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

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.
For the fiscal year ended December 31, 2025

OR

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

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

United Therapeutics Corporation

(Exact Name of Registrant as Specified in Its Charter)

Delaware	52-1984749
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
1000 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	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $.01 per share	UTHR	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 ☒ No ☐

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

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

Indicate by check mark whether the registrant has submitted electronically 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 ☒ No ☐

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	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the Common Stock held by non-affiliates of the registrant, based on the closing price on June 30, 2025, as reported by the Nasdaq Global Select Market was approximately $11,233,042,523.

The number of shares outstanding of the registrant's common stock, par value $0.01 per share, as of February 18, 2026, was 43,827,686.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for the registrant's 2026 annual meeting of shareholders scheduled to be held on June 26, 2026, are incorporated by reference in Part III of this Form 10-K.

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PART I

Item 1. Business

Overview

Founded by our Chairperson and Chief Executive Officer, Martine Rothblatt, to find a cure for her daughter's life-threatening rare disease, pulmonary arterial hypertension (**PAH**), United Therapeutics advances therapies for people living with serious diseases with unmet medical needs. Our mission is to transform the treatment of rare diseases and expand the availability of transplantable organs through innovative organ manufacturing technologies.

As a public benefit corporation (**PBC**), we aim to deliver meaningful impacts for our patients, our people, our shareholders, and other stakeholders. Our public benefit purpose, as outlined in our charter and approved by our shareholders, is *to provide a brighter future for patients through (a) the development of novel pharmaceutical therapies; and (b) technologies that expand the availability of transplantable organs*.

We market and sell the following commercial therapies in the United States to treat PAH:

- Tyvaso DPI® (treprostinil) Inhalation Powder (**Tyvaso DPI**);
- Tyvaso® (treprostinil) Inhalation Solution (**Nebulized Tyvaso**), which includes the Tyvaso Inhalation System;
- Remodulin® (treprostinil) Injection (**Remodulin**); and the Remunity® and RemunityPRO™ Pumps for Remodulin (**Remunity**);
- Orenitram® (treprostinil) Extended-Release Tablets (**Orenitram**); and
- Adcirca® (tadalafil) Tablets (**Adcirca**).

Tyvaso DPI and Nebulized Tyvaso are also approved by the U.S. Food and Drug Administration (**FDA**) to treat pulmonary hypertension associated with interstitial lung disease (**PH-ILD**).

In the United States, we also market and sell an oncology product, Unituxin® (dinutuximab) Injection (**Unituxin**), which is approved by the FDA for the treatment of high-risk neuroblastoma. Outside the United States, we derive revenues from sales of Nebulized Tyvaso, Remodulin, and Unituxin.

We also have products in development for PAH, idiopathic pulmonary fibrosis (**IPF**), and progressive pulmonary fibrosis (**PPF**), and other diseases with unmet medical needs.

Our principal executive offices are located at 1000 Spring Street, Silver Spring, Maryland 20910 and at 55 T.W. Alexander Drive, Durham, North Carolina 27713. 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.

Our Commercial Products

Our commercial product portfolio consists of the following:

Product	Mode of Delivery	Indication	Current Status	Our Territory
Tyvaso DPI	Inhaled dry powder via pre-filled, single-use cartridges	PAH and PH-ILD	Commercial sales in the U.S.	Worldwide
Nebulized Tyvaso	Inhaled solution via ultrasonic nebulizer	PAH and PH-ILD	Commercial sales in the U.S., Japan, and various other countries in Asia, the Middle East, and Latin America	Worldwide
Remodulin	Continuous subcutaneous and continuous intravenous	PAH	Commercial sales in the U.S., most of Europe*, Japan, and various other countries in Asia, the Middle East, and Latin America	Worldwide
Remunity and RemunityPRO Pumps for Remodulin	Continuous subcutaneous	PAH	Commercial sales in the U.S.	Worldwide
Orenitram	Oral tablets	PAH	Commercial sales in the U.S.	Worldwide
Unituxin	Intravenous	High-risk neuroblastoma	Commercial sales in the U.S., Canada, and Japan	Worldwide
Adcirca	Oral tablets	PAH	Commercial sales in the U.S.	United States

* Remodulin is marketed and sold in most of the major European markets other than the United Kingdom for both intravenous and subcutaneous administration. In the United Kingdom, Remodulin is sold on a named-patient basis only.

Products to Treat Pulmonary Hypertension

Pulmonary hypertension (**PH**) has been classified into five groups. PAH is designated as group 1 PH, which includes multiple etiologies such as idiopathic (meaning the cause is unknown) and heritable PAH, as well as PAH associated with connective tissue diseases. PH associated with lung disease, such as PH-ILD and pulmonary hypertension associated with chronic obstructive pulmonary disease (**PH-COPD**), has been classified as group 3 PH. In addition, patients with PAH are classified based on clinical severity, 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.

Most of our PH products were initially approved to treat only PAH. In March 2021, Nebulized Tyvaso was approved to treat PH-ILD in addition to PAH. In May 2022, we also obtained FDA approval of Tyvaso DPI to treat both PAH and PH-ILD. We are engaged in further research and development of additional indications for Nebulized Tyvaso to treat certain fibrotic lung conditions underlying PH-ILD. For further details, see *Research and Development* below.

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.

Current therapies approved by the FDA for PAH focus on four distinct molecular pathways: the prostacyclin pathway, the nitric oxide pathway, the endothelin pathway, and activin signaling pathway. The classes of drugs that target these pathways are:

- *Prostacyclin Analogues and IP Prostacyclin Receptor Agonists.* Patients with PAH have been shown to have reduced levels of prostacyclin, a naturally occurring molecule that relaxes the pulmonary blood vessels, prevents platelet aggregation, and inhibits the proliferation of smooth muscle cells in the pulmonary vessels. Drugs that mimic the action of prostacyclin, known as prostacyclin analogues, are established PAH treatments. Another class of therapy, called IP prostacyclin receptor agonists, also addresses PAH through the prostacyclin pathway. As compared with prostacyclin analogues, which broadly mimic the effect of prostacyclin, IP prostacyclin receptor agonists bind selectively to (and activate) the IP receptor, one of several prostacyclin receptors.
- *Phosphodiesterase Type 5 (**PDE-5**) Inhibitors and Soluble Guanylate Cyclase (**sGC**) Stimulators.* Patients with PAH have also been shown to have reduced levels of the enzyme responsible for producing nitric oxide, a naturally occurring

substance in the body that causes relaxation of the pulmonary blood vessels. Nitric oxide 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 nitric oxide. When nitric oxide 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 peptide 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 (**ERAs**).
- *Activin Signaling Inhibitors*. Activin signaling inhibitors aim to improve the balance between pro- and anti-proliferative signaling to regulate vascular cell proliferation underlying PAH. In March 2024, Merck & Co., Inc. (**Merck**) obtained FDA approval for the first activin signaling inhibitor, known as Winrevair® (sotatercept), to treat PAH, and launched sales of the product shortly thereafter.

