislation and regulations affecting reimbursement of, our therapeutic products by Medicare, Medicaid or other government payers, and changes in reimbursement policies of private health insurance companies, and negative publicity surrounding the cost of high-priced therapies;

Announcements of technological innovations or new products or announcements regarding our existing products, including in particular the development of new, competing PAH therapies;

Substantial sales of our common stock by us or our existing shareholders, or concerns that such sales may occur;

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

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

Failures or delays in our efforts to obtain or maintain regulatory approvals from the FDA or international regulatory agencies;

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 penalties or restrictions on our products, up to the withdrawal of our products from the market;

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

General market conditions.

Provisions of Delaware law and our amended and restated certificate of incorporation, seventh amended and restated By-laws and employment and license agreements, among other things, could prevent or delay a change of control or change in management that may be beneficial to our public shareholders.

Certain provisions of Delaware law and our amended and restated certificate of incorporation and seventh amended and restated By-laws may prevent, delay or discourage:

A merger, tender offer or proxy contest;

The assumption of control by a holder of a large block of our securities; and/or

The replacement or removal of current management by our shareholders.

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

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

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

We enter into certain license agreements that generally prohibit our counterparties or their affiliates from taking necessary steps to acquire or merge with us, directly or indirectly throughout the term of these agreements, plus a specified period thereafter. We are also party to certain license agreements that restrict our ability to assign or transfer the rights licensed to us to third parties, including parties with whom we wish to merge, or those attempting to acquire us. These agreements often require that we obtain prior consent of the counterparties to these agreements if we contemplate a change of control. If these counterparties withhold consent, related agreements could be terminated and we would lose related license rights. For example, Lilly, Samumed, MannKind and Toray Industries, Inc. have the right to terminate our license agreements related to Adcirca, SM04646, Treprostinil Technosphere and esuberaprost, respectively, in the event of certain change of control transactions. These restrictive change of control provisions could impede or prevent mergers or other transactions 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 and our 2018 Credit Agreement contains covenants that may restrict us from doing so. 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.

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ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Maryland We own and occupy a 353,000 square foot combination laboratory and office building complex in Silver Spring, Maryland that serves as our co-headquarters and is used for commercial manufacturing. These manufacturing activities include the synthesis of treprostinil, the active ingredient in Remodulin and Tyvaso, and treprostinil diolamine, the active ingredient in Orenitram, as well as dinutuximab, the active ingredient in Unituxin. We also manufacture finished Remodulin, Tyvaso and Unituxin in our Silver Spring complex. We own several other buildings in Silver Spring used principally for office and laboratory space. We are constructing a 29,000 square foot facility in Silver Spring to serve as a monoclonal antibody manufacturing site.

North Carolina We own a 380,000 square foot combination manufacturing facility and office building in Research Triangle Park, North Carolina (RTP facility), which serves as our co-headquarters and is occupied by our clinical research and development, commercialization and our logistics and manufacturing personnel. We manufacture Orenitram tablets and we package, warehouse and distribute Remodulin, Tyvaso, Orenitram and Unituxin at this location. We also own a 132-acre site containing approximately 330,000 square feet of building space adjacent to our RTP facility, which we use for our research, development and manufacturing facilities related to our lung regeneration program, office space and for future expansion.

District of Columbia We own four adjacent buildings in Washington, D.C. totaling 30,000 square feet, which serve as office space.

Florida We own two buildings in Brevard County, Florida used for strategic operations and planning. We are also constructing a 75,000 square foot building in Jacksonville, Florida, to serve as a regional ex-vivo lung perfusion facility as part of our collaboration with the Mayo Clinic.

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

ITEM 3. LEGAL PROCEEDINGS

Currently, and from time to time, we are subject to claims in legal proceedings arising in the normal course of business. While we presently believe that the ultimate outcome of these proceedings, individually and in the aggregate, will not materially harm our financial position, cash flows or results of operations, legal proceedings are inherently uncertain, and unfavorable rulings could, individually or in aggregate, have a material adverse effect on our business, financial condition or operating results. Please refer to Note 17 *Litigation*, to our consolidated financial statements, which is incorporated herein by reference.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

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PART II

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

Market Information

Our common stock trades on the Nasdaq Global Select Market under the symbol "UTHR".

Number of Holders

As of February 20, 2019, there were 36 holders of record of our common stock.

Dividend Policy

We have never paid and have no present intention to pay cash dividends on our common stock in the foreseeable future and our 2018 Credit Agreement contains covenants that may restrict us from doing so. We intend to retain any earnings for use in our business operations.

Issuer Purchases of Equity Securities

We did not repurchase any of our outstanding equity securities during the three months ended December 31, 2018, as our most recent share repurchase program was completed in September 2017.

Comparison of Five-Year Total Cumulative Shareholder Return

The following chart shows the performance from December 31, 2013 through December 31, 2018 of our common stock, compared with an investment in the stocks represented in each of the Nasdaq U.S. Benchmark TR Index and the Nasdaq ICB: 4577 Pharmaceutical Stock Index, assuming the investment of $100 at the beginning of the period and the reinvestment of dividends, if any.

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ITEM 6. SELECTED FINANCIAL DATA

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

	Year Ended December 31,				
	2018	2017	2016	2015	2014
Consolidated Statements of Operations Data:					
Revenues	$ 1,627.8	$ 1,725.3	$ 1,598.8	$ 1,465.8	$ 1,288.5
Operating income	$ 805.4	$ 814.9	$ 1,061.7	$ 699.0	$ 538.8
Net income	$ 589.2	$ 417.9	$ 713.7	$ 651.6	$ 340.1
Net income per common share:					
Basic[(1)]	$ 13.54	$ 9.50	$ 16.29	$ 14.17	$ 7.06
Diluted[(1)]	$ 13.39	$ 9.31	$ 15.25	$ 12.72	$ 6.28

	As of December 31,				
	2018	2017	2016	2015	2014
Consolidated Balance Sheet Data:					
Cash, cash equivalents and marketable investments	$ 1,858.5	$ 1,430.1	$ 1,053.1	$ 991.8	$ 818.2
Total assets	$ 3,401.0	$ 2,879.4	$ 2,325.6	$ 2,184.4	$ 1,884.4
Total non-current liabilities	$ 316.6	$ 313.7	$ 130.9	$ 144.0	$ 114.5
Total stockholders' equity	$ 2,788.6	$ 2,101.8	$ 1,851.3	$ 1,588.6	$ 1,242.4

(1) Refer to Note 11 *Stockholders' Equity Earnings Per Common Share* to our consolidated financial statements for the computation of basic and diluted net income per share.

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 our consolidated financial statements.

Overview of Marketed Products

We currently market and sell the following commercial products:

Remodulin, a continuously-infused formulation of the prostacyclin analogue treprostinil, approved by the FDA for subcutaneous and intravenous administration to diminish symptoms associated with exercise in PAH patients. Remodulin has also been approved in various countries outside of the United States.

Tyvaso, an inhaled formulation of treprostinil, approved by the FDA and regulatory authorities in Argentina and Israel to improve exercise ability in PAH patients.

Orenitram, a tablet dosage form of treprostinil approved by the FDA to improve exercise capacity in PAH patients.

Adcirca, an oral PDE-5 inhibitor approved by the FDA to improve exercise ability in PAH patients.

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Unituxin, a monoclonal antibody approved by the FDA and Health Canada for the treatment of high-risk neuroblastoma.

For additional detail regarding our commercial products, see *Item 1 Business Our Commercial Products.*

Research and Development

We are engaged in research and development of new formulations, indications and delivery devices for our existing products. In particular, we are developing the Implantable System for Remodulin and the RemUnity system for delivery of intravenous and subcutaneous Remodulin, respectively. We are studying Tyvaso in patients with WHO Group 3 pulmonary hypertension and Orenitram in patients with WHO Group 2 pulmonary hypertension. We are also studying dinutuximab in patients with small cell lung cancer.

In addition, we are developing new products to treat PAH (esuberaprost, RemoPro, Treprostinil Technosphere, Trevyent, ralinepag and Aurora-GT), as well as a product to treat IPF (SM04646). We are also heavily engaged in early-stage research and development of a number of organ transplantation-related technologies including regenerative medicine, xenotransplantation, biomechanical lungs and ex-vivo lung perfusion. Finally, we are engaged in additional, early-stage research and development efforts in PAH and other diseases. For additional detail regarding our research and development programs, see *Item 1 Business Research and Development.*

Revenues

Our net product sales consist of sales of the five commercial products noted above. We have entered into separate, non-exclusive distribution agreements with Accredo and CVS Specialty to distribute Remodulin, Tyvaso and Orenitram in the United States, and we have entered into an exclusive distribution agreement with ASD to distribute Unituxin in the United States. We also sell Remodulin and Tyvaso to distributors internationally. We sell Adcirca through Lilly's pharmaceutical wholesale network. To the extent we have increased the price of any of these products, increases have typically been in the single-digit percentages per year, except for Adcirca, the price of which is set solely by Lilly. In 2018, revenues were higher than we anticipated due to a delay in the launch of generic Adcirca; despite loss of regulatory exclusivity in May 2018, generic Adcirca sales did not commence until August 2018. In 2019, we anticipate revenues will decrease as compared to 2018 because generic Adcirca will be available for the full year in 2019, as compared to only the last four months of 2018. Additional downward pressure on 2019 revenues could result, to a lesser degree, from the launch of a generic version of Remodulin in Austria in January 2019 and the anticipated launch of generic versions of Remodulin in 2019 in the U.S. and other countries in Europe. Longer term, we believe our pipeline of new products and potential label expansions for existing products should result in a return to revenue growth potentially as soon as 2020, although the precise timing depends on a number of factors, including factors that we cannot control. Refer to the risks identified in *Part I, Item 1A Risk Factors*, included in this Report.

We require our specialty pharmaceutical distributors to maintain reasonable levels of inventory reserves because the interruption of Remodulin, Tyvaso or Orenitram therapy can be life threatening. Our specialty pharmaceutical distributors typically place monthly orders based on current utilization trends and contractual minimum inventory requirements. As a result, sales of Remodulin, Tyvaso and Orenitram can vary depending on the timing and magnitude of these orders and do not precisely reflect changes in patient demand.

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Acquisition of SteadyMed Ltd.

On April 29, 2018, we entered into an Agreement and Plan of Merger (Merger Agreement) with SteadyMed Ltd. (SteadyMed) and Daniel 24043 Acquisition Corp Ltd., our wholly-owned subsidiary (Merger Sub). The Merger Agreement provided for the merger of Merger Sub with and into SteadyMed (the Merger), with SteadyMed surviving the Merger as our wholly-owned subsidiary.

On August 30, 2018, we completed the Merger. At the effective time of the Merger, each SteadyMed ordinary share was converted into the right to receive (1) $4.46 in cash, representing aggregate consideration payable to former holders of SteadyMed securities of approximately $141 million; and (2) one contingent value right, representing the right to receive $2.63 in cash upon the achievement of a milestone defined as 3,000 patients initiating treatment using SteadyMed's Trevyent product on a commercial basis on or before August 30, 2023 (the Milestone). Aggregate contingent consideration of $75.0 million will become payable if the Milestone is achieved. Refer to Note 4 *Acquisition*, to our consolidated financial statements for additional information.

Recent License Agreements

During the fourth quarter of 2018, we entered into license agreements with Arena (ralinepag), MannKind (Treprostinil Technosphere) and Samumed (SM04646). For details regarding these license agreements, please see *Item 1 Business Research and Development*.

Operating Expenses

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

Our operating expenses include the following costs:

Cost of Product Sales

Our cost of product sales primarily includes costs to manufacture and acquire products sold to customers, royalty and milestone payments under license agreements granting us rights to sell related products, direct and indirect distribution costs incurred in the sale of products, and the costs of inventory reserves for current and projected obsolescence. These costs also include share-based compensation and salary-related expenses for direct manufacturing and indirect support personnel, quality review and release for commercial distribution, direct materials and supplies, depreciation, facilities-related expenses and other overhead costs. Our cost of product sales for Adcirca increased significantly as a percentage of Adcirca revenues beginning December 1, 2017 as a result of increased royalty and milestone payments, from five percent to an effective rate of approximately 42.5 percent, contained in our amended license agreement with Lilly.

Research and Development

Our research and development expenses primarily include costs associated with the research and development of products and post-marketing research commitments. These costs also include share-based compensation and salary-related expenses for research and development functions, professional fees for preclinical and clinical studies, costs associated with clinical manufacturing, facilities-related expenses, regulatory costs and costs associated with pre-FDA approval payments to third-party contract manufacturers. Expenses also include costs for third-party arrangements, including upfront fees and milestone payments required under license arrangements for therapies under development. We have incurred, and expect to continue to incur, increased clinical trial-related expenses, driven by the recent

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expansion of our pipeline programs, which we expect will result in the enrollment of several large clinical studies.

Selling, General and Administrative

Our selling, general and administrative expenses primarily include costs associated with the commercialization of approved products and general and administrative costs to support our operations. Selling expenses also include share-based compensation, salary-related expenses, product marketing and sales operations costs, and other costs incurred to support our sales efforts. General and administrative expenses also include our core corporate support functions such as human resources, finance and legal, external costs to support our core business such as insurance premiums, legal fees and other professional service fees.

Share-Based Compensation

Historically, we granted stock options under our Amended and Restated Equity Incentive Plan (the 1999 Plan) and awards under our Share Tracking Awards Plans (STAP). In June 2015, our shareholders approved the United Therapeutics Corporation 2015 Stock Incentive Plan (the 2015 Plan), which authorized the issuance of up to 6,150,000 shares of our common stock, and in June 2018, our shareholders approved a 2,900,000 share increase in the number of shares issuable under the 2015 Plan. Following approval of the 2015 Plan, we ceased granting awards under the STAP and the 1999 Plan, and we modified our equity compensation programs to grant stock options to employees and non-employee directors. In June 2016 and October 2017, we also began issuing restricted stock units to non-employee directors and employees, respectively. The grant date fair values of stock options and restricted stock units are recognized as share-based compensation expense ratably over their vesting periods.

The fair values of STAP awards and stock option grants are measured using inputs and assumptions under the Black-Scholes-Merton model. The fair value of restricted stock units is measured using our stock price on the date of grant.

Although we no longer grant STAP awards, we had approximately 2.9 million STAP awards outstanding as of December 31, 2018. We account for STAP awards as liabilities because they are settled in cash. As such, we must re-measure the fair value of STAP awards at the end of each financial reporting period until the awards are no longer outstanding. Changes in our STAP liability resulting from such re-measurements are recorded as adjustments to share-based compensation (benefit) expense and can create substantial volatility within our operating expenses from period to period. The following factors, among others, have a significant impact on the amount of share-based compensation (benefit) expense recognized in connection with STAP awards from period to period: (1) volatility in the price of our common stock (specifically, increases in the price of our common stock will generally result in an increase in our STAP liability and related compensation expense, while decreases in our stock price will generally result in a reduction in our STAP liability and related compensation expense); (2) changes in the number of outstanding awards; and (3) changes in the number of vested and unvested awards.

Future Prospects

As noted above, in 2019 we expect revenues will decrease as compared to 2018, largely due to the anticipated impact of a full year of competition from generic versions of Adcirca, the first of which launched in August 2018, and potentially, to a lesser degree, anticipated generic competition for Remodulin in 2019 in the U.S. and Europe. We believe we can return to revenue growth, potentially as

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early as 2020, by commercializing six key therapeutic platforms in our pipeline, each of which is comprised of multiple enabling technologies:

Platform	Enabling Technologies
Remodulin (parenteral treprostinil)	RemUnity, Implantable System for Remodulin, Trevyent, RemoLife
Tyvaso (inhaled treprostinil)	*BEAT* study, *INCREASE* study, *PERFECT* study, Spiresta, Treprostinil Technosphere
Orenitram (oral treprostinil)	*FREEDOM-EV* results, *SOUTHPAW*
Unituxin (dinutuximab)	*DISTINCT* study (small cell lung cancer), humanized dinutuximab, and additional GD2-expressing tumors
New Chemical Entities and New Biologics	ralinepag, esuberaprost, SM04646, *SAPPHIRE (*gene therapy), Unexisome (exosome product for the treatment of bronchopulmonary dysplasia)
Organ Manufacturing and Transplantation	xenotransplantation, three-dimensional organ printing, regenerative medicine, ex-vivo lung perfusion

We believe this diverse portfolio of six therapeutic platforms with multiple enabling technologies each will lead to significant revenue growth over the medium- and longer-term. For further details regarding our research and development initiatives, please see *Item 1 Business Research and Development.*

Our ability to achieve these objectives, grow our business and maintain profitability will depend on many factors, including among others: (1) the timing and outcome of preclinical research, clinical trials and regulatory approvals for products we develop; (2) the timing and degree of our success in commercially launching new products; (3) the demand for our products; (4) the price of our products and the reimbursement of our products by public and private health insurance organizations; (5) the competition we face within our industry, including competition from generic companies; (6) our ability to effectively manage our business in an increasingly complex legal and regulatory environment; (7) our ability to defend against challenges to our patents; and (8) the risks identified in *Part I, Item 1A Risk Factors*, included in this Report.

We operate in a highly competitive market in which a small number of large pharmaceutical companies control a majority of available PAH therapies. These pharmaceutical companies are well established in the market and possess greater financial, technical and marketing resources than we do. In addition, there are a number of investigational products in late-stage development that, if approved, may erode the market share of our existing commercial therapies and make market acceptance more difficult to achieve for any therapies we attempt to market in the future.

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Results of Operations

Revenues

The following table presents the components of total revenues (dollars in millions):

	Year Ended December 31,			Percentage Change	
	2018	2017	2016	2018 v. 2017	2017 v. 2016
Net product sales:					
Remodulin	$ 599.0	$ 670.9	$ 602.3	(10.7)%	11.4%
Tyvaso	415.2	372.9	404.6	11.3%	(7.8)%
Adcirca	323.7	419.7	372.2	(22.9)%	12.8%
Orenitram	205.1	185.8	157.2	10.4%	18.2%
Unituxin	84.8	76.0	62.5	11.6%	21.6%
Total revenues	$ 1,627.8	$ 1,725.3	$ 1,598.8	(5.7)%	7.9%

2018 Compared to 2017

Revenues for the year ended December 31, 2018 decreased by $97.5 million as compared to the same period in 2017.

Remodulin net product sales decreased by $71.9 million in 2018 as compared to 2017. International Remodulin net product sales decreased by $90.0 million, primarily due to the transfer of additional regulatory and commercial responsibilities to an international distributor in 2017. As a result of this transfer, in 2017 we recognized $47.4 million of net product sales related to the one-time purchase of Remodulin inventory by that distributor and we reduced the price at which we sell Remodulin to that distributor. The remaining decrease was primarily due to a reduction in quantities shipped to that distributor. U.S. Remodulin net product sales increased by $18.1 million, primarily due to a price increase that was implemented in April 2018, which was the first price increase for Remodulin since 2010, and an increase in the number of patients being treated with Remodulin. These increases were partially offset by the one-time $4.5 million impact of a change in contractual minimum inventory levels with a U.S. distributor, as discussed below.

Tyvaso net product sales increased by $42.3 million in 2018 as compared to 2017. This increase was primarily due to price increases that were implemented in April 2017 and January 2018; the reversal in the fourth quarter of 2018 of an estimated $15.4 million liability for Medicaid rebates, of which $13.6 million was initially recorded in 2017; and an increase in the number of patients being treated with Tyvaso. These increases were partially offset by the impact of replacing $6.2 million of commercial Tyvaso product that our specialty pharmaceutical distributor previously used in connection with a clinical trial; and the one-time $3.5 million impact of a change in contractual minimum inventory levels with a U.S. distributor, as discussed below.

Adcirca net product sales decreased by $96.0 million in 2018 as compared to 2017. This decrease was primarily due to a decrease in bottles sold due to the launch of a generic version of Adcirca in August 2018, and was partially offset by price increases that were implemented by Lilly in May 2017 and January 2018. In addition, we increased our allowance for product returns for Adcirca by $16.4 million in 2018 based on our estimates of inventory held by distributors and other downstream customers that would expire unsold as a result of the increased use of a generic version of Adcirca. See the tables in the *Gross-to-Net Deductions* section below for more information on the liability balances related to our allowance for product returns.

Orenitram net product sales increased by $19.3 million in 2018, as compared to 2017, primarily due to an increase in the number of patients being treated with Orenitram, a price increase that was

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implemented in January 2018, and the one-time $3.7 million impact of a change in contractual minimum inventory levels with a U.S. distributor, as discussed below.

Unituxin net product sales increased by $8.8 million in 2018, as compared to 2017, primarily due to an increase in the number of vials sold and price increases that were implemented in April and December 2017.

During the fourth quarter of 2017, we amended our agreements with one of our U.S. specialty pharmacy distributors, in part to make the monthly minimum inventory requirement consistent across Remodulin, Tyvaso, and Orenitram. This change resulted in a one-time decrease in total net product sales of $4.3 million as the distributor adjusted to the new contractual inventory requirement levels in the first quarter of 2018. On an individual product basis, net product sales of Remodulin decreased by $4.5 million, net product sales of Tyvaso decreased by $3.5 million, and net product sales of Orenitram increased by $3.7 million.

2017 Compared to 2016

Revenues for the year ended December 31, 2017 increased by $126.5 million as compared to the same period in 2016.

Remodulin net product sales increased by $68.6 million in 2017 as compared to 2016. International Remodulin net product sales increased by $52.8 million, primarily due to the transfer of additional regulatory and commercial responsibilities to an international distributor in 2017. As a result of this transfer, in 2017 we recognized $47.4 million of net product sales related to the one-time purchase of Remodulin inventory by that distributor. U.S. Remodulin net product sales increased by $15.8 million, due to an increase in the number of patients being treated with Remodulin.