Because any or all of these 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. Tyvaso DPI, Nebulized Tyvaso, Remodulin, and Orenitram are all formulations of treprostinil, a prostacyclin analogue, and Adcirca is a PDE-5 inhibitor.

PH-ILD is also a rare condition, impacting at least 30,000 patients in the United States.

Tyvaso DPI and Nebulized Tyvaso

Tyvaso was initially approved as a nebulized product by the FDA to treat PAH and was launched commercially in the United States in 2009. Following the successful *INCREASE* study of Nebulized Tyvaso in patients with PH-ILD, including patients with underlying idiopathic pulmonary fibrosis (**IPF**) and combined pulmonary fibrosis and emphysema, the FDA approved our efficacy supplement to the Nebulized Tyvaso new drug application (**NDA**) in March 2021. As a result, Nebulized Tyvaso's label was updated to include the PH-ILD indication. In May 2022, the FDA approved our dry powder formulation of inhaled treprostinil called Tyvaso DPI, for the treatment of both PAH and PH-ILD. We developed this product under an in-license from MannKind Corporation (**MannKind**) and launched this product commercially in the United States in June 2022.

We sell Tyvaso DPI and Nebulized Tyvaso to specialty pharmaceutical distributors in the United States. We recognized $1,878.2 million, $1,620.4 million, and $1,233.7 million in combined Tyvaso DPI and Nebulized Tyvaso net product sales, representing 59 percent, 56 percent, and 53 percent of our total revenues for the years ended December 31, 2025, 2024, and 2023, respectively. Nebulized Tyvaso is approved for PAH and PH-ILD in the United States and Japan, and it is also approved for PAH and/or PH-ILD in various countries in Asia, the Middle East, and Latin America. Tyvaso DPI is currently approved only in the United States.

Tyvaso DPI is a drug-device combination product that 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 to treat patients with diabetes. Tyvaso DPI is administered four times per day. We believe that Tyvaso DPI provides substantial lifestyle benefits to PAH and PH-ILD patients, as compared with Nebulized Tyvaso therapy, because it is: (1) less time-consuming to administer and easier to maintain, as the device is provided in pre-filled, single-use, multiple-strength, disposable cartridges, eliminating the need for cleaning and filling; and (2) mobile and more convenient, as the compact design of the inhaler and drug cartridges used with Tyvaso DPI enables the device to easily fit into the patient's pocket and the device does not require electricity to function.

Nebulized Tyvaso is administered four times a day using our proprietary Tyvaso Inhalation System, which consists of an ultrasonic nebulizer and related accessories. Dose titration is achieved by varying the number of breaths per treatment session typically starting at three breaths per session, and increasing the dose in three-breath increments during the titration process. A single ampule containing Nebulized Tyvaso solution is emptied into the Tyvaso Inhalation System once per day, so the Tyvaso Inhalation System only needs to be cleaned once daily. Nebulized Tyvaso is regulated by the FDA as a drug-device combination product approved under an NDA consisting of Tyvaso drug product and the Tyvaso Inhalation System.

Studies establishing the effectiveness of Nebulized Tyvaso to treat PAH included predominately PAH patients with functional class III symptoms (patients who may not have symptoms at rest but whose activities are greatly limited by shortness of breath, fatigue, or near fainting). Nebulized Tyvaso was generally well tolerated in these trials. The most common side effects were transient cough, headache, nausea, dizziness, and flushing. In January and June 2021, data from the *INCREASE* study of Nebulized Tyvaso for PH-ILD were published in the *New England Journal of Medicine* and *The Lancet Respiratory Medicine*, respectively.

Both Nebulized Tyvaso and Tyvaso DPI have no stated maximum dose; they may be titrated to an effective dose based on individual patient tolerability under the supervision of a health care provider.

Remodulin

Remodulin was approved by the FDA for subcutaneous and intravenous administration in 2002 and 2004, respectively, and has been sold commercially in the United States since 2002. We sell Remodulin to specialty pharmaceutical distributors in the United States and to pharmaceutical distributors internationally. We recognized $526.8 million, $538.1 million, and $494.8 million in Remodulin net product sales, representing 17 percent, 19 percent, and 21 percent of our total revenues for the years ended December 31, 2025, 2024, and 2023, 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 and commercialized for the treatment of PAH in most of Europe, Canada, Japan, and various other countries in Asia, the Middle East, and Latin America.

We believe that Remodulin has many qualities that make it an appealing alternative to competitive continuously infused PAH 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 under certain conditions and highly potent, which enables us to manufacture Remodulin in concentrated solutions. This allows therapeutic concentrations of Remodulin to be delivered at low flow rates via infusion pumps for both subcutaneous and intravenous infusion. Remodulin can be continuously infused for up to 72 hours before refilling the external infusion pump, or up to 48 hours for diluted Remodulin. This profile contrasts favorably with non-treprostinil based, continuously infused prostacyclin therapies on the market: Veletri® and generic epoprostenol.

Generic epoprostenol is not stable at room temperature (and therefore requires refrigeration or the use of cooling packs), but Veletri may be stable at room temperature depending on its concentration. Generic epoprostenol and Veletri have shorter half-lives than Remodulin, requiring mixing prior to pump refills. Neither of these competitive products may be administered via subcutaneous infusion, and therefore may only be delivered intravenously which, unlike subcutaneous infusion, requires intravenous infusion line placement and carries the risk of serious bloodstream infection.

We also face competition from manufacturers of generic versions of Remodulin in the United States and abroad. See the section below entitled *Patents and Other Proprietary Rights, Strategic Licenses, and Market Exclusivity—Generic Competition and Challenges to our Intellectual Property Rights*.