Tyvaso net product sales decreased by $31.7 million in 2017 as compared to 2016. This decrease was primarily due to a net decrease in the number of patients being treated with Tyvaso, which we believe was driven by the availability of oral prostacyclin-class therapies and the increased propensity to treat patients with multiple oral therapies earlier in their disease progression, which can delay the need to prescribe inhaled therapies such as Tyvaso. The remaining decrease resulted from an additional one-time $11.1 million liability for estimated Medicaid rebates recorded in 2017 related to Tyvaso sales prior to January 1, 2017. These decreases were partially offset by a price increase implemented in April 2017.

Adcirca net product sales increased by $47.5 million in 2017, as compared to 2016, primarily due to price increases implemented by Lilly in June and December 2016 and May 2017.

Orenitram net product sales increased by $28.6 million in 2017, as compared to 2016, primarily due to an increase in the number of patients being treated with Orenitram.

Unituxin net product sales increased by $13.5 million in 2017, as compared to 2016, primarily due to an increase in the number of vials sold and price increases implemented in April and December 2017.

Gross-to-Net Deductions

We recognize revenues net of: (1) rebates and chargebacks; (2) prompt pay discounts; (3) allowances for sales returns; and (4) distributor fees. These are referred to as gross-to-net deductions and are primarily based on historical experiences and contractual and statutory requirements. We currently estimate our allowance for sales returns using reports from our distributors

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and available industry data, including our estimates of inventory remaining in the distribution channel. The tables below include a reconciliation of the accounts associated with these deductions (in millions):

	Year Ended December 31, 2018				
	Rebates and Chargebacks	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, January 1, 2018	$ 74.0	$ 4.7	$ 7.2	$ 3.4	$ 89.3
Provisions attributed to sales in:					
Current period	232.5	37.7	17.5	19.3	307.0
Prior periods	(8.8)				(8.8)
Payments or credits attributed to sales in:					
Current period	(185.4)	(34.7)		(14.6)	(234.7)
Prior periods	(57.6)	(4.5)	(2.3)	(3.3)	(67.7)
Balance, December 31, 2018	$ 54.7	$ 3.2	$ 22.4	$ 4.8	$ 85.1

	Year Ended December 31, 2017				
	Rebates and Chargebacks	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, January 1, 2017	$ 46.0	$ 4.3	$ 7.7	$ 2.8	$ 60.8
Provisions attributed to sales in:					
Current period	228.2	37.9	0.9	14.5	281.5
Prior periods	13.3			(0.2)	13.1
Payments or credits attributed to sales in:					
Current period	(163.1)	(33.3)		(10.9)	(207.3)
Prior periods	(50.4)	(4.2)	(1.4)	(2.8)	(58.8)
Balance, December 31, 2017	$ 74.0	$ 4.7	$ 7.2	$ 3.4	$ 89.3

	Year Ended December 31, 2016				
	Rebates and Chargebacks	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, January 1, 2016	$ 44.6	$ 3.9	$ 5.3	$ 2.6	$ 56.4
Provisions attributed to sales in:					
Current period	206.3	36.9	3.2	12.6	259.0
Prior periods	4.0				4.0
Payments or credits attributed to sales in:					
Current period	(164.7)	(32.7)		(9.8)	(207.2)
Prior periods	(44.2)	(3.8)	(0.8)	(2.6)	(51.4)
Balance, December 31, 2016	$ 46.0	$ 4.3	$ 7.7	$ 2.8	$ 60.8

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Cost of Product Sales

The table below summarizes cost of product sales by major category (dollars in millions):

	Year Ended December 31,			Percentage Change	
	2018	2017	2016	2018 v. 2017	2017 v. 2016
Category:					
Cost of product sales	$ 201.9	$ 103.1	$ 72.1	95.8%	43.0%
Share-based compensation (benefit) expense[(1)]	(3.2)	2.6	0.6	(223.1)%	333.3%
Total cost of product sales	$ 198.7	$ 105.7	$ 72.7	88.0%	45.4%

(1) Refer to *Share-Based Compensation* section below for discussion.

Cost of Product Sales. The increase in cost of product sales of $98.8 million for the year ended December 31, 2018, as compared to the same period in 2017, was primarily attributable to a $96.9 million increase in royalty expense for Adcirca. As a result of an amendment to our license agreement with Lilly, our royalty rate on net product sales of Adcirca increased from five percent to an effective rate of approximately 42.5 percent effective December 1, 2017.

The increase in cost of product sales of $31.0 million for the year ended December 31, 2017, as compared to the same period in 2016, was primarily attributable to a $21.9 million increase in royalty expense for Adcirca noted above. The remaining increase in cost of product sales was primarily attributable to an increase in sales.

Research and Development Expense

The table below summarizes research and development expense by major category (dollars in millions):

	Year Ended December 31,			Percentage Change	
	2018	2017	2016	2018 v. 2017	2017 v. 2016
Category:					
Research and development projects	$ 370.0	$ 256.4	$ 157.6	44.3%	62.7%
Share-based compensation (benefit) expense[(1)]	(12.1)	8.2	(10.0)	(247.6)%	182.0%
Total research and development expense	$ 357.9	$ 264.6	$ 147.6	35.3%	79.3%

(1) Refer to *Share-Based Compensation* section below for discussion.

Research and development projects. The increase in research and development project expenses of $113.6 million for the year ended December 31, 2018, as compared to the same period in 2017, was driven by the continued investment in our product pipeline, which includes multiple phase III clinical trials in cardiopulmonary diseases and oncology as well as programs in regenerative medicine and organ manufacturing. Research and development expense for the treatment of cardiopulmonary diseases increased by $95.9 million for the year ended December 31, 2018, as compared to the same period in 2017, due to up-front payments of $55.0 million under our licensing and research agreements with MannKind and $10.0 million under our licensing agreement with Samumed, increased spending of $22.9 million on the development of drug delivery devices, including the Implantable System for Remodulin and RemUnity, and increased spending on several

clinical and non-clinical studies. Research and development expense for cancer-related projects increased by $13.9 million for the year ended December 31, 2018, as compared to the same period in 2017, due to an increase in spending on the *DISTINCT* study. Research and development expenses for organ manufacturing projects increased by

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$3.9 million for the year ended December 31, 2018, as compared to the same period in 2017, due to increased preclinical work on technologies designed to increase the supply and distribution of transplantable organs and tissues.

The increase in research and development projects of $98.8 million for the year ended December 31, 2017, as compared to the same period in 2016, was driven by the expansion of our pipeline programs to treat cardiopulmonary disease and cancer and to develop technologies in organ manufacturing. Research and development expense for the treatment of cardiopulmonary diseases increased by $38.4 million for the year ended December 31, 2017, as compared to the same period in 2016, due to increased spending on several clinical and non-clinical studies, including *FREEDOM-EV*, *INCREASE* and *SOUTHPAW*, on the development of new drug products, including RemoPro, and drug delivery device developments, including the Implantable System for Remodulin and the RemUnity system. The increases in research and development expenses were partially offset by a decrease in expenses for esuberaprost formulation and the related *BEAT* study, as the clinical trial was fully enrolled in March 2017. Research and development expense for cancer-related projects increased by $21.3 million for the year ended December 31, 2017, as compared to the same period in 2016, due to an increase in spending on the *DISTINCT* study. Research and development expenses for organ manufacturing projects increased by $36.3 million for the year ended December 31, 2017, as compared to the same period in 2016, due to increased preclinical work on technologies designed to increase the supply and distribution of transplantable organs and tissues.

Selling, General and Administrative Expense

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

	Year Ended December 31,			Percentage Change	
	2018	2017	2016	2018 v. 2017	2017 v. 2016
Category:					
General and administrative	$ 217.8	$ 203.1	$ 210.7	7.2%	(3.6)%
Sales and marketing	59.1	64.3	84.6	(8.1)%	(24.0)%
Share-based compensation (benefit) expense[(1)]	(11.1)	62.7	21.5	(117.7)%	191.6%
Total selling, general and administrative expense	$ 265.8	$ 330.1	$ 316.8	(19.5)%	4.2%

(1) Refer to *Share-Based Compensation* section below for discussion.

General and administrative. The increase in general and administrative expenses of $14.7 million for the year ended December 31, 2018, as compared to the same period in 2017, primarily resulted from: (1) a $10.3 million increase in consulting expenses; (2) a $4.7 million increase in compensation due to an increase in staffing; and (3) a $4.4 million increase in acquisition and integration costs related to the SteadyMed acquisition. The increase was partially offset by a $7.1 million decrease in legal fees incurred in connection with intellectual property litigation and the DOJ investigation of our support of 501(c)(3) organizations that provide financial assistance to patients.

The decrease in general and administrative expenses of $7.6 million for the year ended December 31, 2017, as compared to the same period in 2016, primarily resulted from: (1) a $32.0 million decrease in grants to non-affiliated, non-profit organizations that provide financial assistance to patients with PAH; and (2) a $9.3 million decrease of expenses in connection with the disposition and write down of various properties in 2016. The decrease was partially offset by: (1) a $9.4 million increase in legal fees incurred in connection with intellectual property litigation and the DOJ investigation of our support of 501(c)(3) organizations that provide financial assistance to patients;

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(2) a $9.2 million increase in compensation due to an increase in staffing; and (3) a $6.5 million increase in consulting expenses.

Sales and marketing. The decrease in sales and marketing expenses of $5.2 million for the year ended December 31, 2018, as compared to the same period in 2017, primarily resulted from a decrease in the use of external marketing consultants.

The decrease in sales and marketing expenses of $20.3 million for the year ended December 31, 2017, as compared to the same period in 2016, primarily resulted from a $11.3 million decrease in compensation and related costs associated with the 2016 consolidation of our sales and marketing staff.

Share-Based Compensation

The table below summarizes share-based compensation expense (benefit) by major category (dollars in millions):

	Year Ended December 31,			Percentage Change	
	2018	2017	2016	2018 v. 2017	2017 v. 2016
Category:					
Stock options	$ 58.5	$ 43.0	$ 24.8	36.0%	73.4%
Restricted stock units	7.3	2.2	1.1	231.8%	100.0%
Share tracking awards plan	(93.4)	27.1	(15.2)	(444.6)%	278.3%
Employee stock purchase plan	1.2	1.2	1.4	%	(14.3)%
Total share-based compensation (benefit) expense	$ (26.4)	$ 73.5	$ 12.1	(135.9)%	507.4%

The table below summarizes share-based compensation (benefit) expense by line item on our consolidated statements of operations (dollars in millions):

	Year Ended December 31,			Percentage Change	
	2018	2017	2016	2018 v. 2017	2017 v. 2016
Cost of product sales	$ (3.2)	$ 2.6	$ 0.6	(223.1)%	333.3%
Research and development	(12.1)	8.2	(10.0)	(247.6)%	182.0%
Selling, general and administrative	(11.1)	62.7	21.5	(117.7)%	191.6%
Total share-based compensation (benefit) expense	$ (26.4)	$ 73.5	$ 12.1	(135.9)%	507.4%

Share-based compensation. The increase in share-based compensation benefit of $99.9 million for the year ended December 31, 2018, as compared to the same period in 2017, was primarily due to a $120.5 million increase in STAP benefit related to a decrease in our stock price during 2018, partially offset by: (1) a $15.5 million increase in stock option expense due to additional awards granted and outstanding in 2018; and (2) a $5.1 million increase in restricted stock unit expense due to additional awards granted and outstanding in 2018. We began granting restricted stock units in 2016 and expect the share-based compensation for restricted stock units to increase in the future as additional restricted stock units are granted. Refer to Note 10 *Share-Based Compensation*, to our consolidated financial statements for more information.

The increase in share-based compensation expense of $61.4 million for the year ended December 31, 2017, as compared to the same period in 2016, was primarily due to: (1) a $42.3 million increase in STAP expense related to an increase in our stock price during 2017 and the continued vesting of outstanding awards; and (2) an $18.2 million increase in stock option expense due to additional awards granted and outstanding in 2017.

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Settlement of Loss Contingency

In December 2017, we entered into a civil Settlement Agreement with the U.S. Government to resolve a DOJ investigation related to our support of 501(c)(3) organizations that provide financial assistance to patients. During the second quarter of 2017, we recorded a $210.0 million accrual related to this matter, and ultimately paid this amount, plus interest, to the U.S. Government upon settlement. This matter is described in more detail in Note 17 *Litigation Department of Justice Subpoena*, to our consolidated financial statements.

Impairments of Investments in Privately-Held Companies

During the years ended December 31, 2018 and 2017, we recorded $53.5 million and $49.6 million of impairment charges, respectively, related to our investments in privately-held companies. There were no such impairment charges in the year ended December 31, 2016.

Income Tax Expense

The provision for income taxes was $169.7 million for the year ended December 31, 2018, compared to $351.6 million for the same period in 2017. Our 2018 effective tax rate (ETR) decreased compared to 2017 due to the impacts of The Tax Cuts and Jobs Act (Tax Reform) and the nondeductible portion of an accrual in 2017 in connection with a civil settlement with the Department of Justice. For the years ended December 31, 2018, 2017 and 2016, the effective tax rates were approximately 22 percent, 46 percent and 33 percent, respectively. For additional details, refer to Note 12 *Income Taxes* to our consolidated financial statements.

Tax Reform has multiple provisions that impacted our tax expense. The significant impacts were a reduction in the U.S. federal corporate tax rate from 35 percent to 21 percent, additional limitations on deductions for executive compensation, a reduction of the Orphan Drug Credit, repeal of the Section 199 deduction for domestic manufacturing activities, and the introduction of the foreign derived intangible income (FDII) deduction.

On December 22, 2017, the SEC staff issued Staff Accounting Bulletin No. 118 to address the application of U.S. GAAP in situations when a registrant did not have the necessary information available, prepared, or analyzed in reasonable detail to complete the accounting for certain income tax effects of Tax Reform. As a result of changes under Tax Reform, we recognized a provisional amount of $71.0 million of additional tax expense in our consolidated financial statements for the year ended December 31, 2017. The measurement period prescribed under SAB 118 ended on December 22, 2018 and our analysis and accounting for Tax Reform has been completed as of this date. We recognized a reduction of tax expense of $1.8 million for the year ended December 31, 2018 due to refinements that were made during the measurement period to the calculation of the foreign elements of Tax Reform.

Going forward, we expect to continue to maintain the lower effective tax rate as a result of Tax Reform, principally driven by the reduced federal corporate tax rate and FDII deduction, and partially offset by the reduction of the Orphan Drug Credit and the repeal of the Section 199 deduction.

Share Repurchases

In April 2017, our Board of Directors approved a share repurchase program authorizing up to $250.0 million in aggregate repurchases of our common stock. Pursuant to this authorization, in May 2017, we paid $250.0 million upon entering into an accelerated share repurchase agreement (ASR) with Citibank, N.A. (Citibank). Pursuant to the terms of the ASR, in June 2017, Citibank delivered to us approximately 1.7 million shares of our common stock, representing the minimum number of shares we were entitled to receive under the ASR. Upon termination of the ASR in September 2017, Citibank delivered to us approximately 0.3 million additional shares of our common stock.

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Financial Condition, Liquidity and Capital Resources

We have funded our operations principally through sales of our commercial products and, from time-to-time, third-party financing arrangements. We believe that our current liquidity is sufficient to fund ongoing operations and future business plans as we expect long-term demand for our commercial products, other than Adcirca, to continue to grow. Furthermore, our customer base remains stable and we believe it presents minimal credit risk. However, any projections of future cash flows are inherently subject to uncertainty and we may seek other forms of financing. In June 2018, we entered into a credit agreement (the 2018 Credit Agreement), which provides an unsecured, revolving line of credit of up to $1.0 billion and a second unsecured revolving credit facility of up to $500.0 million (which facilities may, at our request, be increased by up to $300.0 million in the aggregate subject to obtaining commitments from existing or new lenders for such increase and satisfying other conditions), with a current maturity date of June 2023, of which $250.0 million was drawn and outstanding as of December 31, 2018 and $1,050.0 million was outstanding as of February 27, 2019. See *Unsecured Revolving Credit Facility* below for further details.

Cash and Cash Equivalents and Marketable Investments

Cash and cash equivalents and marketable investments comprise the following (dollars in millions):

	Year Ended December 31,		Percentage Change
	2018	2017	2018 v. 2017
Cash and cash equivalents	$ 669.2	$ 705.1	(5.1)%
Marketable investments current	746.7	222.3	235.9%
Marketable investments non-current	442.6	502.7	(12.0)%
Total cash and cash equivalents and marketable investments	$ 1,858.5	$ 1,430.1	30.0%

The increase of $428.4 million in our cash and cash equivalents and marketable investments was primarily due to: (1) $778.4 million in cash generated from operations; and (2) $15.6 million of proceeds from the exercise of stock options, partially offset by: (1) $184.4 million in cash paid to purchase property, plant and equipment; (2) $124.1 million in cash paid related to the acquisition of SteadyMed, net of cash acquired; (3) $46.0 million in deposits; (4) $13.2 million in cash paid for debt issuance costs; and (5) $5.0 million in cash paid for an investment in a privately-held company.

Cash Flows

Cash flows comprise the following (dollars in millions):

	Year Ended December 31,			Percentage Change	
	2018	2017	2016	2018 v. 2017	2017 v. 2016
Net cash provided by operating activities	$ 778.4	$ 474.2	$ 643.6	64.2%	(26.3)%
Net cash (used in) provided by investing activities	$ (820.6)	$ (835.6)	$ 48.3	1.8%	NM(1)
Net cash provided by (used in) financing activities	$ 6.3	$ 43.3	$ (497.7)	(85.5)%	108.7%

(1) Calculation is not meaningful.

Operating Activities

Our operating assets and liabilities consist primarily of accounts receivable, inventories, accounts payable, accrued expenses, liabilities for our STAP awards and tax-related payables and receivables.

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The increase of $304.2 million in net cash provided by operating activities for the year ended December 31, 2018 compared to the year ended December 31, 2017 was primarily due to: (1) a $244.2 million decrease in cash paid for income taxes; and (2) a $210.0 million decrease in cash paid to settle a loss contingency, partially offset by: (1) a $96.9 million increase in the royalty expense for Adcirca; and (2) $65.0 million of upfront payments under our licensing agreements with MannKind and Samumed.

The decrease of $169.4 million in net cash provided by operating activities for the year ended December 31, 2017 compared to the year ended December 31, 2016 was primarily due to: (1) a $210.0 million paid to settle a loss contingency; and (2) a $78.4 million net cash outflow due to changes in other operating assets and liabilities. The decrease was partially offset by: (1) a $126.5 million increase in revenues during the year, which resulted in higher cash collections; and (2) a $15.5 million decrease in cash paid for income taxes due to timing of payments.

Investing Activities

The decrease of $15.0 million in net cash used in investing activities for the year ended December 31, 2018 compared to the year ended December 31, 2017 was primarily due to: (1) a $236.2 million decrease in cash used for net purchases of available-for-sale, held-to-maturity and other investments; and (2) a $55.4 million decrease in cash paid to purchase investments in privately held companies, partially offset by: (1) $124.1 million in net cash paid related to the acquisition of SteadyMed; (2) a $98.1 million increase in cash paid to purchase property, plant and equipment; (3) $46.0 million in deposits; and (4) a $8.3 million decrease in cash proceeds from the sale of property, plant and equipment.

The increase of $883.9 million in net cash used in investing activities for the year ended December 31, 2017 compared to the year ended December 31, 2016 was primarily due to: (1) a $826.9 million increase in cash used for net purchases of available-for-sale, held-to-maturity and other investments; (2) a $48.3 million increase in cash paid to purchase property, plant and equipment; and (3) a $24.4 million increase in cash paid to purchase investments held at cost. The increase in cash used was partially offset by $8.3 million in proceeds from the sale of property, plant and equipment.

Financing Activities

The decrease of $37.0 million in net cash provided by financing activities for the year ended December 31, 2018 compared to the year ended December 31, 2017 was primarily due to: (1) $24.3 million decrease in proceeds from stock option exercises; and (2) $12.5 million increase in payments of debt issuance costs primarily related to the 2018 Credit Agreement.

The increase of $541.0 million in net cash provided by financing activities for the year ended December 31, 2017 compared to the year ended December 31, 2016 was primarily due to: (1) a $250.0 million in proceeds from borrowing under our line of credit used to fund the ASR described in Note 8 *Debt Unsecured Revolving Credit Facility 2016 Credit Agreement*, to our consolidated financial statements; (2) a $250.0 million decrease in repurchases of our common stock; and (3) a $32.2 million increase in proceeds from stock option exercises.

In October 2015, our Board of Directors authorized a new program for the repurchase of up to $500.0 million of our common stock in open or privately negotiated transactions, at our discretion. This program was effective from January 1, 2016 to December 31, 2016. In the aggregate, we repurchased approximately 4.2 million shares of common stock under this program for $500.0 million.

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Unsecured Revolving Credit Facility

In June 2018, we entered into a credit agreement (the 2018 Credit Agreement) providing for an unsecured revolving credit facility of up to $1.5 billion. On June 27, 2018, we borrowed $250.0 million under this facility and used the funds to repay outstanding indebtedness under the existing credit agreement (the 2016 Credit Agreement). In January 2019, we borrowed an additional $800.0 million under this facility and used the funds for an upfront payment related to the global license agreement with Arena. The aggregate balance of $250.0 million remained outstanding as of December 31, 2018, and $1,050.0 million was outstanding as of February 27, 2019. Refer to Note 8 *Debt Unsecured Revolving Credit Facility 2018 Credit Agreement,* to our consolidated financial statements.

Contractual Obligations

At December 31, 2018, we had the following contractual obligations (in millions):

	Payments Due by Period				
	Total	Less than 1 year	2 - 3 Years	4 - 5 Years	More than 5 Years
Operating lease obligations	$ 11.5	$ 4.7	$ 4.2	$ 2.0	$ 0.6
Long-term debt obligations[1]	319.7	13.9	27.9	277.9	
Obligations under the STAP[2]	64.8	64.8			
Obligations under the SERP[3]	76.7	19.9		5.2	51.6
Purchase obligations[4]	430.6	298.0	77.9	27.1	27.6
Total[5]	$ 903.3	$ 401.3	$ 110.0	$ 312.2	$ 79.8

(1) Long-term debt obligations include future interest payments on our LIBOR-based variable rate obligations under the 2018 Credit Agreement. The 2018 Credit Agreement will mature five years after the closing date of the agreement. Refer to Note 8 *Debt* to our consolidated financial statements for further details.

(2) Estimated based on the intrinsic value of exercisable outstanding STAP awards as of December 31, 2018. Refer to Note 10 *Share-based Compensation* to our consolidated financial statements for further details.

(3) Consists of actuarially derived, undiscounted, estimated future payouts of benefits. Refer to Note 13 *Employee Benefit Plans Supplemental Executive Retirement Plan* to our consolidated financial statements for further details.

(4) Purchase obligations primarily include: (1) commitments related to research and development (including clinical trials) for new and existing products; (2) open purchase orders for capital expenditures primarily related to our continued investment in construction of additional facilities to support the development and commercialization of our products and technologies; and (3) open purchase orders for the acquisition of goods and services in the ordinary course of business. Our obligation to pay certain of these amounts may be reduced based on certain future events.

(5) In addition to amounts in the table above, we are contractually obligated to pay additional amounts upon the achievement of various development, regulatory and commercial milestones for agreements we have entered into with third parties. These payments are contingent upon the occurrence of various future events, some of which have a high degree of uncertainty of occurring. These contingent payments have not been included in the table above, and, except with respect to the fair value of the contingent consideration obligations, are not recorded on our consolidated balance sheets. The table above does not include the $800.0 million upfront payment made to Arena in January 2019 related to the global license agreement. Refer to Note 18 *Subsequent Events* to our consolidated financial statements for further details.

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Toray License Obligations

In 2000, we entered into a license agreement with Toray to obtain exclusive rights to develop and market beraprost, a chemically stable oral prostacyclin analogue, in a sustained release formulation in the United States and Canada for the treatment of all cardiovascular indications. Pursuant to a 2007 amendment to this agreement, we issued Toray 200,000 shares of our common stock. Toray has the right to request that we repurchase these shares (which have since split into 400,000 shares) upon 30 days prior written notice at the price of $27.21 per share. To date, Toray has not notified us that it intends to require us to repurchase these shares. In 2011, we amended this agreement to reduce the royalty rates in exchange for a total of $50.0 million in equal, non-refundable payments to Toray over the five-year period ending in 2015. As of December 31, 2015, this obligation was fully satisfied. In March 2017, we amended our license agreement with Toray to further reduce the royalty rate to single digits in exchange for a commitment to make milestone payments to Toray in the event that we do not achieve certain clinical and regulatory events by certain dates.

Obligations Under License and Assignment Agreements

Historically, we paid Lilly a five percent royalty on net product sales of Adcirca. In May 2017, we amended our Adcirca license agreement with Lilly. As a result of this amendment, beginning December 1, 2017, our royalty rate on net product sales of Adcirca increased from five percent to ten percent and we are required to make milestone payments to Lilly equal to $325,000 for each $1,000,000 in net product sales. We pay a single-digit percentage royalty based on net product sales of Orenitram under our license agreement with Supernus. We also pay The Scripps Research Institute a one percent royalty on sales of Unituxin. We have entered into other license rights arrangements under which we are required to make milestone payments upon the achievement of certain developmental and commercialization objectives and royalty payments upon the commercialization of related licensed technology.

Off-Balance Sheet Arrangements

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

Summary of Critical Accounting Policies and Estimates

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

Revenue Recognition

We generate revenues from the sale of our five commercial products: Remodulin, Tyvaso, Orenitram, Unituxin and Adcirca. Revenue is recognized when we transfer control of our products to our distributors, as our contracts have a single performance obligation (delivery of our product). These revenues are subject to various product sales allowances, referred to as gross-to-net deductions, which are deducted from revenues to determine net product sales. For a description of our related accounting policies, refer to Note 2 *Summary of Significant Accounting Policies Revenue Recognition* in the consolidated financial statements.

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The following categories of gross-to-net deductions involve the use of significant estimates and judgments and information obtained from external sources.

Rebates and Chargebacks

Our most significant rebates relate to our participation in state Medicaid programs and contractual rebates offered to managed care organizations covering Medicare Part D and commercial plans. Chargebacks relate to our participation in programs with the U.S. Department of Veterans Affairs and 340B covered entities. Although we accrue for our allowance for rebates and chargebacks in the same period that we recognize revenue, the actual rebate or chargeback on the sale of our product to a distributor is not invoiced to us until a future period, generally within six months from the date of sale. Due to this time lag, we must estimate the amount of rebates and chargebacks to accrue. As of December 31, 2018, we had a $54.7 million liability related to rebates and chargebacks.

Estimates associated with our participation in state Medicaid programs are particularly susceptible to adjustment given the extensive time lag that may occur between our recording of an accrual and its ultimate invoicing by individual state Medicaid programs, which can occur up to several years after the sale of our product. Because of the time lag for Medicaid and other rebates, in any particular quarter, our adjustments may incorporate revisions of accruals for prior quarters. Historically, adjustments to our estimates to reflect actual results or updated expectations have not been material to our overall financial results. Provisions attributed to sales in prior periods have been less than one percent of our net product sales for each of the years ended December 31, 2018, 2017 and 2016.

Allowance for Sales Returns

The sales terms for Adcirca and Unituxin include return rights; however, we have not recorded an allowance for returns of Unituxin because our historical returns have been insignificant. For our sales of Adcirca, we record an allowance for returns in the same period that we recognize revenue. Return rights extend throughout the distribution channel and allow for returns of expired product for up to 12 months past the product's expiration date. As there are generally 24 to 36 months from the initial sale of Adcirca to its expiration date, we must estimate the amount of product that will be returned. Historically, actual returns have not differed materially from our estimates, and have been less than one percent of our net product sales for each of the years ended December 31, 2018, 2017 and 2016. Following the loss of exclusivity for Adcirca in the second quarter of 2018, we may experience an elevated level of product returns as product inventory remaining in the distribution channel expires.

For a roll-forward of the liability accounts associated with our gross-to-net deductions, see the section above entitled *Results of Operations Revenues*.

Share-Based Compensation

Our share-based awards are classified as either liabilities (STAP awards) or as equity (stock options, restricted stock units and rights to purchase stock under our employee stock purchase plan). We recognize related share-based compensation expense based on the fair value of outstanding STAP awards on the grant date and at the end of each reporting period, and based on the grant date fair value of stock options and restricted stock units. With the exception of restricted stock units, we estimate the fair value of all share-based awards using the Black-Scholes-Merton valuation model. We measure the fair value of restricted stock units using the stock price on the grant date. 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 the expected volatility of our stock price and the expected term of awards. Developing these assumptions requires the use of judgment. For additional information on the

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assumptions used in the Black-Scholes-Merton valuation model, see Note 10 *Share-Based Compensation,* to our consolidated financial statements.

Effective January 1, 2017, we adopted the provisions of ASU 2016-09, *Compensation Stock Compensation.* As part of the adoption, we established an accounting policy election to account for forfeitures of share-based awards when they occur. Upon adoption, we recognized a cumulative-effect adjustment for the removal of the forfeiture estimate with respect to awards that were continuing to vest as of January 1, 2017. The adjustment resulted in a decrease to retained earnings of $5.8 million, which is net of a $3.2 million tax benefit.

Performance-Based Stock Options

In March 2017, we began issuing stock options with performance conditions under the 2015 Plan. The awards have vesting conditions tied to the achievement of specified performance conditions. The performance conditions have target performance levels that span from one to three years. Throughout the performance period, we re-assess the estimated performance and update the number of performance-based awards that we believe will ultimately vest. Upon the conclusion of the performance period, the performance level achieved will be measured and the ultimate number of shares that may vest will be determined. The estimation of future performance requires the use of judgment. Share-based compensation expense for these awards is recorded ratably over their vesting period, depending on the specific terms of the award and achievement of the specified performance conditions.

In-Process Research and Development

As part of our business strategy, we may acquire businesses or in-license the rights to develop and commercialize product candidates. For each in-license transaction, we evaluate whether we have acquired processes or activities along with inputs that would be sufficient to constitute a "business" as defined under GAAP. As defined under GAAP, a "business" consists of inputs and processes applied to those inputs that have the ability to create outputs. Although businesses usually have outputs, outputs are not required for an integrated set of activities to qualify as a business. When we determine that we have not acquired sufficient processes or activities to constitute a business, any up-front payments, as well as pre-commercial milestone payments, are immediately expensed as acquired in-process research and development in the period in which they are incurred. Refer to Note 18 *Subsequent Events*, to our consolidated financial statements. Milestone payments made to third parties subsequent to regulatory approval are capitalized as intangible assets and amortized over the estimated remaining useful life of the related product.

Acquired businesses are accounted for using the acquisition method of accounting. The acquisition purchase price is allocated to the net assets of the acquired business at their respective fair values. Amounts allocated to in-process research and development (IPR&D) are recorded at fair value and are considered indefinite-lived intangible assets subject to annual impairment testing until completion or abandonment of the research and development efforts. Upon completion of a project, the carrying value of the related IPR&D is reclassified to intangible assets and is amortized over the estimated useful life of the asset. Our fair value assessments are highly reliant on various assumptions which are considered Level 3 inputs, including estimates of future cash flows (including long-term growth rates), discount rates and the probability of achieving the estimated cash flows. In August 2018, we completed the acquisition of SteadyMed and acquired IPR&D related to the development of Trevyent. We determined the fair value of the acquired IPR&D was $107.3 million based on our fair value assessment which relied on the various assumptions noted above. Refer to Note 4 *Acquisition*, to our consolidated financial statements.

IPR&D projects acquired in a business combination which have not reached technological feasibility or lack regulatory approval at the time of acquisition are reviewed for impairment annually,

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whenever events or changes in circumstances indicate that the carrying amount may not be recoverable and upon establishment of technological feasibility or regulatory approval. We determine impairment by comparing the fair value of the asset to its carrying value. If the asset's carrying value exceeds its fair value, an impairment charge is recorded for the difference and its carrying value is reduced accordingly.

Estimating future cash flows of an IPR&D product candidate for purposes of an impairment analysis requires us to make significant estimates and assumptions regarding the amount and timing of costs to complete the project and the amount, timing and probability of achieving revenues from the completed product similar to how the acquisition date fair value of the project was determined, as described above. There are often major risks and uncertainties associated with IPR&D projects as we are required to obtain regulatory approvals in order to be able to market these products. Such approvals require completing clinical trials that demonstrate a product candidate is safe and effective. Consequently, the eventual realized value of the acquired IPR&D project may vary from its fair value at the date of acquisition, and IPR&D impairment charges may occur in future periods which could have a material adverse effect on our results of operations.

Investments in Privately-Held Companies

We have investments in several privately-held companies that have a strategic connection to our business, most of which are non-controlling equity investments in the form of preferred stock. Upon adoption of ASU 2016-01 on January 1, 2018, we began to measure these investments using the measurement alternative because the fair values of these investments are not readily determinable. Under the measurement alternative, the investments are measured at cost, less any impairment, adjusted for any observable price changes. We monitor these investments individually for any observable price changes or impairment indicators through our periodic correspondence with the relevant companies. We will adjust the measurement of these investments for observable price changes in orderly transactions for the identical or a similar investment of the same issuer. We consider relevant transactions, including any potential funding opportunities, which occur on or before the balance sheet date in evaluating whether any observable price changes have occurred. When a relevant transaction is identified, a careful review of the rights and obligations of the relevant transaction is necessary to evaluate whether the subsequent transaction is deemed to be a similar or identical investment.

At each reporting date, we review these investments individually for impairment by evaluating if events or circumstances have occurred that may have a significant adverse effect on their fair value. If such events or circumstances have occurred, we will estimate the fair value of the investment. In such cases, the estimated fair value of the investment is determined using unobservable inputs including assumptions by the company's management. Because several of these companies are in the early startup or development stages, these entities are more likely to be subject to potential changes in cash flows, valuation, and ability to attract new investors which may be necessary for the liquidity needed to support their operations. If we determine that a decline in the value of an investment has occurred, we recognize an impairment loss in the period in which the decline occurs. If facts and circumstances change, we could be required to account for one or more of these investments under the equity method of accounting or consolidate the company's operations for financial accounting purposes. Refer to Note 5 *Investments Investments in Privately-Held Companies*, to our consolidated financial statements.

Income Taxes

Income taxes are accounted for in accordance with the asset and liability method. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement carrying amounts and tax bases of assets and liabilities, using enacted tax rates in effect for years in which the temporary differences are expected to reverse. A valuation allowance is applied

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against any net deferred tax asset if, based on the available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

We recognize the benefit of an uncertain tax position that has been taken or that we expect to take on income tax returns only if such tax position is more likely than not to be sustained. The benefit recognized is measured as the largest amount that has a greater than 50 percent likelihood of being realized upon settlement. The ultimate resolution of uncertain tax positions could result in amounts different from those recognized in our consolidated financial statements.

Recently Issued Accounting Standards

See Note 3 *Recently Issued Accounting Standards*, to our consolidated financial statements for information on our anticipated adoption of recently issued accounting standards.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Investment Risk

As of December 31, 2018, we have invested $1.1 billion in corporate-debt securities and federally-sponsored agencies. The market value of these investments varies inversely with changes in prevailing market interest rates. In general, as interest rates increase, the market value of a debt investment would be expected to decrease. Conversely, as interest rates decrease, the market value of a debt investment would be expected to increase. To date, we have not experienced significant volatility in the value of these investments. However, to address market risk, we invest in debt securities with terms no longer than three years and typically hold these investments to maturity so that they can be redeemed at their stated or face value. Many of our investments may be called by their respective issuers prior to maturity. The following table summarizes the expected maturities and weighted average interest rates as of December 31, 2018 (dollars in millions):

	Expected Maturity		
	2019	**2020**	**2021**
Held-to-maturity investments	$ 37.4	$ 2.2	$
Available-for-sale investments	705.8	373.0	67.4
Weighted average interest rate	2.6%	2.6%	2.7%

During sustained periods of instability and uncertainty in the financial markets, we may be subjected to additional investment-related risks that could materially affect the value and liquidity of our investments. In light of these risks, we actively monitor market conditions and developments specific to the securities and security classes in which we invest. In addition, we believe that we maintain a conservative investment approach in that we invest exclusively in unstructured, highly-rated securities with relatively short maturities that we believe reduce our exposure to undue risks. While we believe we take prudent measures to mitigate investment related risks, such risks cannot be fully eliminated, as circumstances can occur that are beyond our control.

Interest Rate Risk

As of December 31, 2018 and 2017, we had $250.0 million outstanding on our unsecured revolving credit facility which includes a variable interest rate component. As a result, we are subject to interest rate risk with respect to such floating-rate debt. A 100 basis point increase in the variable interest rate component of our borrowings would increase our annual interest expense by approximately $2.5 million or 18 percent and $2.5 million or 28 percent for the years ended December 31, 2018 and 2017, respectively. In January 2019, we borrowed an additional $800.0 million under this facility and used the funds for an upfront payment related to the global license agreement with Arena. Refer to Note 8 *Debt Unsecured Revolving Credit Facility,* to our consolidated financial statements. As a result of the

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increase in the amount borrowed on our unsecured revolving credit facility, we are subject to increased interest rate risk.

Stock Price Risk

As of December 31, 2018 and 2017, we had 2.9 million and 4.1 million awards outstanding under our Share Tracking Awards Plan, respectively. These awards are referred to as "STAP awards." STAP awards convey the right to receive in cash an amount equal to the appreciation of our common stock, which is measured as the increase in the closing price of our common stock between the dates of grant and exercise. As of December 31, 2018 and 2017, the aggregate STAP liability balance was $72.2 million and $241.3 million, respectively. Estimating the fair value of STAP awards requires the use of certain inputs that can materially impact the determination of fair value and the amount of compensation expense (benefit) we recognize. Inputs used in estimating fair value include the price of our common stock, the expected volatility of the price of our common stock, the risk-free interest rate, the expected term of STAP awards, and the expected dividend yield. As of December 31, 2018 and 2017, a one dollar change in our stock price would, holding other factors constant, increase or decrease the fair value of our STAP liability by approximately $1.8 million and $3.4 million, respectively.

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

UNITED THERAPEUTICS CORPORATION
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of United Therapeutics Corporation

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of United Therapeutics Corporation (the Company) as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes and financial statement schedule listed in the Index at Item 15(a)(2) (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 27, 2019, expressed an unqualified opinion thereon.

Adoption of ASU No. 2014-09

As discussed in Note 2 to the consolidated financial statements, the Company changed its method for accounting for revenue in 2018 due to the adoption of Accounting Standards Update (ASU) No. 2014-09, Revenue from Contracts with Customers (Topic 606), and the amendments in ASUs 2015-14, 2016-08, 2016-10, 2016-12, 2016-20 and 2017-14.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2003.
Tysons, Virginia
February 27, 2019

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Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of United Therapeutics Corporation

Opinion on Internal Control over Financial Reporting

We have audited United Therapeutics Corporation's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, United Therapeutics Corporation (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on the COSO criteria.

As indicated in the accompanying Management Report on Internal Control Over Financial Reporting, management's assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of SteadyMed Ltd., which is included in the 2018 consolidated financial statements of the Company and constituted four percent of total assets as of December 31, 2018, and zero percent and one percent, respectively, of revenues and operating expenses for the year ended December 31, 2018. Our audit of internal control over financial reporting of the Company also did not include an evaluation of the internal control over financial reporting of SteadyMed, Ltd.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive income, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2018 and the related notes and financial statement schedule listed in the Index at Item 15(a)(2) and our report dated February 27, 2019, expressed an unqualified opinion thereon.

Basis for Opinion

The Company'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 are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. 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.

Definition and Limitations of Internal Control Over Financial Reporting

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

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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.

/s/ Ernst & Young LLP

Tysons, Virginia
February 27, 2019

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UNITED THERAPEUTICS CORPORATION

Consolidated Balance Sheets

(In millions, except share and per share data)

	December 31,	
	2018	**2017**
Assets		
Current assets:		
Cash and cash equivalents	$ 669.2	$ 705.1
Marketable investments	746.7	222.3
Accounts receivable, no allowance for 2018 and 2017	175.7	297.1
Inventories, net	101.0	107.9
Other current assets	75.4	115.5
Total current assets	1,768.0	1,447.9
Marketable investments	442.6	502.7
Goodwill and other intangible assets, net	170.8	45.6
Property, plant and equipment, net	699.7	545.7
Deferred tax assets, net	95.7	113.4
Other non-current assets	224.2	224.1
Total assets	$ 3,401.0	$ 2,879.4
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 166.1	$ 171.1
Share tracking awards plan	72.2	240.1
Other current liabilities	38.3	33.5
Total current liabilities	276.6	444.7
Line of credit	250.0	250.0
Other non-current liabilities	66.6	63.7
Total liabilities	593.2	758.4
Commitments and contingencies Note 14		
Temporary equity	19.2	19.2
Stockholders' equity:		
Preferred stock, par value $.01, 10,000,000 shares authorized, no shares issued		
Series A junior participating preferred stock, par value $.01, 100,000 shares authorized, no shares issued		
Common stock, par value $.01, 245,000,000 shares authorized, 70,207,581 and 69,858,840 shares issued, and 43,588,365 and 43,239,624 shares outstanding at December 31, 2018 and 2017, respectively	0.7	0.7
Additional paid-in capital	1,940.2	1,854.3
Accumulated other comprehensive loss	(7.9)	(19.6)
Treasury stock, 26,619,216 shares at December 31, 2018 and 2017	(2,579.2)	(2,579.2)
Retained earnings	3,434.8	2,845.6
Total stockholders' equity	2,788.6	2,101.8
Total liabilities and stockholders' equity	$ 3,401.0	$ 2,879.4

See accompanying notes to consolidated financial statements.

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UNITED THERAPEUTICS CORPORATION

Consolidated Statements of Operations

(In millions, except per share data)

	Year Ended December 31,		
	2018	**2017**	**2016**
Revenues:			
Net product sales	$ 1,627.8	$ 1,725.3	$ 1,598.8
Total revenues	1,627.8	1,725.3	1,598.8
Operating expenses:			
Cost of product sales	198.7	105.7	72.7
Research and development	357.9	264.6	147.6
Selling, general and administrative	265.8	330.1	316.8
Settlement of loss contingency		210.0	
Total operating expenses	822.4	910.4	537.1
Operating income	805.4	814.9	1,061.7
Other income (expense):			
Interest income	28.6	10.9	3.5
Interest expense	(13.9)	(9.0)	(3.9)
Other, net	(7.7)	2.3	(1.1)
Impairments of investments in privately-held companies	(53.5)	(49.6)	
Total other expense, net	(46.5)	(45.4)	(1.5)
Income before income taxes	758.9	769.5	1,060.2
Income tax expense	(169.7)	(351.6)	(346.5)
Net income	$ 589.2	$ 417.9	$ 713.7
Net income per common share:			
Basic	$ 13.54	$ 9.50	$ 16.29
Diluted	$ 13.39	$ 9.31	$ 15.25
Weighted average number of common shares outstanding:			
Basic	43.5	44.0	43.8
Diluted	44.0	44.9	46.8

See accompanying notes to consolidated financial statements.