Patients must use external pumps manufactured by third parties to deliver Remodulin. Historically, Smiths Medical, Inc. (**Smiths Medical**, which was acquired by ICU Medical, Inc., or **ICU Medical**) manufactured the pumps used by most patients in the United States to administer Remodulin, including the CADD-MS®3 (**MS-3**) pump used to deliver subcutaneous Remodulin, and the CADD-Legacy® pump to deliver intravenous Remodulin. In 2015, Smiths Medical notified us that it was planning to discontinue the manufacture of the MS-3 pumps and associated cartridges. In response, we funded Smiths Medical's manufacture of several thousand additional MS-3 pumps and, in parallel, pursued development of the Remunity Pump so that PAH patients would not experience a delay or disruption in their Remodulin therapy. Our specialty pharmacy distributors informed us that supplies of new MS-3 pumps are fully exhausted, although a limited number of refurbished pumps may be available for use with generic treprostinil. In June 2023, our third-party contract manufacturer, Gilero LLC, which was later acquired by Sanner GmbH, obtained FDA clearance for a cartridge to be used with the MS-3 pump for subcutaneous infusion of Remodulin. As discussed below under *Remunity and RemunityPRO Pumps*, our Remunity and RemunityPRO Pumps are now the primary infusion systems used to deliver Remodulin subcutaneously. ICU Medical has also discontinued the CADD-Legacy system, and has made an alternative pump, the CADD-Solis™, available for intravenous infusion of Remodulin.

There are side effects 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 subcutaneous Remodulin may instead use intravenous Remodulin. Intravenous Remodulin is delivered continuously through a surgically implanted central venous catheter, similar to Veletri and generic epoprostenol. Patients who receive therapy through implanted venous catheters have a risk of developing bloodstream infections and a serious systemic infection known as sepsis. Other common side effects associated with both subcutaneous and intravenous Remodulin include headache, diarrhea, nausea, jaw pain, vasodilation, and edema.

Remodulin may require dilution prior to administration based on factors such as patient weight, desired dose, and desired infusion rate. Dilution may be performed with multiple approved sterile diluent solutions, as specified in the full prescribing information. To provide patients with a reliable supply of diluent solution, we manufacture and distribute Sterile Diluent for Remodulin, a high-pH glycine diluent.

Remunity and RemunityPRO Pumps

In February 2021, we launched commercial sales of the Remunity Pump, which is a semi-disposable system for subcutaneous delivery of treprostinil that we developed in collaboration with DEKA Research & Development Corp. (**DEKA**) under an exclusive development and license agreement. The Remunity Pump consists of a small, lightweight, durable pump and controller designed to have a service life of at least three years. The Remunity Pump uses disposable cassettes filled with Remodulin, which can be connected to the pump with less patient manipulation than is typically involved in filling other currently available subcutaneous pumps. In November 2019, we entered into a supply agreement with an affiliate of DEKA to manufacture and supply the Remunity Pump to us. Under the terms of the agreement, we reimburse all of DEKA's and its affiliates' costs to manufacture the Remunity Pump.

In January 2025, DEKA obtained FDA clearance of a new version of the Remunity Pump, which is intended to improve the patient experience by making the pump easier to use and will be offered only as a patient-filled device. We launched this new system, called RemunityPRO, in September 2025.

The majority of patients being treated with subcutaneous Remodulin in the United States are now using the Remunity or RemunityPRO Pump, and we believe that it is the only subcutaneous infusion system widely available in the United States for newly prescribed treprostinil patients, although a limited number of refurbished MS-3 pumps may be available for use with generic treprostinil. The Remunity and RemunityPRO Pumps are classified by the U.S. Centers for Medicare & Medicaid Services (**CMS**) as durable medical equipment. Net product sales of Remodulin include sales of the Remunity and RemunityPRO Pumps.

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 Tyvaso DPI, Nebulized Tyvaso, and Remodulin. We recognized $496.9 million, $434.3 million, and $359.4 million in Orenitram net product sales, representing 16 percent, 15 percent, and 15 percent of our total revenues for the years ended December 31, 2025, 2024, and 2023, respectively. 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 in which PAH patients were not on any approved background PAH therapy. In August 2018, we announced that our clinical 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 clinical worsening event versus placebo by 25 percent (p=0.0391), driven by a 61 percent decrease in the risk of disease progression for patients taking Orenitram, when compared to placebo (p=0.0002). In October 2019, the FDA approved a supplement to the Orenitram NDA to update the product's label to reflect the *FREEDOM-EV* results. As a result, Orenitram is indicated to delay disease progression and improve exercise capacity.

Secondary endpoints in the *FREEDOM-EV* study included changes from baseline in six-minute walk distance (**6MWD**), Borg dyspnea score (shortness of breath test), functional class, NT-proBNP levels, and combined 6MWD and Borg dyspnea score. Secondary endpoint data, which are not included in the updated FDA-approved labeling, are summarized below:

- *Change in 6MWD*: The median 6MWD trended toward improvement at week 24 (Hodges-Lehmann treatment estimate: seven meters). Median 6MWD improved with Orenitram at weeks 36 (13 meters) and 48 (21 meters) compared to placebo.
- *Change in Borg dyspnea score and WHO functional class*: When classified categorically as "improved," "no change," or "deteriorated," participants in the Orenitram group exhibited a significantly positive shift in Borg dyspnea score and WHO functional class compared to placebo at weeks 24, 36, and 48.
- *Change in NT-proBNP levels*: NT-proBNP levels were significantly improved with Orenitram at weeks 24 and 36. Per the study protocol, NT-proBNP was not assessed at week 48.
- *Change in combined 6MWD and Borg dyspnea score*: Combined 6MWD and Borg dyspnea score was significantly improved with Orenitram when assessed at week 24 compared to placebo.

Sixty-eight percent of the initial *FREEDOM-EV* participants enrolled in an open-label extension (**OLE**) study to further assess Orenitram's tolerability, efficacy, and survival. Participants randomized to placebo in the initial *FREEDOM-EV* study who initiated Orenitram therapy after clinical worsening and tolerated treatment through week 48 demonstrated 6MWD improvement of 84 meters (p<0.0001), favorable shifts in functional class (p<0.0001), and a reduction in NT-proBNP of 778 pg/mL (p=0.03), compared to OLE baseline. Modest trends toward benefit were also measured at week 48 for those initially assigned placebo who did not have clinical worsening. Patients initially assigned to the active Orenitram group who did not have clinical worsening and who continued Orenitram during the OLE study were stable at week 48. Mortality rates were similar between Orenitram and placebo groups at the end of randomized treatment. However, in participants for whom data are available (89 percent), Orenitram was associated with a 36 percent decreased risk of mortality compared with placebo at study closure (p=0.013). These mortality data are not reflected in the FDA-approved labeling because they include data accrued in the OLE study.