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UNITED THERAPEUTICS CORPORATION

Consolidated Statements of Comprehensive Income

(In millions)

	Year Ended December 31,		
	2018	**2017**	**2016**
Net income	$ 589.2	$ 417.9	$ 713.7
Other comprehensive income (loss):			
Foreign currency translation gains (losses)		0.2	(3.0)
Defined benefit pension plan:			
Actuarial gain (loss) arising during period, net of tax	10.7	(1.7)	6.0
Amortization of actuarial gain and prior service cost included in net periodic pension cost, net of tax	1.4	0.6	0.6
Total defined benefit pension plan, net of tax	12.1	(1.1)	6.6
Unrealized loss on available-for-sale securities, net of tax	(0.4)	(1.9)	
Other comprehensive income (loss), net of tax	11.7	(2.8)	3.6
Comprehensive income	$ 600.9	$ 415.1	$ 717.3

See accompanying notes to consolidated financial statements.

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UNITED THERAPEUTICS CORPORATION

Consolidated Statements of Stockholders' Equity

(In millions)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Treasury Stock	Retained Earnings	Stockholders' Equity
	Shares	Amount					
Balance, December 31, 2015	69.0	$ 0.7	$ 1,790.6	$ (20.4)	$ (1,902.1)	$ 1,719.8	$ 1,588.6
Net income						713.7	713.7
Foreign currency translation adjustments				(3.0)			(3.0)
Defined benefit pension plan				6.6			6.6
Shares issued under employee stock purchase plan			4.3				4.3
Conversion of 2016 convertible notes	0.1		7.6		(7.5)		0.1
Equity component 2016 convertible notes			0.1				0.1
Shares issued upon expiration of warrants			(30.0)		30.0		
Repurchase of shares					(500.0)		(500.0)
Exercise of stock options	0.2		7.7				7.7
Tax benefit from exercises of non-qualified stock options			5.9				5.9
Share-based compensation			27.3				27.3
Balance, December 31, 2016	69.3	0.7	1,813.5	(16.8)	(2,379.6)	2,433.5	1,851.3
Net income						417.9	417.9
Foreign currency translation adjustments				0.2			0.2
Unrealized loss on available-for-sale securities				(1.9)			(1.9)
Defined benefit pension plan				(1.1)			(1.1)
Shares issued under employee stock purchase plan	0.1		4.1				4.1
Shares issued upon expiration of warrants			(53.2)		53.2		
Repurchase of shares			2.8		(252.8)		(250.0)
Exercise of stock options	0.5		39.9				39.9
Share-based compensation			46.4				46.4
Cumulative effect of accounting change			0.7			(5.8)	(5.1)
Consolidation of variable interest entity			0.1				0.1
Balance, December 31, 2017	69.9	0.7	1,854.3	(19.6)	(2,579.2)	2,845.6	2,101.8
Net income						589.2	589.2
Unrealized loss on available-for-sale securities				(0.4)			(0.4)
Defined benefit pension plan				12.1			12.1
Shares issued under employee stock purchase plan			3.9				3.9
Restricted stock units withheld for taxes			(0.1)				(0.1)
Exercise of stock options	0.3		15.6				15.6

Share-based compensation			66.5				66.5
Balance, December 31, 2018	70.2	$ 0.7	$ 1,940.2	$ (7.9)	$ (2,579.2)	$ 3,434.8	$ 2,788.6

See accompanying notes to consolidated financial statements.

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UNITED THERAPEUTICS CORPORATION

Consolidated Statements of Cash Flows

(In millions)

	Year Ended December 31,		
	2018	**2017**	**2016**
Cash flows from operating activities:			
Net income	$ 589.2	$ 417.9	$ 713.7
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	35.9	31.0	31.6
Share-based compensation (benefit) expense	(26.4)	73.5	12.1
Impairments of investments in privately-held companies	53.5	49.6	
Other	1.8	(19.4)	9.5
Excess tax benefits from share-based compensation			(5.9)
Changes in operating assets and liabilities:			
Accounts receivable	121.4	(82.7)	(21.7)
Inventories	9.3	(0.5)	(24.5)
Accounts payable and accrued expenses	(11.0)	66.2	0.6
Other assets and liabilities	4.7	(61.4)	(71.8)
Net cash provided by operating activities	778.4	474.2	643.6
Cash flows from investing activities:			
Purchases of property, plant and equipment	(184.4)	(86.3)	(38.0)
Proceeds from sale of property, plant and equipment		8.3	
Deposits	(46.0)		
Purchases of held-to-maturity and other investments	(99.3)	(51.8)	(0.8)
Maturities of held-to-maturity investments	88.6	52.9	130.4
Purchases of available-for-sale investments	(762.7)	(718.4)	
Sales/maturities of available-for-sale investments	312.3	20.0	
Purchase of investment in privately-held company	(5.0)	(60.4)	(36.0)
Purchase of investments under the equity method			(2.1)
Consolidation of variable interest entity		0.1	
Acquisition, net of cash acquired	(124.1)		(5.2)
Net cash (used in) provided by investing activities	(820.6)	(835.6)	48.3
Cash flows from financing activities:			
Proceeds from line of credit	250.0	250.0	
Repayment of line of credit	(250.0)		
Principal payments of debt			(8.8)
Payments of debt issuance costs	(13.2)	(0.7)	(6.8)
Payments to repurchase common stock		(250.0)	(500.0)
Proceeds from exercise of stock options	15.6	39.9	7.7
Issuance of stock under employee stock purchase plan	3.9	4.1	4.3
Excess tax benefits from share-based compensation			5.9
Net cash provided by (used in) financing activities	6.3	43.3	(497.7)
Effect of exchange rate changes on cash and cash equivalents		0.2	(3.0)
Net (decrease) increase in cash and cash equivalents	(35.9)	(317.9)	191.2
Cash and cash equivalents, beginning of year	705.1	1,023.0	831.8

Cash and cash equivalents, end of year	$ 669.2	$ 705.1	$ 1,023.0
Supplemental cash flow information:			
Cash paid for interest	$ 9.4	$ 7.5	$ 1.5
Cash paid for income taxes	$ 102.7	$ 346.9	$ 362.4
Cash paid for settlement of loss contingency	$	$ 210.0	$
Non-cash investing and financing activities:			
Non-cash additions to property, plant and equipment	$ 11.5	$ 11.5	$ 2.9
Issuance of common stock upon conversion of convertible notes	$	$	$ 7.5

See accompanying notes to consolidated financial statements.

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements

1. Organization and Business Description

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

We have approval from the U.S. Food and Drug Administration (FDA) to market the following therapies: Remodulin® (treprostinil) Injection (Remodulin), Tyvaso® (treprostinil) Inhalation Solution (Tyvaso), Adcirca® (tadalafil) Tablets (Adcirca), Orenitram® (treprostinil) Extended-Release Tablets (Orenitram) and Unituxin® (dinutuximab) Injection (Unituxin). Our only significant revenues outside the United States are derived from sales of Remodulin in Europe.

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

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

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

Use of Estimates

The preparation of our consolidated financial statements in accordance with GAAP requires our management to make estimates and assumptions that affect reported amounts of assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. We base our estimates on assumptions regarding historical experience, currently available information and anticipated developments that we believe are reasonable and appropriate. However, because the use of estimates involves an inherent degree of uncertainty, actual results could differ from those estimates. Estimates are used for, but not limited to, revenue recognition, share-based compensation, determining the fair value of assets acquired and liabilities assumed in business combinations, marketable investments, fair value measurements (including those related to contingent consideration), inventory reserves, investments in privately-held companies, income taxes, goodwill and other intangible assets, and obligations related to our Supplemental Executive Retirement Plan.

Fair Value Measurements

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

Assets and liabilities subject to fair value measurement disclosures are required to be classified according to a three-level fair value hierarchy with respect to the inputs (or assumptions) used to

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

determine fair value. The level in which an asset or liability is disclosed within the fair value hierarchy is based on the lowest level input that is significant to the related fair value measurement in its entirety. The guidance under the fair value measurement framework applies to other existing accounting guidance in the Financial Accounting Standards Board (FASB) codification that requires or permits fair value measurements. Refer to related disclosures in Note 6 *Fair Value Measurements.*

Fair Value of Financial Instruments

The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable, and accrued expenses approximate fair value because of their short maturities. The fair values of our marketable investments and contingent consideration are reported in Note 5 *Investments* and Note 6 *Fair Value Measurements*, respectively.

Cash Equivalents

Cash equivalents consist of highly liquid investments with maturities of three months or less from the date of acquisition.

Marketable Investments

Our marketable investments are primarily debt securities that we classify as available-for-sale or held-to-maturity. If we have both the positive intent and the ability to hold the securities until maturity, the securities are classified as held-to-maturity. We determine the appropriate classification of the securities at the time they are acquired and evaluate the appropriateness of such classifications at each balance sheet date. Available-for-sale debt securities are recorded at fair value, with unrealized gains and losses included as a component of accumulated other comprehensive income (loss) in stockholders' equity, until realized. Held-to-maturity debt securities are recorded at amortized cost, adjusted for the amortization of discounts or premiums. Related discounts and premiums are amortized over the term of these securities as an adjustment to the yield using the effective interest method. Marketable investments are classified as either current or non-current assets on our consolidated balance sheets based on their contractual maturity dates.

We monitor our investment portfolio for impairment quarterly or more frequently if circumstances warrant. In the event that the carrying value of a debt security exceeds its fair value and the decline in value is determined to be other-than-temporary, we record an impairment charge within earnings attributable to the estimated credit loss. In determining whether a decline in the value of an investment is other-than-temporary, we evaluate currently available factors that may include, among others: (1) general market conditions; (2) the duration and extent to which fair value has been less than the carrying value; (3) the investment issuer's financial condition and business outlook; and (4) our 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.

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

Inventories

Inventories are stated at the lower of cost (first-in, first-out method) or net realizable value and consist of the following, net of reserves (in millions):

	As of December 31,	
	2018	**2017**
Raw materials	$ 24.3	$ 27.9
Work-in-progress	28.0	24.1
Finished goods	48.7	55.9
Total inventories	$ 101.0	$ 107.9

Goodwill and Other Intangible Assets

The carrying amount of goodwill is not amortized but is subject to annual impairment testing. We conduct our impairment testing of goodwill annually during the fourth quarter, or more frequently, if impairment indicators exist. Initially, we evaluate various pertinent qualitative factors to assess whether it is more likely than not that the fair value of a reporting unit to which goodwill has been assigned is less than its carrying value. Such qualitative factors can include, among others: (1) industry and market conditions; (2) present and anticipated sales and cost factors; and (3) overall financial performance. If we conclude based on our qualitative assessment that it is more likely than not that the fair value of a reporting unit is less than its carrying value, we then measure the fair value of the reporting unit and compare its fair value to its carrying value (Step 1 of the goodwill impairment test). If the carrying amount of the reporting unit exceeds its fair value, then the amount of an impairment loss, if any, is measured as the excess of the recorded amount of goodwill over its implied fair value (Step 2 of the goodwill impairment test). We used a qualitative assessment for our goodwill impairment testing for 2018 and 2017. Our evaluation of goodwill completed during the years ended December 31, 2018 and 2017, resulted in no impairment losses.

Indefinite-lived intangible assets are not amortized but are evaluated annually or more frequently for impairment if impairment indicators exist. Our indefinite-lived intangible assets include purchased in-process research and development (IPR&D) projects, which were measured at their estimated fair values as of their acquisition dates. We used a qualitative assessment for our indefinite-lived intangible asset impairment testing. Our evaluation of indefinite-lived intangible assets completed during the years ended December 31, 2018 and 2017, resulted in no impairment losses.

Intangible assets subject to amortization are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an intangible asset may not be recoverable. Impairment losses are measured and recognized to the extent the carrying value of such assets exceeds their fair value. We recorded no impairment losses during the years ended December 31, 2018 and 2017.

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

Goodwill and other intangible assets consist of the following (in millions):

	As of December 31, 2018			As of December 31, 2017		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Goodwill	$ 31.5	$	$ 31.5	$ 13.7	$	$ 13.7
Other intangible assets:						
Technology, patents and trade names	6.7	(5.1)	1.6	6.5	(5.0)	1.5
In-process research and development	137.7		137.7	30.4		30.4
Total	$ 175.9	$ (5.1)	$ 170.8	$ 50.6	$ (5.0)	$ 45.6

For more information related to changes in the current year, refer to Note 4 *Acquisition*.

Related amortization expense for the years ended December 31, 2018, 2017 and 2016, was $0.1 million, $0.5 million and $0.6 million, respectively. As of December 31, 2018, aggregate amortization expense related to definite-lived intangible assets for each of the five succeeding years and thereafter is estimated at less than $1.0 million per year.

Property, Plant and Equipment

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

Land improvements	15 Years
Buildings	25 - 39 Years
Building improvements	10 - 39 Years
Furniture, equipment and vehicles	3 - 25 Years
Leasehold improvements	Remaining lease term, or the estimated useful life of the improvement, whichever is shorter

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

	As of December 31,	
	2018	2017
Land and land improvements	$ 69.0	$ 60.5
Buildings, building improvements and leasehold improvements	533.3	408.0
Buildings under construction	126.5	119.8
Furniture, equipment and vehicles	205.5	159.9
	934.3	748.2
Less accumulated depreciation	(234.6)	(202.5)
Property, plant and equipment, net	$ 699.7	$ 545.7

Depreciation expense for the years ended December 31, 2018, 2017 and 2016, was $35.8 million, $30.5 million and $31.0 million, respectively.

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

Buildings under construction consists of direct costs related to our construction projects.

Treasury Stock

Repurchased treasury stock is recorded at cost, including commissions and fees. The cost of treasury shares sold or reissued 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

On January 1, 2018, we adopted Topic 606 using the modified retrospective approach applied to those contracts in effect as of January 1, 2018. Under this transition method, results for reporting periods beginning after January 1, 2018 are presented under the new standard, while prior period amounts are not adjusted and continue to be reported in accordance with our historical accounting under Topic 605, *Revenue Recognition*. See Note 3 *Recently Issued Accounting Standards* for further discussion of the adoption of Topic 606, including the impact on our 2018 financial statements.

To determine revenue recognition for contractual arrangements that we determine are within the scope of Topic 606, we perform the following five steps: (1) identify each contract with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to our performance obligations in the contract; and (5) recognize revenue when (or as) we satisfy the relevant performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer.

We generate revenues from the sale of our five commercially approved products: Remodulin, Tyvaso, Orenitram, Unituxin and Adcirca. We recognize revenue when we transfer control of our products to our distributors, as our contracts have a single performance obligation (delivery of our product). Except for Adcirca sales, the performance obligation is generally satisfied when our products are delivered to the distributor's designated location. We recognize revenue from Adcirca sales upon shipment from an Eli Lilly and Company (Lilly) distribution center. Future revenue from delivery of our products will be based on purchase orders provided to us by our distributors. We are not required to disclose the value of unsatisfied performance obligations as our contracts have a non-cancelable duration of one year or less.

See Note 15 *Segment Information*, for information on revenues disaggregated by commercial product, geographic area and customer.

Gross-to-Net Deductions

As is customary in the pharmaceutical industry, our product sales are recorded net of various forms of gross-to-net deductions. These deductions vary the consideration to which we are entitled in exchange for the sale of our products to our distributors, and include reserves for: (1) rebates and chargebacks; (2) prompt payment discounts; (3) allowances for sales returns; and (4) distributor fees and other allowances. We estimate these reserves in the same period that we recognize revenue for product sales to distributors. The net product sales amount recognized represents the amount we believe will not be subject to a significant future reversal of revenue.

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

Estimating gross-to-net deductions involves the use of significant assumptions and judgments, as well as information obtained from external sources. For our rebate and chargeback liabilities, in particular, the time lag experienced in the payment of the rebate or chargeback may result in revisions of these accruals in future periods. However, based on our significant history and experience estimating these accruals and our development of these accruals based on the expected value method, we do not believe there will be significant changes to our estimates recorded during the period of sale. We recognized an aggregate $8.8 million increase in our net product sales for the year ended December 31, 2018 and an aggregate $13.1 million decrease in our net product sales for the year ended December 31, 2017, related to revenue recognized from product sales in prior periods. In 2018 we recorded a change in estimate that resulted in the reversal of an estimated liability for Medicaid rebates of $13.6 million, which had initially been recorded in 2017. Additional adjustments to accruals for prior periods primarily related to our participation in state Medicaid programs and contracts with commercial payers.

Rebates and chargebacks. Allowances for rebates include mandated discounts due to our participation in various government health care programs and contracted discounts with commercial payers. We estimate our rebate liability on a product-by-product basis, considering actual revenue, contractual discount rates, expected utilization under each contract and historical payment experience. We also consider changes in our product pricing and information regarding changes in program regulations and guidelines. Our chargebacks represent contractual discounts payable to distributors for the difference between the invoice price paid to us by the distributor for a particular product and the contracted price that the distributor's customer pays for that product. Our chargebacks primarily relate to sales of Adcirca. We estimate our chargeback liability on a product-by-product basis, primarily considering historical payment experience. Although we accrue a liability for rebates and chargebacks in the same period the product is sold, third-party reporting and payment of the rebate or chargeback amount occur on a time lag, with the majority of rebates and chargebacks paid within six months from date of sale. Our liability for rebates and chargebacks is included in accounts payable and accrued expenses on our consolidated balance sheets.

Prompt payment discounts. We offer prompt pay discounts to many of our distributors, typically for payments made within 30 days. Prompt pay discounts are estimated in the period of sale based on our experience with sales to eligible distributors. Our domestic distributors have routinely taken advantage of these discounts and we expect them to continue to do so. Prompt pay discounts are recorded as a deduction to the accounts receivable balance presented on our consolidated balance sheets.

Product returns. The sales terms for Adcirca and Unituxin include return rights that extend throughout the distribution channel. For Adcirca, we recognize an allowance for returns as customers have the right to return expired product for up to 12 months past the product's expiration date (generally 24 to 36 months after the initial sale). Returned product is destroyed. Regulatory exclusivity for Adcirca expired in May 2018, and a generic version of Adcirca became available for purchase in the third quarter of 2018. Due to the availability of the generic version, we have experienced a significant decline in Adcirca demand, which could result in inventory held by distributors and other downstream customers expiring unsold. As a result, we increased our allowance for product returns for Adcirca from $7.2 million as of December 31, 2017 to $22.4 million as of December 31, 2018. We record our allowance for product returns in other current and non-current liabilities on our consolidated balance sheets. We developed our returns liability as of December 31, 2018, based on our estimate of the

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

amount of Adcirca inventory in the downstream channel and the amount of that inventory that we expect will not be dispensed to patients, using forecasted sales and demand estimates. The estimates were developed using reports from our distributors and third-party data, including the historical impact of generic entrants on other branded products that we deemed comparable to Adcirca.

For Unituxin, we ship product with expiration dates that are generally 9 to 14 months after the initial sale. However, our historical returns have not been material and, therefore, we do not record a returns allowance for Unituxin. For sales of our other commercial products, we do not offer our customers a general right of return.

Distributor fees and other allowances. Distributor fees include distribution and other service fees paid to certain distributors. These fees are based on contractual amounts or rates applied to purchases of our product or units of service provided in a given period. Our liability for distributor fees is included in accounts payable and accrued expenses on our consolidated balance sheets.

Trade Receivables

We invoice and receive payment from our customers after we recognize revenue, resulting in receivables from our customers that are presented as accounts receivable on our consolidated balance sheets. Accounts receivable consist of short-term amounts due from our distributors (generally 30 to 90 days) and are stated at the amount we expect to collect. We establish an allowance for doubtful accounts, if deemed necessary, based on our assessment of the collectability of specific distributor accounts. We did not recognize any impairment losses for accounts receivable for each of the years ending December 31, 2018 and 2017. Changes in accounts receivable are primarily due to the timing and magnitude of orders of our products, the timing of when control of our products is transferred to our distributors and the timing of cash collections.

Adcirca

Adcirca is manufactured for us by Lilly and distributed through its pharmaceutical wholesaler network. Specifically, Lilly handles all of the administrative functions associated with the sale of Adcirca on our behalf, including the receipt and processing of customer purchase orders, shipment to customers, and invoicing and collection of customer payments. We recognize sales of Adcirca on a gross basis (net of reserves for gross-to-net deductions) based on our determination that we are acting as a principal due to our control of the product prior to its transfer to our customers. Our control is evidenced by our substantive ownership of product inventory, the fact that we bear all inventory risks, our primary responsibility for the acceptability of the product to our customers, and our ability to influence net product sales through our contracting decisions with commercial payers and participation in governmental-funded programs.

Research and Development

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

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

As part of our business strategy, we may in-license the rights to develop and commercialize product candidates. For each in-license transaction, we evaluate whether we have acquired processes or activities along with inputs that would be sufficient to constitute a "business" as defined under GAAP. As defined under GAAP, a "business" consists of inputs and processes applied to those inputs that have the ability to create outputs. Although businesses usually have outputs, outputs are not required for an integrated set of activities to qualify as a business. When we determine that we have not acquired sufficient processes or activities to constitute a business, any up-front payments, as well as pre-commercial milestone payments, are immediately expensed as acquired in-process research and development in the period in which they are incurred. Milestone payments made to third parties subsequent to regulatory approval are capitalized as intangible assets and amortized over the estimated remaining useful life of the related product.

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

costs associated with in-house or contracted manufacturing activities prior to receiving FDA approval for such facilities, or for major unproven changes to our manufacturing processes;

costs incurred in-licensing the rights to technologies in the research and development stage that have no alternative future use; and

up-front payments made in connection with arrangements to obtain license and distribution rights to pharmaceutical product candidates prior to regulatory approval, absent any alternative future use.

Share-Based Compensation

Generally, the fair value of a stock option grant is measured on its grant date and related compensation expense is recognized ratably over the requisite service period. We issue new shares of our common stock upon the exercise of stock options. Additionally, certain executives have stock options with performance conditions that have vesting rights tied to achievement of specific targeted criteria. Share-based compensation expense for all awards is recorded ratably over their vesting period, depending on the specific terms of the award and achievement of the specified performance conditions. Refer to Note 10 *Share-Based Compensation*.

We measure the fair value of restricted stock units using the stock price on the date of grant and related compensation expense is recognized ratably over the vesting period. Each restricted stock unit entitles the holder to receive one share of our common stock upon vesting. We issue new shares of our common stock upon the vesting of restricted stock units.

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

We measure the fair value of stock to be purchased through our employee stock purchase plan at the beginning of an offering period, or grant date, and recognize related compensation expense ratably

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

2. Summary of Significant Accounting Policies (Continued)

over the requisite service period (the offering period). We issue new shares of our common stock upon the end of each offering period, or exercise date.

Income Taxes

We account for income taxes in accordance with the asset and liability method. Under this method, we determine deferred tax assets and liabilities based on the difference between the financial statement carrying amounts and the tax bases of assets and liabilities, using enacted tax rates in effect for years in which the temporary differences are expected to reverse. We apply a valuation allowance against any net deferred tax asset if, based on the available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

We recognize the benefit of an uncertain tax position that has been taken or that we expect to take on income tax returns only if such tax position is more likely than not to be sustained. We recognize the benefit in an amount equal to the largest amount that we determine has a greater than 50 percent likelihood of being realized upon settlement. The ultimate resolution of uncertain tax positions could result in amounts different from those recognized in our consolidated financial statements.

Earnings per Share

Basic earnings per share is computed by dividing net income by the weighted average number of shares of common stock outstanding during the period. Diluted earnings per common share is computed by dividing net income by the weighted average number of shares of common stock outstanding during the period, plus the potential dilutive effect of other securities if such securities were converted or exercised. During periods in which we incur net losses, both basic and diluted loss per share is calculated by dividing the net loss by the weighted average shares outstanding. Potentially dilutive securities are excluded from the calculation because their effect would be anti-dilutive.

Concentration of Credit Risk

Financial instruments that are exposed to credit risk consist of cash, money market funds, certificates of deposit, marketable debt securities, and trade receivables. We maintain our cash and money market funds with financial institutions that are federally insured. While balances deposited in these institutions often exceed Federal Deposit Insurance Corporation limits, we have not experienced any losses on related accounts to date. Furthermore, we limit our risk exposure by maintaining funds in financial institutions that we believe are creditworthy and financially sound. Our investments in marketable debt securities have been issued by corporate entities and government-sponsored enterprises with high credit ratings. We mitigate investment risks by investing in highly-rated securities with relatively short maturities that we believe do not subject us to undue investment or credit risk. In addition, our investment policy does not provide for investments in complex or structured financial instruments. At any given time, our trade receivables are concentrated among a small number of principal customers. If any of these financial institutions, issuers or customers fail to perform their obligations under the terms of these financial instruments, our maximum exposure to potential losses would be equal to amounts reported on our consolidated balance sheets.

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

3. Recently Issued Accounting Standards

Accounting Standards Adopted During 2018

In May 2014, the Financial Accounting Standards Board (FASB) issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)* (ASU 2014-09). The new standard supersedes the revenue recognition requirements in Topic 605, *Revenue Recognition (Topic 605)*, and requires entities to recognize revenue when control of the promised goods or services is transferred to customers. Revenue is recognized in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. We adopted the new standard on January 1, 2018, using the modified retrospective approach, applied only to contracts in effect as of January 1, 2018. Upon adoption, we changed the timing of revenue recognition for sales of Adcirca to recognize revenue when control of Adcirca is transferred to a distributor, which occurs at the time Adcirca is shipped from a Lilly distribution center. Previously, we recognized sales of Adcirca when Adcirca was delivered to distributors. This change did not result in an adjustment to amounts previously recognized as revenue under Topic 605 as all shipments had reached the distributor as of December 31, 2017. Overall, adoption of the new standard did not have a material impact on the amounts reported in our financial statements and there were no other significant changes impacting the timing or measurement of our revenue or our business processes and controls. We have included additional disclosures related to our adoption of Topic 606 in Note 2 *Summary of Significant Accounting Policies Revenue Recognition*.

In January 2016, the FASB issued ASU No. 2016-01, *Financial Instruments Overall: Recognition and Measurement of Financial Assets and Financial Liabilities* (ASU 2016-01), which requires equity investments to be measured at fair value through net income. Equity investments that are accounted for under the equity method are not impacted. ASU 2016-01 provides a new measurement alternative for equity investments without readily determinable fair values. These investments are measured at cost, less any impairment, adjusted for observable price changes. ASU 2016-01 requires separate presentation of the financial assets and liabilities by category and form. ASU 2016-01 should be applied prospectively and is effective for fiscal years beginning after December 15, 2017, and for interim periods within those fiscal years. We adopted the new standard on January 1, 2018, with no material impact to our financial statements. Effective January 1, 2018, we elected to record our equity investments in privately-held companies that do not have readily determinable fair values using the measurement alternative method.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows Classification of Certain Cash Receipts and Cash Payments* (ASU 2016-15), which reduces existing diversity in the classification of certain cash receipts and cash payments on the statements of cash flows. ASU 2016-15 is effective for fiscal years beginning after December 15, 2017, and for interim periods within those fiscal years. We adopted the new standard on January 1, 2018, with no material impact to our financial statements.

In October 2016, the FASB issued ASU No. 2016-16, *Income Taxes Intra-Entity Transfers of Assets Other Than Inventory* (ASU 2016-16), which requires that an entity recognize the income tax consequences of an intra-entity transfer of assets other than inventory when the transfer occurs. ASU 2016-16 is effective for annual reporting periods beginning after December 15, 2017. We adopted the new standard on January 1, 2018, with no material impact to our financial statements.

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

3. Recently Issued Accounting Standards (Continued)

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations Clarifying the Definition of a Business* (ASU 2017-01). This update narrows the definition of a business by providing a screen to determine when an integrated set of assets and activities is not a business. The screen specifies that an integrated set of assets and activities is not a business if substantially all of the fair value of the gross assets acquired or disposed of is concentrated in a single asset or a group of similar identifiable assets. ASU 2017-01 should be applied prospectively and is effective for annual reporting periods beginning after December 15, 2017, and for interim periods within those fiscal years. We adopted the new standard on January 1, 2018, with no material impact to our financial statements.

In March 2017, the FASB issued ASU No. 2017-07, *Improving the Presentation of Net Periodic Pension Cost and Net Periodic Postretirement Benefit Cost* (ASU 2017-07), which requires the service cost component to be reported separately from the other components of net pension cost. Service cost will be presented in the same line item as other employer compensation costs within operating expenses. The other components of net pension cost are required to be presented outside of operations and will be presented in "Other, net" on our consolidated statements of operations. Only the service cost component will be eligible for asset capitalization. Companies are required to apply the change in income statement presentation retrospectively, and the change in capitalized benefit cost prospectively. We adopted the new standard on January 1, 2018, with no material impact to our financial statements.

Accounting Standards Not Yet Adopted

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (ASU 2016-02), which requires that assets and liabilities arising under leases be recognized on the balance sheet. ASU 2016-02 also requires additional quantitative and qualitative disclosures that provide the amount, timing, and uncertainty of cash flows related to lease arrangements. ASU 2016-02 is effective for annual reporting periods beginning after December 15, 2018. In July 2018, the FASB issued ASU No. 2018-11, *Leases (Topic 842) Targeted Improvements* (ASU 2018-11). ASU 2018-11 allows entities to elect an optional transition method, allowing for application of ASU 2016-02 at the adoption date, with recognition of a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. We adopted the standard on January 1, 2019 utilizing the simplified transition method. We have identified all leases involved in the relevant timeframe. On January 1, 2019, we elected the practical expedient package permitted under the transition guidance within the new standard, which among other things, allows us to carry forward the historical lease classification. We also elected the simplified approach practical expedient, allowing us to not restate comparative periods and apply ASC 842 on a prospective basis beginning on January 1, 2019. We elected the lessee component election, allowing us to account for the lease and non-lease components as a single lease component. As the majority of our leases do not provide an implicit rate, we use our incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. We made an accounting policy election to keep leases with an initial term of 12 months or less off of the consolidated balance sheet. We will recognize those lease payments in the consolidated statements of operations on a straight-line basis over the lease term. We also expect most of our build-to-suit leases to be de-recognized upon adoption as our current build-to-suit leases will no longer qualify for build-to-suit accounting and will instead be recognized as operating leases under ASC 842. We have updated our internal controls, business processes, and accounting policies related to both the implementation of, and ongoing compliance with, the new guidance. Although we are still finalizing our evaluation of the standard update and the quantification of its impact, we do not expect its adoption will have a material

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

3. Recently Issued Accounting Standards (Continued)

impact to our financial statements. We will include expanded quantitative and qualitative disclosures about our lease arrangements beginning in the first quarter of 2019.

In January 2017, the FASB issued ASU No. 2017-04, *Intangibles Goodwill and Other: Simplifying the Test for Goodwill Impairment* (ASU 2017-04), which simplifies how an entity is required to test goodwill for impairment. A goodwill impairment will be measured by the amount by which a reporting unit's carrying value exceeds its fair value, with the amount of impairment not to exceed the carrying amount of goodwill. ASU 2017-04 is effective for goodwill impairment tests in fiscal years beginning after December 15, 2019, and for interim periods within those fiscal years, and must be adopted on a prospective basis. Early adoption is permitted. We do not expect the adoption of this guidance to have a material impact on our financial statements.

In February 2018, the FASB issued ASU No. 2018-02, *Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income* (ASU 2018-02). The standard provides financial statement preparers with an option to reclassify stranded tax effects within accumulated other comprehensive income to retained earnings in each period in which the effect (or portion thereof) of the change in the U.S. federal corporate income tax rate in the Tax Cuts and Jobs Act (Tax Reform) is recorded. ASU 2018-02 is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. We do not expect the adoption of this guidance to have a material impact on our financial statements.

In August 2018, the FASB issued ASU No. 2018-14, *Compensation Retirement Benefits Defined Benefit Plans General (Topic 715-20): Disclosure Framework Changes to the Disclosure Requirements for Defined Benefit Plans* (ASU 2018-14). The standard modifies the disclosure requirements for employers that sponsor defined benefit pension or other postretirement plans. ASU 2018-14 is effective for fiscal years beginning after December 15, 2020. Early adoption is permitted. We do not expect the adoption of this guidance to have a material impact on our financial statements.

4. Acquisition

SteadyMed Merger

On April 29, 2018, we entered into an Agreement and Plan of Merger (Merger Agreement) with SteadyMed Ltd. (SteadyMed) and Daniel 24043 Acquisition Corp Ltd., our wholly-owned subsidiary (Merger Sub). The Merger Agreement provides for the merger of Merger Sub with and into SteadyMed (the Merger), with SteadyMed surviving the Merger as our wholly-owned subsidiary.

On August 30, 2018 (the Closing Date), we completed the Merger. At the effective time of the Merger, each SteadyMed ordinary share was converted into the right to receive (1) $4.46 in cash, representing aggregate consideration payable to former holders of SteadyMed securities of approximately $141 million; and (2) one contingent value right, representing the right to receive $2.63 in cash upon the achievement of a milestone defined as 3,000 patients initiating treatment using SteadyMed's Trevyent® product on a commercial basis on or before August 30, 2023 (the Milestone). Aggregate contingent consideration of $75.0 million will become payable if the Milestone is achieved.

Trevyent is a post-phase III, development-stage drug-device combination product that combines SteadyMed's two-day, single-use, disposable PatchPump® technology with treprostinil, for the subcutaneous treatment of pulmonary arterial hypertension (PAH).

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

4. Acquisition (Continued)

Following the acquisition, the operating results of SteadyMed have been included in our consolidated financial statements. For the period from the Closing Date through December 31, 2018, SteadyMed contributed revenues and loss before income taxes of zero and $6.2 million, respectively.

Purchase Price Allocation

The Merger meets the definition of a business combination in accordance with ASC 805, *Business Combinations*, and we applied the acquisition method to account for the transaction, which requires, among other things, that assets acquired and liabilities assumed be recognized at their fair values as of the closing date. The aggregate purchase price noted above was allocated to the major categories of assets acquired and liabilities assumed based upon their estimated fair values at the closing date using primarily Level 2 and Level 3 inputs. These Level 2 and Level 3 valuation inputs included an estimate of future cash flows and discount rates. Additionally, estimated fair values are based, in part, upon third-party valuations of certain assets, including specifically-identified intangible assets.

The purchase price allocation is considered complete as of December 31, 2018. The following table summarizes the consideration paid for the acquisition and the amounts of the assets acquired and liabilities assumed as of the Closing Date:

Purchase Price Allocation

	Fair Value (in millions)
Cash	$ 17.1
Intangible assets:	
In-process research and development	107.3
Goodwill[(1)]	17.8
Trademark	0.2
Property, plant and equipment	6.2
Other assets	0.4
Total fair value of assets acquired	$ 149.0
Accounts payable and accrued expenses	4.3
Other current liabilities	3.5
Total fair value of liabilities assumed	$ 7.8
Total purchase price	$ 141.2

(1) We expect the full amount of goodwill to be deductible for income tax purposes over the next 15 years.

We determined the fair value of in-process research and development (IPR&D) using the multi-period earnings method under the income approach. This method reflects the present value of the projected cash flows that are expected to be generated by the IPR&D, less charges representing the required return on other assets to sustain those cash flows. The multi-period earnings method is a Level 3 fair value measurement. Significant assumptions inherent in determining fair value of the

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

4. Acquisition (Continued)

IPR&D included annual net cash flows over a period of time and a discount rate applied to those cash flows to reflect the overall risk of the asset.

We ascribed no value to the contingent value rights based on a probability-weighted discounted cash flow model, utilizing probability adjusted expectations for achieving the Milestone. In making this determination we considered expectations regarding the timing and probability of FDA approval of Trevyent, the potential patient population, and estimates of product penetration and uptake by August 30, 2023. As of December 31, 2018, there have been no material changes in assumptions used as of the closing date and, therefore, no changes to the value of the contingent consideration.

Acquisition-related costs

Costs incurred to complete the Merger and integrate SteadyMed into our business were expensed as incurred and included within selling, general and administrative costs on our consolidated statements of operations. During the year ended December 31, 2018, we recognized $5.4 million of acquisition-related costs. These costs represented transaction costs, legal fees and professional third-party service fees.

5. Investments

Marketable Investments

Available-for-Sale Investments

Marketable investments classified as available-for-sale consisted of the following (in millions):

As of December 31, 2018	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. government and agency securities	$ 1,077.4	$ 0.7	$ (3.9)	$ 1,074.2
Corporate notes and bonds	72.3		(0.3)	72.0
Corporate equity securities	3.7		(0.2)	3.5
Total	$ 1,153.4	$ 0.7	$ (4.4)	$ 1,149.7

Reported under the following captions on the consolidated balance sheets:	
Cash and cash equivalents	$
Current marketable investments	709.3
Non-current marketable investments	440.4
Total	$ 1,149.7

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

5. Investments (Continued)

As of December 31, 2017	Amortized Cost	Gross Unrealized Losses	Fair Value
U.S. government and agency securities	$ 726.5	$ (3.0)	$ 723.5
Corporate notes and bonds	13.9		13.9
Total	$ 740.4	$ (3.0)	$ 737.4

Reported under the following captions on the consolidated balance sheets:	
Cash and cash equivalents	$ 41.7
Current marketable investments	194.6
Non-current marketable investments	501.1
Total	$ 737.4

The following table summarizes the contractual maturities of available-for-sale marketable investments (in millions):

	As of December 31, 2018	
	Amortized Cost	Fair Value
Due within one year	$ 708.2	$ 705.8
Due in one to three years	441.5	440.4
Total	$ 1,149.7	$ 1,146.2

Held-to-Maturity Investments

Our current and long-term marketable investments included $39.6 million and $29.3 million of investments classified as held-to-maturity as of December 31, 2018 and 2017, respectively. Marketable investments classified as held-to-maturity are comprised of government-sponsored enterprises and corporate notes and bonds. 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 recovery of their amortized cost basis. Furthermore, we do not believe that these securities expose us to undue market risk or counterparty credit risk. As such, we do not consider these securities to be other than temporarily impaired.

The following table summarizes the contractual maturities of held-to-maturity marketable investments (in millions):

	As of December 31, 2018	
	Amortized Cost	Fair Value

Due within one year	$ 37.4	$ 37.4
Due in one to three years	2.2	2.2
Total	$ 39.6	$ 39.6

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

5. Investments (Continued)

Investments in Privately-Held Companies

As of December 31, 2018, we maintained non-controlling equity investments in privately-held companies of $135.5 million in the aggregate. Upon adoption of ASU 2016-01 on January 1, 2018, we began to measure these investments using the measurement alternative because the fair values of these investments are not readily determinable. Under this alternative, the investments are measured at cost, less any impairment, adjusted for any observable price changes. We made payments of $5.0 million and $60.4 million for investments in privately-held companies during the years ended December 31, 2018 and 2017, respectively. We include our investments in privately-held companies within other non-current assets on our consolidated balance sheets. These investments are subject to a periodic impairment review and if impaired, the investment is measured and recorded at fair value in accordance with ASC 820, *Fair Value Measurements*.

During the quarter ended September 30, 2018, one of the privately-held companies in which we have invested underwent a significant change in management and a change in business outlook and strategy, all of which triggered our review of the recoverability of our investment in the company. We determined the fair value of our investment using an income approach based on the company's discounted projected cash flows, which is considered a Level 3 fair value measurement. We corroborated the implied revenue multiples from the income approach with the observed revenue multiples of comparable public companies. We concluded that the fair value of our investment was lower than its carrying value, resulting in an impairment charge of $12.4 million. During the fourth quarter of 2018, the same privately-held company had significant liquidity concerns. We performed a qualitative evaluation of our investment concluding that there were additional indicators of impairment present at December 31, 2018. We then determined the fair value of the investment using an income approach based on the company's updated discounted projected cash flows. The carrying value was in excess of the fair value, resulting in an impairment charge of $41.1 million during the fourth quarter of 2018.

During the year ended December 31, 2017, we recorded $49.6 million of impairment charges related to our investments in privately-held companies.

Variable Interest Entity

In April 2017, we made a $7.5 million minority investment in a privately-held company. In addition to our investment, we entered into an exclusive license, development and commercialization agreement (the License Agreement) with this company. The License Agreement entitles us to control rights sufficient to require us to consolidate its balance sheet and results of operations, as the primary beneficiary of this company. The control rights relate to additional research and development funding that we may provide to this company over a period of six years. We are also entitled to representation on a joint development committee that approves the company's use of funding provided by us. In 2018, we provided $8.2 million of financial support to the company. We have the right, at any time and for any reason, to cease our funding of this company's activities.

As of December 31, 2018, our consolidated balance sheet included $12.3 million of cash maintained by this company that can only be used to settle its obligations. Additionally, our consolidated balance sheets included an $8.8 million in-process research and development intangible asset, $3.4 million of goodwill and $8.3 million of preferred stock due to the consolidation of this company. The preferred stock is recorded in temporary equity on our consolidated balance sheets.

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

5. Investments (Continued)

During the year ended December 31, 2018, this company incurred a net loss of $8.8 million. This company's creditors have no recourse against our assets and general credit.

6. Fair Value Measurements

Assets and liabilities subject to fair value measurements are required to be disclosed within a fair value hierarchy. The fair value hierarchy ranks the quality and reliability of inputs used to determine fair value. Accordingly, assets and liabilities carried at, or permitted to be carried at, fair value are classified within the fair value hierarchy in one of the following categories based on the lowest level input that is significant in measuring fair value:

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

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

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

We account for certain assets and liabilities at fair value and rank these assets and liabilities within the fair value hierarchy. Other current assets and other current liabilities have fair values that approximate their carrying values.

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

	As of December 31, 2018			
	Level 1	Level 2	Level 3	Balance
Assets				
Money market funds[1]	$ 247.6	$	$	$ 247.6
Time deposits[2]		35.9		35.9
U.S. government and agency securities[2]		1,074.2		1,074.2
Corporate debt securities[2]		75.7		75.7
Corporate equity securities[3]	3.5			3.5
Total assets	$ 251.1	$ 1,185.8	$	$ 1,436.9
Liabilities				
Contingent consideration[4]			13.4	13.4
Total liabilities	$	$	$ 13.4	$ 13.4

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

6. Fair Value Measurements (Continued)

	As of December 31, 2017			
	Level 1	Level 2	Level 3	Balance
Assets				
Money market funds[1]	$ 217.9	$	$	$ 217.9
Time deposits[2]		25.2		25.2
U.S. government and agency securities[2]		723.5		723.5
Corporate debt securities[2]		18.0		18.0
Total assets	$ 217.9	$ 766.7	$	$ 984.6
Liabilities				
Contingent consideration[4]			12.8	12.8
Total liabilities	$	$	$ 12.8	$ 12.8

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

(2) Included in cash equivalents and current and non-current marketable investments on the accompanying consolidated balance sheets. The fair value of these securities is principally measured or corroborated by trade data for identical securities in which related trading activity is not sufficiently frequent to be considered a Level 1 input or comparable securities that are more actively traded.

(3) Included in non-current marketable investments on the accompanying consolidated balance sheets. The fair value of these securities is based on quoted market prices for identical instruments in active markets.