In 2020, we published the results of a retrospective study in which a competing therapy, selexipag, was associated with 67 percent higher PAH-associated healthcare costs on average, during the first six months of therapy, compared to Orenitram. Selexipag and Orenitram are the only FDA-approved oral prostacyclin-class therapies.

The studies that established efficacy included predominately patients with functional class II-III symptoms and etiologies of idiopathic or heritable PAH (66 percent) or PAH associated with connective tissue disease (26 percent). The most common side effects observed in our clinical studies were headache, nausea, and diarrhea. Orenitram is currently only approved in the United States.

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. We recognized $30.0 million, $23.8 million, and $28.9 million in Adcirca net product sales, representing one percent of our total revenues for each of the years ended December 31, 2025, 2024, and 2023.

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.

The current term of our Adcirca license agreement expires December 31, 2026.

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, interleukin-2, and 13-cis-retinoic acid, 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 monoclonal antibody composed of a combination of mouse and human DNA 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. Unituxin has also been approved in Canada and Japan.

We recognized $226.8 million, $238.7 million, and $198.9 million in Unituxin net product sales, representing seven percent, eight percent, and nine percent of our total revenues for the years ended December 31, 2025, 2024, and 2023, respectively.

Research and Development

We focus our research and development efforts on the following pipeline programs. We also engage in a variety of additional research and development efforts, including efforts to develop new and improved devices to deliver our current commercial products and other small molecule therapies, some of which are intended for once-daily or as-needed administration, for a variety of pulmonary indications. In addition, we are developing technologies designed to increase the supply of transplantable organs and organ alternatives and improve outcomes for transplant recipients through xenotransplantation, regenerative medicine, and *ex vivo* lung perfusion.

Select Pipeline Programs

Product	Mode of Administration	Indication	Current Status STUDY NAME	Our Territory
Nebulized Tyvaso (treprostinil)	Inhaled	IPF	Phase 3 *TETON 1* and *TETON 2* studies	Worldwide
Nebulized Tyvaso (treprostinil)	Inhaled	PPF	Phase 3 *TETON PPF* study	Worldwide
Ralinepag (IP receptor agonist)	Oral	PAH	Phase 3 *ADVANCE OUTCOMES* study	Worldwide

Nebulized Tyvaso — *TETON* studies

On September 2, 2025, we announced that the *TETON 2* phase 3 study of Nebulized Tyvaso in patients with IPF met its primary efficacy endpoint of demonstrating improvement in absolute forced vital capacity (**FVC**) relative to placebo. Nebulized Tyvaso demonstrated superiority over placebo for the change in absolute FVC by 95.6 mL (Hodges-Lehmann estimate, $p < 0.0001$) from baseline to week 52 in patients with IPF. Benefits of Nebulized Tyvaso were observed across all subgroups, such as use of background therapy (nintedanib, pirfenidone, or no background therapy), smoking status, and supplemental oxygen use.

Statistically significant improvements relative to placebo were also observed in most secondary endpoints, including time to first clinical worsening event, as well as changes from baseline to week 52 in percent predicted FVC, King's Brief Interstitial Lung Disease quality of life questionnaire, and diffusion capacity of lungs for carbon monoxide. While not statistically significant, both time to first acute exacerbation of IPF and overall survival at week 52 trended in favor of Nebulized Tyvaso.

Treatment with Nebulized Tyvaso was well-tolerated, and the safety profile was consistent with previous Nebulized Tyvaso studies and known prostacyclin-related adverse events. No new safety signal was seen.

The *TETON 2* study enrolled 597 patients and was conducted outside the United States and Canada. A second phase 3 study of Nebulized Tyvaso in IPF patients, called *TETON 1*, enrolled 598 patients in the United States and Canada. We intend to use the data from both the *TETON 2* study and the ongoing *TETON 1* study to support a supplemental NDA to the FDA to add IPF to the labeled indications for Nebulized Tyvaso. Data readout from *TETON 1* is expected late in the first quarter, or early in the second quarter, of 2026.

The *TETON 1* and *TETON 2* studies were prompted by data from the *INCREASE* study of Nebulized Tyvaso for the treatment of PH-ILD, which demonstrated in a post-hoc analysis that treatment with Nebulized Tyvaso resulted in significant improvements in percent predicted FVC at weeks 8 and 16, with subjects having an underlying etiology of IPF showing the greatest improvement (week 8: 2.5 percent; p=0.038 and week 16: 3.5 percent; p=0.015). Further, OLE data published in 2023 showed that these improvements in FVC were sustained for at least 64 weeks. For those patients who received placebo during the *INCREASE* study, marked improvements in FVC were observed following transition to Nebulized Tyvaso during the OLE study. These data points, combined with substantial preclinical evidence of antifibrotic activity of treprostinil and the results of the *TETON 2* study, suggest that Nebulized Tyvaso may offer a treatment option for patients with IPF. We believe there are approximately 100,000 IPF patients in the United States.

We are also conducting a phase 3 study of Nebulized Tyvaso called *TETON PPF* for the treatment of progressive pulmonary fibrosis (**PPF**); we enrolled the first patient in *TETON PPF* in October 2023. The primary endpoint of the *TETON PPF* study is the change in absolute FVC from baseline to week 52. The *TETON PPF* study was also prompted by a post-hoc analysis of data from the *INCREASE* study. PPF is a group of ILD conditions that exhibit progressive, self-sustaining fibrosis, and a similar disease course to IPF. PPF includes idiopathic interstitial pneumonias, autoimmune ILDs, chronic fibrosing hypersensitivity pneumonitis, and fibrotic ILDs related to environmental/occupational exposure. We are targeting enrollment of 698 patients in the *TETON PPF* study. We believe the U.S. PPF population is similar in size to the IPF population, although it could be larger as some estimates indicate the U.S. population exceeds 180,000 patients.

We and our distributors will also consider seeking amendments to the marketing authorizations for Nebulized Tyvaso in other countries where it is approved, to include IPF and/or PPF indications, and we will also consider seeking approval of Nebulized Tyvaso for these indications in countries where it is not yet approved. Both the FDA and the European Medicines Agency have granted orphan designation for treprostinil to treat IPF, but not for PPF.