(4) Included in non-current liabilities on the accompanying consolidated balance sheets. The fair value of contingent consideration has been estimated using probability-weighted discounted cash flow models (DCFs). The DCFs incorporate Level 3 inputs including estimated discount rates that we believe market participants would consider relevant in pricing and the projected timing and amount of cash flows, which are estimated and developed, in part, based on the requirements specific to each acquisition agreement.

Fair Value of Financial Instruments

The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable, and accrued expenses approximate fair value because of their short maturities. The fair values of our marketable investments are reported above within the fair value hierarchy. Refer to Note 5 *Investments*. The carrying value of our debt is a reasonable estimate of the fair value of the outstanding debt based on the variable interest rate of the debt.

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

7. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following by major categories (in millions):

	As of December 31,	
	2018	**2017**
Accounts payable	$ 23.1	$ 8.4
Accrued expenses:		
Sales related (royalties, rebates and fees)	81.0	104.6
Payroll related	37.9	34.6
Other	24.1	23.5
Total accrued expenses	$ 143.0	$ 162.7
Total accounts payable and accrued expenses	$ 166.1	$ 171.1

8. Debt

Unsecured Revolving Credit Facility 2018 Credit Agreement

In June 2018, we entered into a credit agreement (the 2018 Credit Agreement) with Wells Fargo Bank, National Association (Wells Fargo), as administrative agent and a swingline lender, and various other lender parties, providing for (1) an unsecured revolving credit facility of up to $1.0 billion; and (2) a second unsecured revolving credit facility of up to $500.0 million (which facilities may, at our request, be increased by up to $300 million in the aggregate subject to obtaining commitments from existing or new lenders for such increase and satisfying other conditions). The facilities will mature five years after the closing date of the 2018 Credit Agreement, subject to the lenders' ability to extend the maturity date by one year if we request such an extension in accordance with the terms of the 2018 Credit Agreement, up to a maximum of two such extensions.

At our option, amounts borrowed under the 2018 Credit Agreement bear interest at either the LIBOR rate or a fluctuating base rate, in each case, plus an applicable margin determined on a quarterly basis based on our consolidated ratio of total indebtedness to EBITDA (as calculated in accordance with the 2018 Credit Agreement).

On June 27, 2018, we borrowed $250.0 million under the 2018 Credit Agreement, and used the funds to repay outstanding indebtedness under the 2016 Credit Agreement as discussed below under *Unsecured Revolving Credit Facility 2016 Credit Agreement*. As we no longer intend to repay the full outstanding balance within one year, the outstanding balance has been reclassified from short-term to long-term within the consolidated balance sheet. We elected to have interest on this draw calculated at LIBOR plus an applicable margin. During the year ended December 31, 2018, we recorded $6.8 million of interest expense related to the credit facility.

On January 24, 2019, we paid an upfront payment of $800.0 million related to the global license agreement with Arena Pharmaceuticals, Inc. (Arena) and funded the payment by borrowing $800.0 million under the 2018 Credit Agreement. Refer to Note 18 *Subsequent Events.*

The 2018 Credit Agreement contains customary events of default and customary affirmative and negative covenants. As of December 31, 2018, we were in compliance with such covenants. Lung Biotechnology PBC is our only subsidiary that guarantees our obligations under the 2018 Credit

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

8. Debt (Continued)

Agreement though, from time to time, one or more of our other subsidiaries may be required to guarantee our obligations.

In connection with the 2018 Credit Agreement, we incurred debt issuance costs of $13.2 million. We capitalized $12.6 million of these costs. These issuance costs are being amortized to interest expense over the contractual term of the 2018 Credit Agreement. As of December 31, 2018, $2.5 million is recorded in other current assets and $8.8 million in other non-current assets on our consolidated balance sheet.

Unsecured Revolving Credit Facility 2016 Credit Agreement

In January 2016, we entered into a credit agreement (the 2016 Credit Agreement) with Wells Fargo, as administrative agent and a swingline lender, and various other lender parties, providing for an unsecured revolving credit facility of up to $1.0 billion. On June 1, 2017, we borrowed $250.0 million under this facility and used the funds to initiate an accelerated share repurchase program. Refer to Note 11 *Stockholders' Equity Share Repurchase.*

On June 27, 2018, we repaid in full all our obligations under the 2016 Credit Agreement in connection with the termination of the 2016 Credit Agreement and our entry into the 2018 Credit Agreement. There were no penalties associated with the early termination of the 2016 Credit Agreement.

Convertible Note Hedge and Warrant Transactions

In October 2011, we issued $250.0 million in aggregate principal value 1.0 percent Convertible Senior Notes due September 15, 2016 (Convertible Notes). Upon maturity of the Convertible Notes in September 2016, we fulfilled all remaining settlement and repayment obligations.

In connection with the issuance of the Convertible Notes, we sold to Deutsche Bank AG London (DB London) warrants to acquire up to approximately 5.2 million shares of our common stock at a strike price of $67.56 per share. The warrants expired incrementally on a series of expiration dates during December 2016 and January 2017. The warrants were settled on a net-share basis. As the price of our common stock exceeded the strike price of the warrants on each of the series of related incremental expiration dates, we delivered 2.8 million shares of common stock previously held as treasury stock to DB London, including 1.7 million shares that were delivered during the first quarter of 2017.

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

8. Debt (Continued)

Interest Expense

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

	Year Ended December 31,		
	2018	2017	2016
Credit Facility interest expense[1]	$ 13.9	$ 7.1	$ 3.2
Convertible Notes interest expense			0.1
Other interest expense		1.9	0.6
Total interest expense	$ 13.9	$ 9.0	$ 3.9

(1) Represents interest expense related to debt and amortization of issuance costs associated with our 2018 and 2016 Credit Agreements.

9. Temporary Equity

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

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

	As of December 31,	
	2018	2017
Common stock subject to repurchase[1]	$ 10.9	$ 10.9
Preferred stock with redemption rights[2]	8.3	8.3
Total	$ 19.2	$ 19.2

(1) In connection with our license agreement with Toray Industries Inc. (Toray), we issued 200,000 shares of our common stock (which have since split into 400,000 shares) to Toray in 2007, and provided Toray the right to require us to repurchase the shares at a price of $27.21 per share.

(2) The preferred stock issued by the variable interest entity we consolidate includes rights that allow the holders to redeem the preferred stock at the original issuance price in exchange for cash. Refer to Note 5 *Investments Variable Interest Entity* for more information.

10. Share-Based Compensation

As of December 31, 2018, we have two shareholder-approved equity incentive plans: the United Therapeutics Corporation Amended and Restated Equity Incentive Plan (the 1999 Plan) and the

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

10. Share-Based Compensation (Continued)

United Therapeutics Corporation 2015 Stock Incentive Plan (the 2015 Plan). The 2015 Plan was approved by our shareholders in June 2015 and provided for the issuance of up to 6,150,000 shares of our common stock pursuant to awards granted under the 2015 Plan. On June 26, 2018, our shareholders approved an amendment and restatement of the 2015 Plan to increase the maximum number of shares of our common stock that may be issued under the 2015 Plan by 2,900,000 shares. As a result of the approval of the 2015 Plan, no further awards will be granted under the 1999 Plan. Currently, we grant equity-based awards including stock options and restricted stock units under the 2015 Plan. Refer to the sections entitled *Employee Stock Options* and *Restricted Stock Units* below.

We previously issued awards under the United Therapeutics Corporation Share Tracking Awards Plan (2008 STAP) and the United Therapeutics Corporation 2011 Share Tracking Awards Plan (2011 STAP). We refer to the 2008 STAP and the 2011 STAP collectively as the "STAP" and awards outstanding under either of these plans as "STAP awards." Refer to the section entitled *Share Tracking Awards Plans* below. We discontinued the issuance of STAP awards in June 2015.

In 2012, our shareholders approved the United Therapeutics Corporation Employee Stock Purchase Plan (ESPP), which is structured to comply with Section 423 of the Internal Revenue Code. Refer to the section entitled *Employee Stock Purchase Plan* section below.

The following table reflects the components of share-based compensation expense (benefit) recognized in our consolidated statements of operations (in millions):

	Year Ended December 31,		
	2018	2017	2016
Stock Options	$ 58.5	$ 43.0	$ 24.8
Restricted Stock Units	7.3	2.2	1.1
Share Tracking Awards	(93.4)	27.1	(15.2)
Employee Stock Purchase Plan	1.2	1.2	1.4
Total Share-based compensation (benefit) expense before tax	$ (26.4)	$ 73.5	$ 12.1
Share-based compensation capitalized as part of inventory	$ 0.7	$ 0.4	$ 0.2

As a result of the adoption of ASU 2016-09, we established an accounting policy election to account for forfeitures of share-based awards and STAPs when they occur. Upon adoption, we recognized a cumulative-effect adjustment for the removal of the forfeiture estimate with respect to awards that were continuing to vest as of January 1, 2017. The adjustment decreased retained earnings by $5.8 million, net of tax.

Employee Stock Options

We estimate the fair value of stock options using the Black-Scholes-Merton valuation model, which requires us to make certain assumptions that can materially impact the estimation of fair value and related compensation expense. The assumptions used to estimate fair value include the price of our common stock, the expected volatility of our common stock, the risk-free interest rate, the expected term of stock option awards and the expected dividend yield.

In March 2017, we began issuing stock options with performance conditions to certain executives. The stock options have vesting conditions tied to the achievement of specified performance criteria,

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

10. Share-Based Compensation (Continued)

which have target performance levels that span from one to three years. Upon the conclusion of the performance period, the performance level achieved is measured and the ultimate number of shares that may vest is determined. Share-based compensation expense for these awards is recorded ratably over their vesting period, depending on the specific terms of the award and anticipated achievement of the specified performance criteria. During 2018, we granted 0.9 million stock options with performance vesting conditions with a grant date fair value of $23.7 million based on achievement of target performance levels. During the years ended December 31, 2018 and 2017, we recorded $39.9 million and $16.7 million, respectively, of share-based compensation expense related to the 2017 and 2018 performance-based grants.

A description of the key inputs, requiring estimates, used in determining the fair value of Employee Stock Options are provided below:

Expected term The expected term reflects the estimated time period we expect an award to remain outstanding. For the years ended December 31, 2018, 2017 and 2016, we used the simplified approach to develop this input for our stock options as we do not have sufficient historical data related to stock option exercises. Under the simplified approach, the expected term reflects the weighted average midpoint between the vesting date and the expiration date of the awards. For the expected term input related to our STAP awards, refer to the *Share Tracking Awards Plan* section below.

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

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

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

The following weighted-average assumptions were used in estimating the fair value of stock options granted to employees during the twelve months ended December 31, 2018, December 31, 2017, and December 31, 2016:

	Year Ended December 31,		
	2018	**2017**	**2016[1]**
Expected term of options (in years)	6.3	6.1	5.8
Expected volatility	36.2%	35.7%	34.8%
Risk-free interest rate	2.7%	2.2%	1.6%
Expected dividend yield	0.0%	0.0%	0.0%

(1) Prior to the adoption of ASU 2016-09 on January 1, 2017, the weighted-average expected forfeiture rate used in estimating the fair value of stock options granted to employees was 5.4 percent in 2016.

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

10. Share-Based Compensation (Continued)

A summary of the activity and status of stock options under our equity incentive plans is presented below:

	Options	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in millions)
Outstanding at January 1, 2018	5,878,323	$ 119.61		
Granted	996,775	111.05		
Exercised	(289,393)	53.99		
Forfeited	(285,902)	130.28		
Outstanding at December 31, 2018	6,299,803	$ 120.78	6.8	$ 32.7
Exercisable at December 31, 2018	3,441,138	$ 113.74	5.4	$ 32.5
Unvested at December 31, 2018	2,858,665	$ 129.26	8.4	$ 0.2

The weighted average fair value of a stock option granted during each of the years in the three-year period ended December 31, 2018, was $45.01, $56.07 and $42.59, respectively. The total fair value of stock options that vested for each of the years in the three-year period ended December 31, 2018, was $33.9 million, $13.1 million and $19.9 million, respectively.

Total share-based compensation expense related to stock options is as follows (in millions):

	Year Ended December 31,		
	2018	2017	2016
Cost of product sales	$ 0.9	$ 1.3	$ 0.5
Research and development	3.7	3.7	1.4
Selling, general and administrative	53.9	38.0	22.9
Share-based compensation expense before tax	58.5	43.0	24.8
Related income tax benefit	(13.3)	(15.8)	(9.1)
Share-based compensation expense, net of tax	$ 45.2	$ 27.2	$ 15.7

As of December 31, 2018, the unrecognized compensation cost was $78.6 million. Unvested outstanding stock options as of December 31, 2018 had a weighted average remaining vesting period of 1.7 years.

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

10. Share-Based Compensation (Continued)

Stock option exercise data is summarized below (dollars in millions):

	Year Ended December 31,		
	2018	2017	2016
Number of options exercised	289,393	461,465	243,624
Cash received from options exercised	$ 15.6	$ 39.9	$ 7.7
Total intrinsic value of options exercised	$ 17.0	$ 29.3	$ 21.9
Tax benefits realized from options exercised[(1)]	$	$	$ 5.9

(1) On January 1, 2017, we adopted ASU 2016-09. Upon adoption of ASU 2016-09, we began to recognize excess tax benefits as income tax benefits on our consolidated statements of operations.

Restricted Stock Units

In June 2016, we began issuing restricted stock units to our non-employee directors. In October 2017, we also began issuing restricted stock units to our employees. Each restricted stock unit entitles the recipient to one share of our common stock upon vesting. We measure the fair value of restricted stock units using the stock price on the date of grant. Share-based compensation expense for the restricted stock units is recorded ratably over their vesting period.

A summary of the activity with respect to, and status of, restricted stock units under the 2015 Plan is presented below:

	Number of Restricted Stock Units	Weighted-Average Grant Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in millions)
Unvested at January 1, 2018	23,040	$ 128.98		
Granted	198,888	112.34		
Vested	(19,051)	131.79		
Forfeited/canceled	(16,622)	111.46		
Unvested at December 31, 2018	186,255	$ 112.48	9.3	$ 20.3

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

10. Share-Based Compensation (Continued)

Total share-based compensation expense related to restricted stock units is recorded as follows (in millions):

	Year Ended December 31,		
	2018	**2017**	**2016**
Cost of product sales	$ 0.5	$	$
Research and development	1.7		
Selling, general and administrative	5.1	2.2	
Share-based compensation expense before tax	7.3	2.2	
Related income tax benefit	(1.7)	(0.8)	
Share-based compensation expense, net of tax	$ 5.6	$ 1.4	$

As of December 31, 2018, unrecognized compensation cost related to the grant of restricted stock units was $15.3 million. Unvested outstanding restricted stock units as of December 31, 2018 had a weighted average remaining vesting period of 2.2 years.

Share Tracking Awards Plans

STAP awards convey the right to receive in cash an amount equal to the appreciation of our common stock, which is measured as the increase in the closing price of our common stock between the dates of grant and exercise. STAP awards expire on the tenth anniversary of the grant date, and in most cases they vest in equal increments on each anniversary of the grant date over a four-year period. The STAP liability includes vested awards and awards that are expected to vest.

The aggregate STAP liability balance was $72.2 million and $241.3 million at December 31, 2018 and 2017, respectively, of which zero and $1.2 million, respectively, have been classified as other non-current liabilities on our consolidated balance sheets based on their vesting terms.

Estimating the fair value of STAP awards requires the use of certain inputs that can materially impact the determination of fair value and the amount of compensation expense (benefit) we recognize. Inputs used in estimating fair value include the price of our common stock, the expected volatility of the price of our common stock, the risk-free interest rate, the expected term of STAP awards, and the expected dividend yield. The fair value of the STAP awards is measured at the end of each financial reporting period because the awards are settled in cash. Refer to the descriptions of these key inputs, requiring estimates, used in determining the fair value of the awards in the *Employee Stock Options* section above. A description of the expected term input for STAP awards is provided below:

Expected term The expected term reflects the estimated time period we expect an award to remain outstanding. For the years ended December 31, 2017 and 2016 and for the nine months ended September 30, 2018, we used historical data to develop this input for our STAP awards. As of December 31, 2018, we no longer believed historical exercise data was a reasonable approach to determine the expected exercise behavior of outstanding STAPs given the prolonged volatility of the price of our common stock. As such, we determined the expected term assumption as of December 31, 2018 using the weighted average midpoint of the remaining contractual term for outstanding awards.

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

10. Share-Based Compensation (Continued)

The midpoint method resulted in a remaining weighted average expected term of 2.5 years, which is longer than the remaining weighted averaged expected term of 1.0 year calculated under our historical approach. We believe the midpoint method represents the best estimate of the expected term of outstanding STAP awards. The application of the midpoint method during the fourth quarter of 2018 resulted in an increase to the STAP liability of approximately $22.7 million, holding other factors constant.

The table below includes the weighted-average assumptions used to measure the fair value of the outstanding STAP awards:

	As of December 31,		
	2018	2017	2016[1]
Expected term of awards (in years)	2.5	1.8	2.5
Expected volatility	30.9%	31.7%	36.1%
Risk-free interest rate	2.5%	1.8%	1.4%
Expected dividend yield	0.0%	0.0%	0.0%

(1) Prior to the adoption of ASU 2016-09 on January 1, 2017, the weighted-average expected forfeiture rate used in estimating the fair value of STAP awards granted to employees was 8.8 percent in 2016.

The closing price of our common stock was $108.90, $147.95, and $143.43 on December 31, 2018, 2017 and 2016, respectively.

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 millions)
Outstanding at January 1, 2018	4,096,394	$ 95.60		
Granted				
Exercised	(1,116,643)	57.99		
Forfeited	(111,772)	156.97		
Outstanding at December 31, 2018	2,867,979	$ 107.85	4.9	$ 65.4
Exercisable at December 31, 2018	2,646,723	$ 103.77	4.8	$ 64.8
Unvested at December 31, 2018	221,256	$ 156.73	6.1	$ 0.6

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Notes to Consolidated Financial Statements (Continued)

10. Share-Based Compensation (Continued)

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

	Year Ended December 31,		
	2018	2017	2016
Cost of product sales	$ (4.7)	$ 1.2	$
Research and development	(17.9)	4.1	(11.8)
Selling, general and administrative	(70.8)	21.8	(3.4)
Share-based compensation (benefit) expense before tax	(93.4)	27.1	(15.2)
Related income tax expense (benefit)	21.3	(10.0)	5.6
Share-based compensation (benefit) expense, net of tax	$ (72.1)	$ 17.1	$ (9.6)

Cash paid to settle STAP exercises during the years ended December 31, 2018, 2017 and 2016 was $75.7 million, $63.4 million, and $69.5 million, respectively.

Employee Stock Purchase Plan

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

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

11. Stockholders' Equity

Earnings Per Common Share

The components of basic and diluted earnings per share comprised the following (in millions, except per share amounts):

	Year Ended December 31,		
	2018	**2017**	**2016**
Numerator:			
Net income	$ 589.2	$ 417.9	$ 713.7
Denominator:			
Weighted average outstanding shares basic	43.5	44.0	43.8
Effect of dilutive securities[1]:			
Warrants		0.1	2.3
Stock options, restricted stock units and employee stock purchase plan	0.5	0.8	0.7
Weighted average shares diluted[2]	44.0	44.9	46.8
Earnings per common share:			
Basic	$ 13.54	$ 9.50	$ 16.29
Diluted	$ 13.39	$ 9.31	$ 15.25
Stock options, restricted stock units and warrants excluded from calculation[2]	4.7	3.3	5.2

(1) Calculated using the treasury stock method.

(2) Certain convertible notes, stock options, restricted stock units and warrants have been excluded from the computation of diluted earnings per share because their impact would be anti-dilutive. Under the convertible note hedge agreement we entered into in connection with our Convertible Notes, we were entitled to receive shares required to be issued to investors upon conversion of our Convertible Notes. Since related shares used to compute dilutive earnings per share would be anti-dilutive, they have been excluded from the calculation above.

Share Repurchases

In April 2017, our Board of Directors approved a share repurchase program authorizing up to $250.0 million in aggregate repurchases of our common stock. Pursuant to this authorization, in May 2017, we paid $250.0 million to enter into an accelerated share repurchase agreement (ASR) with Citibank, N.A. (Citibank). Pursuant to the terms of the ASR, in June 2017, Citibank delivered to us approximately 1.7 million shares of our common stock, representing the minimum number of shares we were entitled to receive under the ASR. Upon termination of the ASR in September 2017, Citibank delivered to us approximately 0.3 million additional shares of our common stock. The ASR was accounted for as an equity transaction and the shares we repurchased under the ASR were included in treasury stock when the shares were received.

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

11. Stockholders' Equity (Continued)

Shareholder Rights Plan

In June 2008, we entered into an Amended and Restated Rights Agreement with The Bank of New York as Rights Agent (the Plan), which amended and restated our original Rights Agreement dated December 17, 2000. The Plan, as amended and restated, extended the expiration date of the Preferred Share Purchase Rights (Rights) from December 29, 2010 to June 26, 2018, and increased the purchase price of each Right from $64.75 to $400.00, respectively. Each Right entitled holders to purchase one one-thousandth of a share of our Series A Junior Participating Preferred Stock. Rights were 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. The Plan expired on June 26, 2018 in accordance with its terms. As of December 31, 2018, we have not issued any shares of our Series A Preferred Stock.