Treprostinil SMI

We are developing a version of inhaled treprostinil that will be a drug-device combination consisting of treprostinil solution and a device known as a soft mist inhaler (**SMI**). SMI devices are propellant-free, hand-held mechanical devices that deliver an aerosol cloud of medication via a single breath. SMI devices would be more convenient for our patients than the current Tyvaso nebulizer, which requires several breaths using a much larger device that needs electricity. SMI devices are pocket-sized and disposable, and would be delivered pre-filled with drug product, ready to use, without the need to fill it every day like a nebulizer. SMI devices could also provide a favorable adverse event profile compared to dry powder inhalers. We are targeting the same indications for which Nebulized Tyvaso is already approved (PAH and PH-ILD), as well as those for which we plan to seek FDA approval in the future (IPF and PPF). Additionally, we are planning a phase 2 study of treprostinil SMI to treat patients with PH-COPD.

Ralinepag

Ralinepag is a next-generation, once-daily, oral, extended-release, titratable, selective, and potent prostacyclin receptor agonist that we are developing for the treatment of PAH. A phase 2 study of an immediate-release formulation of ralinepag in 61 PAH patients (40 patients on active ralinepag, 21 on placebo) met its primary endpoint, showing a 29.8 percent reduction (p=0.03) in median pulmonary vascular resistance (**PVR**, the force or resistance that blood encounters as it flows through the blood vessels in the lungs) after 22 weeks of treatment with ralinepag compared with placebo. After participation in the phase 2 study, 45 patients entered into an OLE study to further determine if ralinepag may be safe and effective for long-term use to treat patients with PAH. The study found that ralinepag had a manageable side effect profile, with a decrease in side effects for patients who continued taking ralinepag over time. Moreover, two years after entering the OLE study, the study showed that ralinepag improved the ability to exercise as the 6MWD significantly increased by a mean of 36.3 meters (p=0.004), and over 85 percent of patients remained stable in their functional class. Additionally, hemodynamic measures (metrics to measure how well the heart is working) taken either one or two years after entering the OLE study demonstrated significant improvements (p=0.05) in both median PVR and mean pulmonary arterial pressure (the pressure in the blood vessels connecting the heart).

In June 2025, we concluded enrollment of the *ADVANCE OUTCOMES* study, which is a phase 3, event-driven clinical trial of an extended-release formulation of ralinepag in PAH patients with a primary endpoint of time to first clinical worsening event. *ADVANCE OUTCOMES* is a global, multi-center, placebo-controlled trial that includes patients on approved oral background PAH therapies. We continued accruing clinical worsening events in this study through the end of 2025, and plan to release topline data from the study late in the first quarter, or early in the second quarter, of 2026.

If approved and launched, we expect ralinepag's once-daily dosing profile to position it favorably compared with Uptravi (selexipag), which is a twice-daily IP-receptor agonist marketed by Johnson & Johnson for the treatment of PAH. In 2025, Johnson & Johnson reported global sales of Uptravi of over $1.9 billion, including over $1.5 billion in U.S. sales, reflecting a growth rate of approximately 5 percent over 2024.

Assuming the *ADVANCE OUTCOMES* study is successful, we plan to develop an oral triple-combination therapy consisting of ralinepag, an endothelin receptor antagonist, and a PDE-5 inhibitor.

Manufactured Organs and Organ Alternatives

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 and organ alternatives is now principally an engineering challenge, and we are dedicated to finding engineering solutions. We are engaged in research and development of a variety of technologies designed to increase the supply of transplantable organs and tissues and to improve outcomes for transplant recipients through xenotransplantation, regenerative medicine, and *ex vivo* lung perfusion.

While we continue to develop and commercialize therapies for rare and life-threatening conditions, we view manufactured organs and organ alternatives as complementary solutions for a broad array of diseases, many of which (such as PAH and PH-ILD) have proven incurable to date despite the availability of pharmaceutical and biologic therapies. For this reason, we included the development of "*technologies that expand the availability of transplantable organs*" as part of our express public benefit purpose when we converted United Therapeutics to a PBC in 2021.

Xenotransplantation

Our xenotransplantation program includes three development-stage organ products known as "xenografts", which are intended to be transplanted from gene-edited pigs into humans.

The UKidney™ is a development-stage kidney from a pig with ten gene edits to support organ functioning in the human body. Six human genes were added to the pig genome to facilitate immune acceptance of the organ, while four genes were inactivated: three that contribute to porcine organ rejection in humans and one that can cause organ growth beyond what is normal for humans. The UHeart™ is a heart from the same pig with ten gene edits.

The UThymoKidney™ is a development-stage kidney from a pig with a single gene edit, together with tissue from the pig's thymus. The pig's thymus tissue is intended to condition the recipient's immune system to recognize the UThymoKidney as "self" and reduce the likelihood of rejection. The single gene that is disrupted in the pig is responsible for the synthesis of alpha-gal, a sugar on the surface of cells that can cause immediate rejection of a porcine organ when transplanted into the human body. Because tissues from pigs containing this gene edit do not contain detectable levels of the alpha-gal sugar, we refer to materials derived from this pig as GalSafe®. In December 2020, the GalSafe pig was approved by the FDA for use as human food and as a potential source for biomedical purposes. Meat from GalSafe pigs is currently being provided to individuals with alpha-gal syndrome, an allergy to meat caused by a bite from the lone star tick. This approval marked only the second FDA approval of a gene-edited animal as a source of food, and the first such approval for a mammal.

Johns Hopkins University (**JHU**), New York University (**NYU**), the University of Alabama at Birmingham (**UAB**), and the University of Maryland, Baltimore (**UMB**) performed preclinical testing of our porcine xenografts in animal models. In addition, we worked with NYU and UAB to employ innovative preclinical human models to obtain insights into how xenografts function inside the human body.

In January 2025, the FDA cleared our Investigational New Drug application (**IND**) related to the *EXPAND* study of our UKidney product. This study is expected to enroll an initial cohort of six end-stage renal disease (**ESRD**) patients, expanding to up to 50 participants, and we intend to use the results of this study to support a BLA with the FDA. This study is designed as a combination phase 1/2/3 trial (sometimes referred to as a "phaseless" study) to evaluate safety and efficacy seamlessly without moving through separate phase 1, phase 2, and phase 3 studies that are typically associated with conventional drug approvals. The first transplant in this study occurred in the fourth quarter of 2025, and the study is ongoing.

In July 2025, we submitted an IND to the FDA related to our anticipated *EXTEND* clinical study of our UThymoKidney product. In August 2025, the FDA cleared this IND, enabling us to commence this study, which we expect will be similar in size and scope to the *EXPAND* study described above.