Accumulated Other Comprehensive Loss

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

	Defined Benefit Pension Plan[1]	Foreign Currency Translation Losses	Unrealized Gains and (Losses) on Available-for-Sale Securities	Total
Balance, January 1, 2018	$ 0.2	$ (17.9)	$ (1.9)	$ (19.6)
Other comprehensive income (loss) before reclassifications	10.7		(0.4)	10.3
Amounts reclassified from accumulated other comprehensive income	1.4			1.4
Net current-period other comprehensive income (loss)	12.1		(0.4)	11.7
Balance, December 31, 2018	$ 12.3	$ (17.9)	$ (2.3)	$ (7.9)

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

11. Stockholders' Equity (Continued)

	Defined Benefit Pension Plan[(1)]	Foreign Currency Translation Losses	Unrealized Gains and (Losses) on Available-for-Sale Securities	Total
Balance, January 1, 2017	$ 1.3	$ (18.1)	$	$ (16.8)
Other comprehensive (loss) income before reclassifications	(1.7)	0.2	(1.9)	(3.4)
Amounts reclassified from accumulated other comprehensive income	0.6			0.6
Net current-period other comprehensive (loss) income	(1.1)	0.2	(1.9)	(2.8)
Balance, December 31, 2017	$ 0.2	$ (17.9)	$ (1.9)	$ (19.6)

(1) Refer to Note 13 *Employee Benefit Plans Supplemental Executive Retirement Plan*, which identifies the captions within our consolidated statement of operations where reclassification adjustments were recognized and their associated tax impact.

12. Income Taxes

Tax Reform has multiple provisions that impacted our tax expense. The significant impacts were a reduction in the U.S. federal corporate tax rate from 35 percent to 21 percent, additional limitations on deductions for executive compensation, a reduction of the Orphan Drug Credit, repeal of the Section 199 deduction for domestic manufacturing activities, and the introduction of the foreign derived intangible income deduction.

On December 22, 2017, the SEC staff issued Staff Accounting Bulletin No. 118 to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed in reasonable detail to complete the accounting for certain income tax effects of Tax Reform. As a result of changes under Tax Reform, we recognized a provisional amount of $71.0 million of additional tax expense in our consolidated financial statements for the year ended December 31, 2017. The additional tax expense was primarily due to the revaluing of our ending net deferred tax assets at December 31, 2017 because of the reduction in the U.S. corporate income tax rate under Tax Reform. The measurement period prescribed under SAB 118 ended on December 22, 2018 and our analysis and accounting for Tax Reform has been completed as of this date. We recognized a reduction of tax expense of $1.8 million for the year ended December 31, 2018 due to refinements that were made during the measurement period to the calculation of the foreign elements of Tax Reform.

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

12. Income Taxes (Continued)

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

	Year Ended December 31,		
	2018	2017	2016
Current:			
Federal	$ 136.6	$ 261.3	$ 311.9
State	17.4	23.9	24.1
Total current	154.0	285.2	336.0
Deferred			
Federal	12.7	67.2	8.3
State	3.0	(0.8)	2.2
Total deferred	15.7	66.4	10.5
Total income tax expense	$ 169.7	$ 351.6	$ 346.5

Presented below is a reconciliation of income tax expense computed at the statutory federal tax rate of 21 percent in 2018 and 35 percent in both 2017 and 2016 to income tax expense as reported (in millions):

	Year Ended December 31,		
	2018	2017	2016
Federal taxes at the statutory rate	$ 159.4	$ 269.2	$ 371.1
State taxes, net of federal benefit	15.3	14.2	17.1
General business credits	(14.9)	(15.1)	(10.5)
Change in valuation allowance for investments	11.2	17.5	1.1
Nondeductible compensation expense	2.1	1.8	(11.4)
Impact of windfall tax benefits upon exercise of stock options	(1.9)	(4.5)	
Tax reform	(1.8)	71.0	
Other	0.3	1.3	1.1
Section 199 deduction		(22.8)	(22.0)
Nondeductible portion of DOJ Settlement		19.0	
Total income tax expense	$ 169.7	$ 351.6	$ 346.5

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

12. Income Taxes (Continued)

Components of the net deferred tax assets are as follows (in millions):

	As of December 31,	
	2018	**2017**
Deferred tax assets:		
Nonqualified stock options	$ 43.2	$ 34.3
Intangible assets	36.5	24.6
NOLs	34.3	2.4
Impairments	23.1	11.6
Other	20.7	10.0
STAP Awards	13.8	47.7
SERP	10.7	12.6
Reserves	9.3	6.2
Total deferred tax assets	191.6	149.4
Deferred tax liabilities:		
Plant and equipment principally due to differences in depreciation	(20.2)	(13.6)
Basis differences in foreign entities	(24.8)	
Other	(8.3)	(5.5)
Net deferred tax assets before valuation allowance	138.3	130.3
Valuation allowance	(42.6)	(16.9)
Net deferred tax assets	$ 95.7	$ 113.4

Unrecognized tax benefits as of December 31, 2018 and 2017, were $0.5 million, and included $0.3 million of tax benefits that, if recognized, would impact our ETR. We record interest and penalties related to uncertain tax positions as a component of income tax expense. As of December 31, 2018 and 2017, we have not accrued any material interest expense related to uncertain tax positions. We are unaware of any material positions for which it is reasonably possible that the total amounts of unrecognized tax benefits will significantly increase or decrease within the next twelve months.

We are subject to federal and state taxation in the United States and various foreign jurisdictions. We are no longer subject to income tax examinations by the Internal Revenue Service and all other major jurisdictions for tax years prior to 2011. At December 31, 2018, we have gross federal, foreign and state net operating loss carryforwards of $15.9 million, $133.1 million and $68.0 million, respectively, which will either expire at various dates beginning in 2030 or have no expiration date. We expect that a significant amount of these carryforwards will expire unused, so we have established valuation allowances for the related deferred tax assets. Certain of our investments in privately-held companies have been impaired and have associated deferred tax assets. We expect that the benefit of any potential tax losses related to the impairments will ultimately not be recognized due to their capital nature, so we have established valuation allowances for the full amount of the deferred tax assets.

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

13. Employee Benefit Plans

Supplemental Executive Retirement Plan

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

Participants who retire at age 60 or older are eligible to receive either monthly payments or a lump sum payment based on an average of their total gross base salary over the last 36 months of active employment, subject to certain adjustments. Related benefit payments commence on the first day of the sixth month after retirement. Participants who elect to receive monthly payments will continue to receive payments through the remainder of their life. Alternatively, participants who elect to receive a lump sum distribution will receive a payment equal to the present value of the estimated monthly payments that would have been received upon retirement. As of December 31, 2018 and 2017, all SERP participants had elected to receive a lump sum distribution. Participants who terminate employment for any reason other than death, disability, or change in control prior to age 60 will not be entitled to receive any benefits under the SERP.

Because we do not fund the SERP, we recognize a liability equal to the projected benefit obligation as measured at the end of each fiscal year.

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

	Year Ended December 31,	
	2018	2017
Projected benefit obligation at the beginning of the year	$ 55.9	$ 49.5
Service cost	2.4	2.2
Interest cost	1.6	1.6
Benefits paid	(0.2)	
Net actuarial (gain) loss[1]	(12.9)	2.6
Projected benefit obligation at the end of the year	$ 46.8	$ 55.9
Amount included in Other current liabilities[2]	$ 19.9	$ 16.4
Amount included in Other non-current liabilities	$ 26.9	$ 39.5

(1) During the fourth quarter of 2018, a participant in the SERP departed before retirement age under the terms of the SERP. As a result, we recorded a $7.0 million reduction to the benefit obligation as of December 31, 2018.

(2) This amount represents the benefit obligation due to participants who are eligible to retire and whose benefit payments could commence within one year of the respective balance sheet date.

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

13. Employee Benefit Plans (Continued)

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

	Year Ended December 31,	
	2018	**2017**
Discount rate	3.92%	3.36%
Salary increases	4.00%	4.00%
Lump-sum distribution rate	4.50%	3.75%

The components of net periodic pension cost recognized on our consolidated statements of operations consisted of the following (in millions):

	Year Ended December 31,		
	2018	**2017**	**2016**
Service cost	$ 2.4	$ 2.2	$ 2.7
Interest cost	1.6	1.6	1.5
Amortization of prior service cost	1.5	1.5	1.4
Amortization of net actuarial gain	(0.2)	(0.6)	(0.4)
Total	$ 5.3	$ 4.7	$ 5.2

For the year ended December 31, 2018, the service cost component is reported within "Operating expenses" and the other components are reported in "Other, net" on the consolidated statements of operations. For the years ended December 31, 2017 and 2016, all components of net periodic pension cost are reported within "Operating expenses" on the consolidated statements of operations. We did not reclassify prior year amounts to conform with current year presentation as these amounts were not material to our financial statements. See Note 3 *Recently Issued Accounting Standards* for further discussion of our adoption of ASC 2017-07.

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

	Year Ended December 31,		
	2018	**2017**	**2016**
Net actuarial gain (loss)	$ 12.7	$ (3.2)	$ 11.0
Prior service cost (benefit)	1.5	1.5	(0.6)
Total recognized in other comprehensive income (loss)	14.2	(1.7)	10.4
Tax (expense) benefit	(2.1)	0.6	(3.8)

Total, net of tax	$ 12.1	$ (1.1)	$ 6.6

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

13. Employee Benefit Plans (Continued)

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

	Year Ended December 31,		
	2018	2017	2016
Net actuarial gain	$ (19.3)	$ (6.6)	$ (9.8)
Prior service cost	4.7	6.2	7.7
Total included in accumulated other comprehensive loss	(14.6)	(0.4)	(2.1)
Tax expense	2.3	0.2	0.8
Total, net of tax	$ (12.3)	$ (0.2)	$ (1.3)

Estimated amounts included in accumulated other comprehensive loss as of December 31, 2018, that are expected to be recognized as components of net periodic pension cost on our consolidated statements of operations for the year ended December 31, 2019, comprise the following (in millions):

Amortization of prior service cost	$ 1.5
Amortization of net actuarial gain	(2.4)
Total	$ (0.9)

The accumulated benefit obligation, a measure that does not consider future increases in participants' salaries, was $39.8 million and $44.8 million at December 31, 2018 and 2017, respectively.

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

Year Ended December 31,	
2019	$ 19.9
2020	
2021	
2022	
2023	5.2
Thereafter	51.6
Total	$ 76.7

Employee Retirement Plan

We maintain a Section 401(k) Salary Reduction Plan which is open to all eligible full-time employees. Under the 401(k) Plan, eligible employees can make pre-tax or after-tax contributions up to statutory limits. Currently, we make discretionary matching contributions to the 401(k) Plan equal to 40 percent of a participant's elected salary deferral. Matching contributions vest immediately for participants who have been employed for three years; otherwise, matching contributions vest annually, in one-third increments over a three-year period until the three-year employment requirement has been met.

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

14. Commitments and Contingencies

Operating Leases

We lease facilities and equipment under operating lease arrangements that have terms expiring at various dates through 2024. Certain lease arrangements include renewal options and escalation clauses. In addition, various lease agreements to which we are party require that we comply with certain customary covenants throughout the term of these leases. If we are unable to comply with these covenants and cannot reach a satisfactory resolution in the event of noncompliance, these agreements could terminate.

Future minimum lease payments under non-cancelable operating leases as of December 31, 2018, are as follows (in millions):

Year Ending December 31,	
2019	$ 4.7
2020	2.3
2021	1.9
2022	1.4
2023	0.6
Thereafter	0.6
Total	$ 11.5

Total rent expense was $4.2 million, $4.8 million and $4.4 million for the years ended December 31, 2018, 2017 and 2016, respectively.

Milestone Payments and Royalty Obligations

We are party to certain license agreements and acquisition agreements pursuant to which we have in-licensed or acquired intellectual property rights covering our commercial and/or development-stage products. Generally, these agreements require that we make milestone payments in cash upon the achievement of certain product development and commercialization goals and payments of royalties upon commercial sales. The following table outlines our financial obligations under certain of these agreements:

Counterparty	**Relevant Product**	**Our Financial Obligation**
Supernus Pharmaceuticals, Inc.	Orenitram	Single-digit royalty on net product sales of Orenitram, through the second quarter of 2026
Lilly	Adcirca	Five percent royalty on net product sales of Adcirca through November 2017; from December 1, 2017 through December 31, 2020, ten percent royalty on net sales, plus milestone payments of $325,000 for each $1,000,000 in net product sales

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

14. Commitments and Contingencies (Continued)

Counterparty	Relevant Product	Our Financial Obligation
The Scripps Research Institute	Unituxin	One percent royalty on net product sales of Unituxin
Toray	Esuberaprost	Single-digit royalty on net product sales of esuberaprost, certain developmental milestone payments and additional contingent milestone payments in the event we do not achieve certain clinical and regulatory events by certain dates
Medtronic	Implantable System for Remodulin	Ten percent royalty on net product sales of Remodulin delivered via the Implantable System for Remodulin. Reimbursement of Medtronic's development costs and costs incurred in providing commercialization support
DEKA	RemUnity	Product fees and single-digit royalties on net product sales of the RemUnity system and on net sales of Remodulin for use with the system; reimbursement of DEKA's development costs
Samumed	SM04646	Low double-digit royalties on SM04646 net product sales and up to $340.0 million in developmental milestone payments
MannKind	Treprostinil Technosphere	Low double-digit royalties on net product sales of Treprostinil Technosphere and up to $50.0 million in developmental milestone payments
Arena	Ralinepag	Low double-digit, tiered royalties on net product sales of ralinepag (any route of administration); a one-time payment of $250.0 million upon FDA approval of an inhaled formulation of ralinepag to treat PAH; and a one-time payment of $150.0 million upon approval in certain non-US jurisdictions of an oral version of ralinepag to treat any indication

Acquisition Agreement

Under our Merger Agreement with SteadyMed, we are obligated to pay $75.0 million in aggregate additional consideration to former SteadyMed securityholders if 3,000 patients initiate treatment using

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

14. Commitments and Contingencies (Continued)

SteadyMed's Trevyent product on a commercial basis on or before August 30, 2023. For further details, see Note 4 *Acquisition.*

15. Segment Information

We currently operate as one operating segment with a focus on the development and commercialization of products to address the unmet needs of patients with chronic and life-threatening conditions. Our Chief Executive Officer, as our chief operating decision maker, manages and allocates resources to the operations of our company on a consolidated basis. This enables our Chief Executive Officer to assess the overall level of resources available and how to best deploy these resources across functions, therapeutic areas, and research and development projects that are in line with our long-term company-wide strategic goals.

Net product sales, cost of product sales and gross profit for each of our commercial products were as follows (in millions):

	Remodulin	Tyvaso	Adcirca	Orenitram	Unituxin	Total
Year Ended December 31, 2018						
Net product sales	$ 599.0	$ 415.2	$ 323.7	$ 205.1	$ 84.8	$ 1,627.8
Cost of product sales	14.1	17.3	139.8	13.2	14.3	198.7
Gross profit	$ 584.9	$ 397.9	$ 183.9	$ 191.9	$ 70.5	$ 1,429.1
Year Ended December 31, 2017						
Net product sales	$ 670.9	$ 372.9	$ 419.7	$ 185.8	$ 76.0	$ 1,725.3
Cost of product sales	15.9	18.5	43.1	15.3	12.9	105.7
Gross profit	$ 655.0	$ 354.4	$ 376.6	$ 170.5	$ 63.1	$ 1,619.6
Year Ended December 31, 2016						
Net product sales	$ 602.3	$ 404.6	$ 372.2	$ 157.2	$ 62.5	$ 1,598.8
Cost of product sales	10.5	19.6	21.4	13.7	7.5	72.7
Gross profit	$ 591.8	$ 385.0	$ 350.8	$ 143.5	$ 55.0	$ 1,526.1

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

Year Ended December 31,	2018	2017	2016
United States	$ 1,528.2	$ 1,536.8	$ 1,461.9
Rest-of-World[(1)]	99.6	188.5	136.9
Total	$ 1,627.8	$ 1,725.3	$ 1,598.8

(1) Primarily Europe.

We recorded revenue from two specialty pharmaceutical distributors comprising 51 percent and 18 percent of total revenues in 2018, 46 percent and 15 percent of total revenues in 2017, and 50 percent and 14 percent of total revenues in 2016, respectively. All of our revenues for Adcirca are distributed through Lilly's pharmaceutical wholesaler network.

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

15. Segment Information (Continued)

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

Year Ended December 31,	2018	2017	2016
United States	$ 684.0	$ 544.5	$ 481.1
Rest-of-World	15.7	1.2	8.2
Total	$ 699.7	$ 545.7	$ 489.3

16. Quarterly Financial Information (Unaudited)

Summarized quarterly financial information for each of the years ended December 31, 2018 and 2017 are as follows (in millions, except per share amounts):

	Quarter Ended			
	December 31, 2018	September 30, 2018	June 30, 2018	March 31, 2018
Total revenues	$ 381.4	$ 412.7	$ 444.5	$ 389.2
Cost of product sales	31.9	51.9	61.7	53.2
Gross profit	349.5	360.8	382.8	336.0
Net income[1]	65.3	106.5	172.9	244.5
Net income per share basic	$ 1.50	$ 2.44	$ 4.01	$ 5.65
Net income per share diluted	$ 1.48	$ 2.42	$ 3.98	$ 5.57

	Quarter Ended			
	December 31, 2017	September 30, 2017	June 30, 2017	March 31, 2017
Total revenues	$ 464.7	$ 445.5	$ 444.6	$ 370.5
Cost of product sales	53.0	19.5	18.9	14.3
Gross profit	411.7	426.0	425.7	356.2
Net income (loss)[2]	19.0	276.3	(56.0)	178.6
Net income (loss) per share basic	$ 0.44	$ 6.37	$ (1.25)	$ 4.01
Net income (loss) per share diluted	$ 0.43	$ 6.27	$ (1.25)	$ 3.89

(1) Operating results for the quarters ended December 31, 2018, September 30, 2018, June 30, 2018 and March 31, 2018 included $(10.3) million, $24.8 million, $2.1 million and $(88.7) million, net of tax, for STAP related share-based compensation (benefit) expense, respectively.

(2) Operating results for the quarters ended December 31, 2017, September 30, 2017, June 30, 2017 and March 31, 2017 included $66.2 million, $(24.1) million, $(9.4) million and $(15.6) million, net of tax, for STAP related share-based compensation expense (benefit), respectively.

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UNITED THERAPEUTICS CORPORATION

Notes to Consolidated Financial Statements (Continued)

17. Litigation

Department of Justice Subpoena

In May 2016, we received a subpoena from the U.S. Department of Justice (DOJ) requesting documents regarding our support of 501(c)(3) organizations that provide financial assistance to patients. Other companies received similar inquiries as part of a DOJ investigation regarding whether that support may violate the Federal Anti-Kickback Statute and the Federal False Claims Act. On December 19, 2017, we entered into a civil Settlement Agreement with the DOJ and the Office of Inspector General (OIG) of the Department of Health and Human Services (collectively the "United States Government"). The Settlement Agreement is neither an admission of facts nor liability, nor a concession by the United States Government that its contentions are not well-founded. Under the Settlement Agreement, we paid to the United States Government the sum of approximately $210.0 million. During 2017, we recorded a $210.0 million accrual related to this matter. In connection with the civil settlement, we also entered into a Corporate Integrity Agreement with the OIG, effective as of December 18, 2017, which requires us to maintain our corporate compliance program and to undertake a set of defined corporate integrity obligations for a period of five years, ending in December 2022.

18. Subsequent Events

Arena Pharmaceuticals, Inc.

On November 15, 2018, we entered into a global license agreement with Arena related to ralinepag, a next-generation, oral, selective and potent prostacyclin receptor agonist in development for the treatment of PAH. On January 24, 2019, in connection with the closing of the transactions contemplated by the license agreement, (1) Arena granted to us perpetual, irrevocable and exclusive rights throughout the universe to develop, manufacture and commercialize ralinepag; (2) Arena transferred to us certain other assets related to ralinepag, including, among others, related domain names and trademarks, permits, certain contracts, inventory, regulatory documentation, Investigational New Drug (IND) Application No. 109021 (related to ralinepag) and non-clinical, pre-clinical and clinical trial data; (3) we assumed certain limited liabilities from Arena, including, among others, all obligations arising after the closing under the assumed contracts and the IND described above; and (4) we paid Arena an upfront payment of $800.0 million, which was expensed in the first quarter of 2019. We will also pay Arena (1) a one-time payment of $250.0 million for the first, if any, marketing approval we receive in the United States for an inhaled version of ralinepag to treat pulmonary arterial hypertension; (2) a one-time payment of $150.0 million for the first, if any, marketing approval we receive in any of Japan, France, Italy, the UK, Spain or Germany for an oral version of ralinepag to treat any indication; and (3) low double-digit, tiered royalties on net sales of any pharmaceutical product containing ralinepag as an active ingredient, subject to certain adjustments for third party license payments. We expensed the $800.0 million upfront payment to Arena as acquired in-process research and development and will include within research and development expenses on our consolidated statements of operations in the first quarter of 2019.

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United Therapeutics Corporation
Schedule II Valuation and Qualifying Accounts
Years Ended December 31, 2018, 2017 and 2016
(In millions)

	Valuation Allowance on Deferred Tax Assets				
	Balance at Beginning of Year	Additions Charged to Expense	Other Additions	Deductions	Balance at End of Year
Year Ended December 31, 2018[1]	$ 16.9	$ 14.9	$ 11.0	$ (0.2)	$ 42.6
Year Ended December 31, 2017[2]	$ 4.7	$ 11.8	$ 1.6	$ (1.2)	$ 16.9
Year Ended December 31, 2016	$ 3.4	$ 1.3	$	$	$ 4.7

(1) Other Additions consists of valuation allowances related to the acquisition of SteadyMed, SteadyMed dual consolidated loss limitation, and changes in deferred taxes related to our investment in a variable interest entity that were not charged to expense.