In February 2024, we completed a designated pathogen-free (**DPF**) facility in Virginia. We expect this DPF facility to supply xenografts compliant with FDA current Good Manufacturing Practices (**cGMP**) for human clinical trials, with a target capacity of up to 125 organs per year. We are constructing two additional DPF facilities in Minnesota and Texas. While we believe these DPF facilities will be capable of producing organs for commercial use, we are also planning to build additional and potentially larger cGMP DPF facilities for commercial use. While these projects will be capital-intensive, the timing and volume of these expenditures will be staggered and paced in a manner intended to balance our need to address market

demand as soon as possible following FDA approval with the need to defer the most significant capital expenditures until we achieve certain clinical trial milestones.

Additional key accomplishments in our xenotransplantation program include the following:

- **First Successful Xenotransplants of Porcine Hearts.** University of Maryland School of Medicine (**UMSOM**) surgeons transplanted UHearts into two living human patients. Each of these procedures were authorized by the FDA on a single-patient, expanded access (also called "compassionate use") basis, and marked the first known examples of transplanting whole organs from gene-edited pigs to humans. The FDA's compassionate use regulations allow a physician to apply to use an unapproved product outside of a clinical trial to treat an individual patient with a serious or immediately life-threatening disease or condition when no satisfactory alternative therapy is available. The first patient, who received a xenotransplant in January 2022, survived for approximately two months with the UHeart. In June 2022, data from this procedure were published in the *New England Journal of Medicine*. The second patient, who received a xenotransplant in September 2023, survived for approximately six weeks with the UHeart. We and our collaborators continue to evaluate data from these human transplants.
- **First Successful Transplantation of Porcine Thymokidney.** In April 2024, surgeons at NYU Langone Health transplanted a UThymoKidney into a living patient under an FDA authorization for compassionate use. The patient was suffering from heart and kidney failure, and received a left ventricular assist device to stabilize heart function prior to the UThymoKidney transplant. The procedure marked the first known transplantation of a thymokidney into a human, the first known transplantation of a gene-edited porcine kidney into a human using only FDA-cleared immunosuppression drugs, and the first known procedure combining the use of a heart pump with a transplanted porcine xenokidney. After 47 days, surgeons electively removed the UThymoKidney and returned the patient to dialysis. According to NYU Langone Health, the UThymoKidney had sustained significant injury from episodes of insufficient blood flow due to reduced blood pressure generated by the heart pump and, on balance, was no longer contributing enough to justify continuing the patient's immunosuppression regimen. NYU Langone Health noted that a biopsy of the UThymoKidney did not show signs of rejection.
- **Second Successful Transplantation of a Porcine Kidney.** In November 2024, surgeons at NYU Langone Health transplanted a UKidney into a living patient under an FDA authorization for compassionate use. In March 2025, the patient developed an infection unrelated to the transplant that led to the reduction of immunosuppression drugs and the rejection of the organ. As a result, the UKidney was removed and the patient returned to dialysis. The UKidney performed well for over four months.
- **Successful UKidney and UHeart Tests in Preclinical Human Models.** In 2021, surgeons at NYU and UAB tested UThymoKidneys and UKidneys from our gene-edited pigs in brain-dead organ donors maintained on artificial support, providing preclinical evidence that gene-edited pig organs could transcend the most proximate immunological barriers to xenotransplantation. These studies using a preclinical human decedent model were conducted in brain-dead organ donors whose organs were determined to be ineligible for donation, with the consent of each donor's family. Results of the UAB experiments were published in the *American Journal of Transplantation* in January 2022 and the *Journal of Clinical Investigation* in January 2024, and results of the NYU experiments were published in the *New England Journal of Medicine* in May 2022.

  In June and July 2022, NYU surgeons tested two UHearts from our gene-edited pigs in brain-dead organ donors maintained on artificial support. In each case, normal function was observed for our UHearts over a three-day study period, without signs of early rejection. The results were published in *Nature Medicine* in July 2023.

  In September 2023, NYU surgeons completed a 61-day study of a UThymoKidney in a brain-dead organ donor maintained on artificial support. At the time, this experiment marked the longest documented case of a xenotransplanted organ functioning in a human body.

Regenerative Medicine

- **Miromatrix**. In December 2023, we acquired Miromatrix Medical Inc. (**Miromatrix**), a company based in Minnesota focused on the development of new technologies for generating manufactured kidneys and liver alternatives composed of human primary cells. The development-stage Miromatrix external liver assist product, called miroliver*ELAP*®, uses a decellularized porcine liver matrix that has been seeded with human-derived cells and an extracorporeal blood circuit to maintain liver support in patients experiencing acute liver failure. Miromatrix first used its decellularization technology to successfully develop two acellular products, MiroMesh® and MiroDerm®, which received FDA 510(k) clearance for hernia repair and wound care applications, respectively, and which were later spun off by Miromatrix. In January 2026 we announced that Miromatrix completed a phase 1 study of miroliver*ELAP* in patients with acute liver failure. This study, which was the first human clinical trial of a manufactured organ alternative, met its primary endpoint. Miromatrix is planning to commence a phase 2 study. Miromatrix is also developing miroliver®, a fully implantable manufactured liver alternative product, and mirokidney®, a fully implantable manufactured kidney alternative product, both of which are based on decellularized porcine organ scaffolds that have been reseeded with human-derived cells. Initially the Miromatrix products are intended to be made with cells from a human donor other than the recipient (also called "allogeneic" cells), requiring the use of standard immunosuppression protocols. Future versions may be based on the patient's own cells (known as "autologous" cells), reducing or eliminating the need for immunosuppression drugs.

- **ULobe™**. The ULobe is a development-stage engineered lung lobe alternative made using a porcine lung scaffold that is decellularized and then re-cellularized with allogeneic human cells. In 2025, our Regenerative Medicine Laboratory in Research Triangle Park, North Carolina (**RTP**) produced 830 decellularized lung scaffolds, 345 recellularized lungs, and 1.65 trillion human cells for use in recellularization.
- **ULung™**. The ULung is a development-stage engineered lung alternative composed of a three-dimensional (**3D**) printed lung scaffold cellularized with either allogeneic or autologous human lung cells, with the goal of reducing or eliminating the need for immunosuppression. The lung scaffold used in the ULung is printed using 3D printers being developed in collaboration with 3D Systems, Inc. Our Organ Manufacturing Group, located in Manchester, New Hampshire, has achieved recognition for developing the world's most complex 3D printed object. Its lung scaffold designs consist of a record 44 trillion voxels that lay out 4,000 kilometers of pulmonary capillaries and 200 million alveoli, which demonstrate gas exchange in preclinical models. Under our agreement with 3D Systems, we also have the exclusive right to develop additional human solid organ alternatives using 3D Systems' printing technology.
- **IVIVA**. In October 2023, we completed the acquisition of IVIVA Medical, Inc. (**IVIVA**), a preclinical stage company based in Massachusetts, focused on bio-artificial manufactured kidney alternative products. IVIVA's preclinical implantable kidney alternative product uses autologous cells to mimic important physiological functions of native kidneys in recipients to support their native kidney function without the need for immunosuppression. The product is designed to replace the need for external kidney dialysis.

Ex Vivo Lung Perfusion

Our *ex vivo* lung perfusion (**EVLP**) program uses the first FDA-approved acellular EVLP technology on the market, the XVIVO Perfusion System (**XPS**™) with Steen Solution™ Perfusate, to offer the only commercially-available centralized EVLP service in the United States. EVLP technology increases the number of transplantable lungs by giving surgeons the ability to assess the function of donor lungs to determine if the lungs are suitable for transplantation. This allows for the transplantation of lungs that would have otherwise not been transplanted. Centralized EVLP services make EVLP available to small and large transplant centers and remove barriers to the transplantation process to optimize organ utilization and increase the supply of transplantable lungs.

Our wholly-owned subsidiary, Lung Bioengineering Inc., provides commercial EVLP services on a fee-for-service basis to transplant centers through dedicated facilities located in Silver Spring, Maryland and Jacksonville, Florida, using the XPS System. In 2024, Lung Bioengineering completed a registrational study of another centralized EVLP technology called the Centralized Lung Evaluation System (**CLES**) and submitted a premarket approval application to the FDA in September 2024 for commercial approval of CLES, which is under review by the FDA.

Over 730 patients have received lung transplants following use of our centralized EVLP service.

Sustainable Delivery of Organs and Organ Alternatives

Together with our work on therapeutic interventions, we are working with third parties to develop scalable technologies to efficiently deliver an unlimited supply of manufactured organs and organ alternatives to transplant centers and waiting patients, while minimizing environmental impact. Our organ delivery research efforts are focused on the development of piloted and autonomous electric vertical take-off and landing aircraft systems to quickly, reliably, and sustainably deliver organs and organ alternatives from manufacturing facilities to transplant centers.

Beginning in 2017, we entered into a series of agreements with BETA Technologies, Inc. to support the development of all-electric aircraft to help us meet our future distribution requirements for manufactured organs and organ alternatives. In October 2021, we successfully completed the first-ever drone delivery of a human lung for transplant at Toronto General Hospital, demonstrating the feasibility of our goal of delivering our manufactured organs and organ alternatives with zero carbon footprint aircraft. In October 2024, we entered into a collaboration agreement with Robinson Helicopter Company to support our efforts to develop and certify zero-emission, hydrogen-electric powered helicopters based on Robinson's R44 and R66 helicopter models. In March 2025, we completed what we believe was the world's first successful test flight of a piloted hydrogen-electric powered helicopter at our test and development facility located in Quebec.

Sales and Marketing

Our marketing strategy for our commercial PAH and PH-ILD products is to use our sales and marketing teams to reach out to the prescriber community to: (1) increase PAH and PH-ILD awareness; (2) increase understanding of the progressive nature of PAH and the importance of early treatment; (3) communicate the increased risks when ILD patients develop PH-ILD; and (4) 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 Tyvaso DPI, Nebulized Tyvaso, Remodulin, Remunity and RemunityPRO Pumps, Orenitram, and Unituxin

We distribute Tyvaso DPI, Nebulized Tyvaso, Remodulin, the Remunity and RemunityPRO Pumps, and Orenitram in the United States through two contracted specialty pharmaceutical distributors: Accredo Health Group, Inc. and its affiliates (**Accredo**) and Caremark, L.L.C. (**CVS Specialty**). These distributors are required to maintain certain minimum inventory levels to facilitate 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 inventory held by our distributors.

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 in the United States through an exclusive distribution agreement with Cencora Global Procurement Ltd (**Cencora**). Under this agreement, we sell Unituxin to Cencora at a transfer price that we establish, and we pay Cencora 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, 2026 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.

International Distribution of Tyvaso DPI, Nebulized Tyvaso, Remodulin, Orenitram, and Unituxin

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, the Middle East, Asia, and South and Central America. Our primary distributor outside the United States is Grupo Ferrer Internacional, S.A. (**Ferrer**), which holds Remodulin marketing authorization rights in many of these territories. We also sell Nebulized Tyvaso exclusively through Mochida Pharmaceutical Co., Ltd. (**Mochida**), in Japan, where the product was approved to treat PAH in late 2022, and to treat PH-ILD in 2024. In addition, we sell Nebulized Tyvaso commercially to distributors that have exclusive distribution rights in various countries in Asia, the Middle East, and Latin America, where it is approved for PAH and/or PH-ILD. We also distribute Remodulin and Unituxin in Canada through a specialty pharmaceutical wholesaler. In some of the markets where we are not licensed to market Remodulin, Remodulin is available, but not marketed, 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. Similar named-patient programs are also available for Nebulized Tyvaso in certain countries. We entered into exclusive agreements with Ferrer to distribute Orenitram and Nebulized Tyvaso in the territories where it also has distribution rights for Remodulin. Feedback from the EMA indicated that approval of either Orenitram or Nebulized Tyvaso would require another large clinical trial of the applicable product. As a result, we have terminated our contract with Ferrer concerning Orenitram. We plan to revisit seeking EMA approval for Nebulized Tyvaso if the *TETON* program is successful. In 2025, Ferrer submitted a marketing authorisation application (**MAA**) to the U.K. Medicines and Healthcare products Regulatory Authority (**MHRA**) seeking approval for Nebulized Tyvaso to treat PH-ILD. We distribute Unituxin in Japan exclusively through Ohara Pharmaceutical Co., Ltd., which obtained Japanese marketing authorization during the second quarter of 2021. Tyvaso DPI is not yet approved or distributed in any countries outside the United States.

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

Our success depends in part on our ability to obtain and maintain patent protection for our products, preserve trade secrets, prevent third parties from infringing upon our proprietary rights, and operate without infringing upon the proprietary rights of others in the United States and worldwide. Many of these proprietary rights stem from licenses and other strategic relationships with third parties. In addition to intellectual property rights, U.S. and international regulatory authorities often provide periods of market exclusivity for manufacturers of biopharmaceutical products.