(2) Other Additions consists of valuation allowances related to our investment in a variable interest entity.

	Inventory Reserves			
	Balance at Beginning of Year	Additions Charged to Expense	Deductions	Balance at End of Year
Year Ended December 31, 2018	$ 25.1	$ 11.7	$ (10.8)	$ 26.0
Year Ended December 31, 2017	$ 17.5	$ 12.1	$ (4.5)	$ 25.1
Year Ended December 31, 2016	$ 12.1	$ 8.2	$ (2.8)	$ 17.5

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with participation of our Chairman and Chief Executive Officer and Chief Financial Officer and Treasurer, 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, 2018. Based on that evaluation, our Chairman and Chief Executive Officer and Chief Financial Officer and Treasurer concluded that our disclosure controls and procedures were effective as of December 31, 2018. As permitted by the SEC's guidance with respect to newly acquired entities, the scope of management's assessment of the effectiveness of the design and operation of our disclosure controls and procedures includes all of our consolidated operations except for those disclosure controls and procedures of SteadyMed that are subsumed by internal control over financial reporting.

Management's Report on Internal Control Over Financial Reporting

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

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2018, based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control Integrated Framework (2013)*. 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, 2018, our internal control over financial reporting was effective.

We are in the process of evaluating the existing controls and procedures of SteadyMed and integrating SteadyMed into our internal control over financial reporting. In accordance with SEC Staff guidance permitting a company to exclude an acquired business from management's assessment of the effectiveness of internal control over financial reporting for the year in which the acquisition is completed, we have excluded SteadyMed from our assessment of the effectiveness of internal control over financial reporting as of December 31, 2018. SteadyMed represented four percent of our total assets as of December 31, 2018, and zero percent of our revenues and one percent of our operating expenses for the year ended December 31, 2018.

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 Report.

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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 Report 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, 2018 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting. We are currently evaluating SteadyMed's internal control over financial reporting. Any changes resulting from this evaluation that materially affect or are reasonably likely to materially affect our internal control over financial reporting will be disclosed as required by applicable law.

ITEM 9B. OTHER INFORMATION

On February 25, 2019, we entered into a commercialization agreement with Medtronic, Inc. relating to the commercialization of the Implantable System for Remodulin in the United States. For details, see *Item I Business Patents and Other Proprietary Rights, Strategic Licenses and Market Exclusivity Medtronic Agreements*.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information as to the individuals serving on our board of directors is set forth below under the heading *Board of Directors*. Additional information required by Item 10 regarding nominees and directors appearing under Proposal No. 1: *Election of Directors* in our definitive proxy statement for our 2019 annual meeting of shareholders currently scheduled for June 26, 2019 (the 2019 Proxy Statement) is hereby incorporated herein by reference. Information regarding our executive officers appears in *Item 1* of this Report 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 2019 Proxy Statement is hereby incorporated herein by reference.

Information appearing under the heading *Section 16(a) Beneficial Ownership Reporting Compliance* in our 2019 Proxy Statement is hereby incorporated herein by reference.

We have a written Code of Conduct and Business 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 Business Ethics is available on our Internet website at *http://ir.unither.com/corporate-governance*. A copy of the Code of Conduct and Business Ethics will be provided free of charge by making a written request and mailing it to our corporate headquarters offices to the attention of the Investor Relations Department. If any amendment to, or a waiver from, a provision of the Code of Conduct and Business Ethics that applies to the principal executive officer, principal financial officer and principal accounting officer is made, we intend to post such information on our Internet website within four business days at *www.unither.com*.

Board of Directors

Christopher Causey, M.B.A.

Principal, Causey Consortium

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Raymond Dwek, F.R.S.

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

Richard Giltner

Former portfolio manager at Lyxor Asset Management, an asset management group at Société Générale, S.A.

Katherine Klein, Ph.D.

Vice-Dean and Professor, The Wharton School of the University of Pennsylvania

Ray Kurzweil

Director of Engineering, Google Inc.

Nilda Mesa, J.D.

Adjunct Professor and Director of the Urban Sustainability and Equity Planning Program, Columbia University

Judy D. Olian, Ph.D.

President, Quinnipiac University

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

Founding Principal, Patusky Associates, LLC

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

Chairman and Chief Executive Officer of United Therapeutics

Louis Sullivan, M.D.

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

Tommy Thompson, J.D.

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

ITEM 11. EXECUTIVE COMPENSATION

Information concerning executive compensation required by Item 11 will appear under the headings *Director Compensation*, *Compensation Discussion and Analysis, Summary Compensation Table and Grants of Plan-Based Awards in 2018, Narratives to Summary Compensation Table and Grants of Plan-Based Awards Table, Summary of Terms of Plan-Based Awards, Supplemental Executive Retirement Plan, Rabbi Trust, Potential Payments Upon Termination or Change in Control, and Director Compensation* in our 2019 Proxy Statement and is incorporated herein by reference.

Information concerning the Compensation Committee required by Item 11 will appear under the heading *Compensation Committee Report* in our 2019 Proxy Statement and is incorporated herein by reference.

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

The information regarding beneficial ownership of our common stock required by Item 12 will appear under *Beneficial Ownership of Common Stock* in our 2019 Proxy Statement and is incorporated herein by reference.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table presents information as of December 31, 2018, regarding our securities authorized for issuance under equity compensation plans:

Plan category	Number of securities to be issued upon exercise of outstanding options and restricted stock units (a)[2]	Weighted average exercise price of outstanding options (b)[3]	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)[4]
Equity compensation plan approved by security holders[1]	6,486,058	$ 120.78	7,080,024
Total	6,486,058	$ 120.78	7,080,024

(1) All outstanding stock options were issued under our two equity incentive plans approved by security holders in 1999 (the 1999 Plan) and 2015 (the 2015 Plan). All outstanding restricted stock units (RSUs) were issued under the 2015 Plan. In addition, our employees have outstanding rights to purchase our common stock at a discount as part of our Employee Stock Purchase Plan (ESPP). Information regarding these plans is contained in Note 10 *Share-Based Compensation* to our consolidated financial statements. Aside from stock options issued under the 1999 Plan, stock options and RSUs issued under the 2015 Plan, and shares issued under the ESPP, we do not have any outstanding stock options, warrants or rights that are outstanding or available for issuance as described in Regulation S-K Item 201(d). No further awards will be issued under the 1999 Plan.

(2) Column (a) includes 6,299,803 shares of our common stock issuable upon the exercise of outstanding stock options issued under the 1999 and 2015 Plan and 186,255 shares issuable upon the vesting of outstanding RSUs issued under the 2015 Plan. The 2015 Plan uses a share counting formula for determining the number of shares available for issuance under the plan. In accordance with this formula, each option issued under the 2015 Plan counts as one share, while each RSU issued under the 2015 Plan counts as 2.14 shares. The number under column (a) represents the actual number of shares issuable under our outstanding awards without giving effect to the share counting formula.

(3) Column (b) represents the weighted-average exercise price of the outstanding stock options only. The outstanding RSUs are not included in this calculation because they do not have an exercise price.

(4) Column (c) includes 4,335,439 and 2,744,585 of shares available for future issuance under the 2015 Plan and ESPP, respectively. Under the ESPP, employees may purchase shares based upon a 6-month offering period at an amount equal to the lesser of (1) 85 percent of the closing market price of the Common Stock on the first day of the offering period, or (2) 85 percent of the closing market price of the Common Stock on the last day of the offering period. Refer to Note 10 *Share-Based Compensation Employee Stock Purchase Plan* for more information. The number under column (c) assumes that all 186,255 outstanding RSUs included in column (a) vest. Each RSU is only counted as one share in column (a) since only one share is issuable upon vesting.

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However, if any RSU does not vest, the number of shares available for future issuance will increase by 2.14 because of the share counting formula described in note (2) above.

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

Information concerning related party transactions and director independence required by Item 13 will appear under the headings *Other Matters Certain Relationships and Related Party Transactions, Board of Directors, Committees, Corporate Governance Director Independence and Committees of our Board of Directors* in our 2019 Proxy Statement and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Information required by Item 14 concerning the principal accounting fees paid by the Registrant and the Audit Committee's pre-approval policies and procedures, will appear under the heading *Report of the Audit Committee and Information on our Independent Auditors* in our 2019 Proxy Statement and is incorporated herein by reference.

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PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

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

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

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

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

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

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

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EXHIBIT INDEX

Exhibit No.	Description
2.1	Agreement and Plan of Merger, dated April 29, 2018, by and among United Therapeutics Corporation, SteadyMed and Daniel 24043 Acquisition Corp Ltd., incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed May 1, 2018.
2.2+	Exclusive License Agreement, dated as of November 15, 2018, by and between Arena Pharmaceuticals, Inc. and the Registrant, incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K filed January 25, 2019.
3.1	Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Registration Statement on Form S-1 (Registration No. 333-76409).
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K, filed on June 28, 2010.
3.3	Seventh Amended and Restated By-laws of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed on June 28, 2018.
3.4	Form of Certificate of Designation, Preferences and Rights of Series A Junior Participating Preferred Stock of the Registrant, incorporated by reference to Exhibit A to Exhibit 4 to the Registrant's Current Report on Form 8-K, filed December 18, 2000.
4.1	Reference is made to Exhibits 3.1, 3.2, 3.3 and 3.4.
10.1	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.
10.2**	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**	Amendment to Amended and Restated Executive Employment Agreement between the Registrant and Martine Rothblatt, Ph.D., dated as of January 1, 2015, incorporated by reference to Exhibit 10.1 to Registrant's Current Report on Form 8-K filed December 17, 2014.
10.4**	Employment Agreement, dated as of June 26, 2016, between the Registrant and Michael Benkowitz, incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed June 22, 2016.
10.5**	Change in Control Severance Agreement between the Registrant and Michael Benkowitz, dated as of February 14, 2012, incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed April 28, 2016.
10.6**	Employment Agreement, dated as of March 13, 2015, between the Registrant and James Edgemond, incorporated by reference to Exhibit 10.55 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2014.

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Exhibit No.	Description
10.7**	Amendment to Employment Agreement, dated as of October 25, 2016, between the Registrant and James Edgemond, incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2016.
10.8**	Change in Control Severance Agreement between the Registrant and James Edgemond, dated as of November 12, 2014, incorporated by reference to Exhibit 10.56 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2014.
10.9**	Employment Agreement dated as of June 16, 2001 between the Registrant and Paul 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.
10.10**	Amendment dated December 11, 2002 to Employment Agreement between the Registrant and Paul Mahon, incorporated by reference to Exhibit 10.43 of the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2002.
10.11**	Amendment dated December 29, 2004 to Employment Agreement between Paul A. Mahon and the Registrant dated June 16, 2001, as previously amended, incorporated by reference to Exhibit 10.4 of the Registrant's Current Report on Form 8-K filed on December 29, 2004.
10.12**	Amendment, dated as of July 31, 2006, to amended Employment Agreement, dated June 16, 2001, between Paul 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.
10.13**	Form of Amendment to Employment Agreement between the Registrant and Paul Mahon, 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.
10.14**	Form of Amendment to Employment Agreement between the Registrant and Paul Mahon, dated as of February 22, 2010, incorporated by reference to Exhibit 10.46 of the Registrant's Annual Report on Form 10-K for the year ended December 31, 2009.
10.15**	United Therapeutics Corporation Amended and Restated Equity Incentive Plan, as amended effective as of September 24, 2004, incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2004.
10.16**	First Amendment to the United Therapeutics Corporation Amended and Restated Equity Incentive Plan, effective as of June 2, 2015, incorporated by reference to Exhibit 10.6 to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015.
10.17**	Form of terms and conditions for awards granted to Employees by the Registrant under the Amended and Restated Equity Incentive Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on December 17, 2004.
10.18**	Form of terms and conditions for awards granted to Non-Employees by the Registrant under the Amended and Restated Equity Incentive Plan, incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on December 17, 2004.

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Exhibit No.	Description
10.19**	United Therapeutics Corporation Supplemental Executive Retirement Plan, effective as of July 1, 2006, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on May 4, 2006.
10.20	United Therapeutics Corporation Supplemental Executive Retirement Plan Rabbi Trust Document entered into on December 28, 2007, by and between the Registrant and Wilmington Trust Company, as trustee, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on December 28, 2007.
10.21**	United Therapeutics Corporation Share Tracking Awards Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008.
10.22**	First Amendment to the United Therapeutics Corporation Share Tracking Awards Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on September 18, 2009.
10.23**	Second Amendment to the United Therapeutics Corporation Share Tracking Awards Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on February 6, 2012.
10.24**	Form of terms and conditions for awards granted to non-employees by the Registrant under the United Therapeutics Corporation Share Tracking Awards Plan, incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008.
10.25**	Form of terms and conditions for awards granted to employees by the Registrant prior to January 1, 2010, under the United Therapeutics Corporation Share Tracking Awards Plan, incorporated by reference to Exhibit 10.3 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008.
10.26**	Form of terms and conditions for awards granted to employees by the Registrant on or after January 1, 2010, under the United Therapeutics Corporation Share Tracking Awards Plan, incorporated by reference to Exhibit 10.48 of the Registrant's Annual Report on Form 10-K for the year ended December 31, 2009.
10.27**	Form of terms and conditions for awards granted to employees on or after March 15, 2011 under the United Therapeutics Corporation 2011 Share Tracking Awards Plan and the United Therapeutics Corporation 2008 Share Tracking Awards Plan, incorporated by reference to Exhibit 10.2 of Registrant's Registration Statement on Form S-8 (Registration No. 333-173858) filed on May 2, 2011.
10.28**	Form of grant letter used by Registrant under the United Therapeutics Corporation Share Tracking Awards Plan, incorporated by reference to Exhibit 10.4 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008.
10.29	Stipulation of Settlement, dated October 25, 2010, among the parties to a derivative lawsuit against the directors and officers of the Registrant identified therein, incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2010.
10.30**	United Therapeutics Corporation 2011 Share Tracking Awards Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on March 18, 2011.

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Exhibit No.	Description
10.31**	First Amendment to the United Therapeutics Corporation 2011 Share Tracking Awards Plan, incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on February 6, 2012.
10.32**	Second Amendment to the United Therapeutics Corporation 2011 Share Tracking Awards Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2012.
10.33**	Third Amendment to the United Therapeutics Corporation 2011 Share Tracking Awards Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on February 4, 2013.
10.34**	Fourth Amendment to the United Therapeutics Corporation 2011 Share Tracking Awards Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on January 31, 2014.
10.35**	Form of terms and conditions for awards granted to non-employees by the Registrant on or after March 15, 2011 under the United Therapeutics Corporation Share Tracking Awards Plan or the United Therapeutics Corporation 2011 Share Tracking Awards Plan, incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed on March 18, 2011.
10.36**	Form of grant letter used by Registrant under the United Therapeutics Corporation 2011 Share Tracking Awards Plan, incorporated by reference to Exhibit 10.4 of the Registrant's Current Report on Form 8-K filed on March 18, 2011.
10.37**	United Therapeutics Corporation Employee Stock Purchase Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2012.
10.38**	United Therapeutics Corporation Amended and Restated 2015 Stock Incentive Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on June 28, 2018.
10.39**	Form of Grant Notice and Standard Terms and Conditions for Non-Qualified Stock Options Granted to Non-Employee Directors under the United Therapeutics Corporation 2015 Stock Incentive Plan, incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on June 29, 2015.
10.40**	Form of Grant Notice and Standard Terms and Conditions for Non-Qualified Stock Options Granted to Certain Executives under the United Therapeutics Corporation 2015 Stock Incentive Plan, incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed on June 29, 2015.
10.41**	Form of Grant Notice and Standard Terms and Conditions for Non-Qualified Stock Options Granted to Employees under the United Therapeutics Corporation 2015 Stock Incentive Plan, incorporated by reference to Exhibit 10.4 of the Registrant's Current Report on Form 8-K filed on June 29, 2015.
10.42**	Form of Grant Notice and Standard Terms and Conditions for Restricted Stock Units Granted to Non-Employee Directors under the United Therapeutics Corporation 2015 Stock Incentive Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016.

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Exhibit No.	Description
10.43**	Form of Grant Notice and Standard Terms and Conditions for Non-Qualified Stock Options Granted to Employees (Performance Vesting) under the United Therapeutics Corporation 2015 Stock Incentive Plan, incorporated by reference to Exhibit 10.59 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2017.
10.44**	Form of Grant Notice and Standard Terms and Conditions for Restricted Stock Units Granted to Employees under the United Therapeutics Corporation 2015 Stock Incentive Plan, incorporated by reference to Exhibit 10.45 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2017.
10.45**(***)	Form of Grant Notice and Standard Terms and Conditions for Stock Options Granted to Certain Executives under the United Therapeutics Corporation Amended and Restated 2015 Stock Incentive Plan (applicable to 2019-2022 Stock Options).
10.46*	Wholesale Product Purchase Agreement, dated January 1, 2018, by and between Priority Healthcare Distribution, Inc., doing business as CuraScript SD Specialty Distribution, and the Registrant, incorporated by reference to Exhibit 10.51 to the Registrant's Quarterly Report on Form 10-K for the year ended December 31, 2017.
10.47***	First Amendment to Wholesale Product Purchase Agreement, dated November 27, 2018, by and between Priority Healthcare Distribution, Inc., doing business as CuraScript SD Specialty Distribution, and the Registrant.
10.48***	Second Amendment to Wholesale Product Purchase Agreement, dated February 1, 2019, by and between Priority Healthcare Distribution, Inc., doing business as CuraScript SD Specialty Distribution, and the Registrant.
10.49***+	Third Amendment to Wholesale Product Purchase Agreement, dated as of March 1, 2019, by and between Priority Healthcare Distribution, Inc., doing business as CuraScript SD Specialty Distribution, and the Registrant.
10.50	Specialty Pharmacy Network Agreement, dated as of January 1, 2018, between the Registrant and Accredo Health Group, Inc., incorporated by reference to Exhibit 10.52 to the Registrant's Quarterly Report on Form 10-K for the year ended December 31, 2017.
10.51*	Settlement Agreement, dated September 29, 2015, between the Registrant and Sandoz Inc., incorporated by reference to Exhibit 10.2 to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015.
10.52	Credit Agreement, dated as of June 27, 2018, among the Registrant, certain of its subsidiaries party thereto, as guarantors, the lenders referred to therein and Wells Fargo Bank, National Association, as administrative agent and swingline lender, incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on June 28, 2018.
10.53	Settlement Agreement, dated December 19, 2017, among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General of the Department of Health and Human Services, and the Registrant, incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on December 20, 2017.

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Exhibit No.	Description
10.54	Corporate Integrity Agreement, dated December 18, 2017, between the Registrant and the Office of Inspector General of the Department of Health and Human Services, incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on December 20, 2017.
10.55***	Commercialization Agreement, dated February 25, 2019, by and between the Registrant and Medtronic Inc.
21***	Subsidiaries of the Registrant.
23.1***	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.
31.1***	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.
31.2***	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934.
32.1***	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2***	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101***	The following financial information from our Annual Report on Form 10-K for the year ended December 31, 2018, filed with the SEC on February 27, 2019, formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets as of December 31, 2018 and 2017, (ii) Consolidated Statements of Operations for each of three years in the period ended December 31, 2018, (iii) Consolidated Statements of Comprehensive Income for each of the three years in the period ended December 31, 2018, (iv) Consolidated Statements of Stockholders' Equity for each of the three years in the period ended December 31, 2018, (v) Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2018, and (vi) Notes to Consolidated Financial Statements.

+ Confidential treatment has been requested with respect to certain portions of this exhibit pursuant to Rule 24b-2 of the Securities Act of 1934, as amended. The omitted portions of this document have been filed with the Securities and Exchange Commission. Exhibits and schedules to this agreement have been omitted pursuant to the rules of the Securities and Exchange Commission. We will submit copies of such exhibits and schedules to the Securities and Exchange Commission upon request.

* Confidential treatment has been granted with respect to certain portions of this exhibit pursuant to Rule 406 of the Securities Act of 1933, as amended or Rule 24b-2 of the Securities Act of 1934, as amended. The omitted portions of this document have been filed with the Securities and Exchange Commission.

** Designates management contracts and compensation plans.

*** Filed herewith.

Note: Except as otherwise noted above, all exhibits incorporated by reference to the Registrant's previously filed reports with the Securities and Exchange Commission are filed under File No. 000-26301.

ITEM 16. FORM 10-K SUMMARY

None.

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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 and Chief Executive Officer

February 27, 2019

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Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signatures	Title	Date
/s/ MARTINE A. ROTHBLATT Martine A. Rothblatt	Chairman and Chief Executive Officer (Principal Executive Officer)	February 27, 2019
/s/ JAMES C. EDGEMOND James C. Edgemond	Chief Financial Officer and Treasurer (Principal Financial Officer and Principal Accounting Officer)	February 27, 2019
/s/ CHRISTOPHER CAUSEY Christopher Causey	Director	February 27, 2019
/s/ RAYMOND DWEK Raymond Dwek	Director	February 27, 2019
/s/ RICHARD GILTNER Richard Giltner	Director	February 27, 2019
/s/ KATHERINE KLEIN Katherine Klein	Director	February 27, 2019
/s/ RAYMOND KURZWEIL Raymond Kurzweil	Director	February 27, 2019
/s/ NILDA MESA Nilda Mesa	Director	February 27, 2019
/s/ JUDY D. OLIAN Judy D. Olian	Director	February 27, 2019
/s/ CHRISTOPHER PATUSKY Christopher Patusky	Director	February 27, 2019

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Signatures	Title	Date
/s/ LOUIS W. SULLIVAN Louis W. Sullivan	Director	February 27, 2019
/s/ TOMMY G. THOMPSON Tommy Thompson	Director	February 27, 2019