Patents provide the owner with a right to exclude others from practicing an invention. Patents may cover the active ingredients, uses, formulations, doses, administrations, delivery mechanisms, manufacturing processes, and other aspects of a product. The period of patent protection for any given product 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 (**IPR**), 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.

Tyvaso DPI, Nebulized Tyvaso, Remodulin, and Orenitram Proprietary Rights

We have issued patents and pending patent applications covering our treprostinil-based products, Tyvaso DPI, Nebulized Tyvaso, Remodulin, and Orenitram. We have two unexpired patents related to the manufacture of 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 Tyvaso DPI, Nebulized Tyvaso, Remodulin, and Orenitram.

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

- *Tyvaso DPI*. We have two Orange Book-listed U.S. patents that we license from MannKind directed to the composition of Tyvaso DPI drug product, which expire in 2030 and 2035. We have another issued U.S. patent listed in the Orange Book directed to a method of improving exercise capacity in patients with PH-ILD expiring in 2042. We also have an issued U.S. patent listed in the Orange Book directed to a method of treating pulmonary hypertension using inhaled treprostinil expiring in 2027. Additionally, our license agreement with MannKind includes rights to a substantial portfolio of additional issued U.S. patents related to a component of the drug product and methods of making the drug product, which expire at various dates through 2035, and pending applications that, if issued, could provide protection to 2042 or beyond.
- *Nebulized Tyvaso*. We have been granted two U.S. 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. We have also been granted a patent on methods of treating pulmonary hypertension by administering treprostinil by inhalation, which expires in 2027. This patent is also listed in the Orange Book. Additionally, we have been granted a patent directed to a method of improving exercise capacity in PH-ILD patients, which expires in 2042.
- *Remodulin*. We have been granted three U.S. patents covering an improved diluent for Remodulin, which expire in 2028 and 2029. All three of these patents are listed in the Orange Book.
- *Orenitram*. Our U.S. patents for Orenitram 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 2026 and 2031.

We have international counterparts to many of the patents discussed above and additional pending U.S. and international patent applications related to Tyvaso DPI, Nebulized Tyvaso, Remodulin, and Orenitram.

Orange Book

In seeking approval of a drug through an NDA or upon issuance of new patents following approval of an NDA, applicants are required to submit to the FDA each patent 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. Tyvaso DPI currently has six unexpired Orange Book-listed patents with expiration dates ranging from 2027 to 2042. Nebulized Tyvaso currently has six unexpired Orange Book-listed patents expiring at various dates from 2027 to 2042. Remodulin currently has five unexpired Orange Book-listed patents with expiration dates ranging from 2028 to 2029. Orenitram currently has twelve unexpired Orange Book listed patents with expiration dates ranging from 2026 to 2031. Additional patent applications are pending, and if granted, may be eligible for listing in the Orange Book.

Regulatory Exclusivity

- *Tyvaso DPI and Nebulized Tyvaso.* In 2010, the FDA granted orphan drug designation for Tyvaso, which resulted in an orphan exclusivity period that expired in July 2016. In March 2021, the FDA granted three-year clinical trial exclusivity for PH-ILD as a result of the *INCREASE* study and the expansion of the Nebulized Tyvaso label to include a PH-ILD indication. This exclusivity period covered both Nebulized Tyvaso and Tyvaso DPI for PH-ILD, and expired in March 2024. Additionally, the FDA determined in August 2024 that we were entitled to a period of exclusivity for Nebulized Tyvaso and Tyvaso DPI based on a clinical trial conducted to obtain approval for a PH-ILD indication; this exclusivity expired on May 23, 2025. In 2004, the European Commission designated Nebulized 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. In December 2020, the FDA granted orphan designation for treprostinil for the treatment of IPF. Thus, if we obtain FDA approval to update the Tyvaso DPI and/or Nebulized Tyvaso labeling to include an IPF indication, then the FDA should grant seven-year orphan drug exclusivity for this new indication. The EMA has also granted orphan drug designation for treprostinil to treat IPF.
- *Remodulin.* Regulatory exclusivity for Remodulin in the United States and Europe has expired.
- *Orenitram.* In November 2019, following approval of our supplemental NDA to reflect the *FREEDOM-EV* results in the Orenitram label, the FDA granted orphan exclusivity for the new indication that Orenitram delays disease progression in PAH patients. This exclusivity expires in October 2026.

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. The term of this royalty expires during the fourth quarter of 2026.

Manufactured Organ and Organ Alternative Proprietary Rights

We have a large portfolio of pending patent applications and issued patents that could protect our proprietary rights in our manufactured organs and organ alternative products. We own patents, and have licensed rights under third-party patents, covering various aspects of these products; we do not view any one patent or group of patents as critical. For example, we have over 150 pending patent applications and multiple issued patents covering various aspects of our 3D organ alternative bioprinting program, and we have exclusively licensed an extensive 3D printing patent portfolio from 3D Systems for use in the field of manufacturing solid organ alternatives. Our xenotransplantation patent portfolio includes over 150 pending applications and issued patents, including nearly one hundred issued patents in the U.S. and abroad. Our regenerative medicine patent portfolio includes over 300 pending applications and issued patents.

Our patent portfolio covers various aspects of our manufactured organ and organ alternative programs, including genetic constructs, manufacturing methods, end products, and components used in the manufacture of these products. The applicability of our patent portfolio to our programs will depend on the final commercial organ manufacturing products we provide and processes we use and the timing of regulatory approvals. In addition, we may rely on trade secret protection for certain aspects of our manufactured organ and organ alternative programs.

Generic Competition and Challenges to our Intellectual Property Rights

Remodulin—Generic Competition

We settled litigation with Sandoz Inc. (**Sandoz**) related to its abbreviated new drug application (**ANDA**) seeking FDA approval to market a generic version of Remodulin and in March 2019, Sandoz announced the availability of its generic product in the United States. We have also entered into similar settlement agreements with other generic companies, some of which have also launched sales of generic versions of Remodulin. Through December 31, 2025, we have seen limited erosion of Remodulin sales as a result of generic treprostinil competition in the United States. We are currently engaged in litigation with

Sandoz and its marketing partner, RareGen, LLC (**RareGen**) (now a subsidiary of Liquidia Corporation, the parent company of Liquidia Technologies, Inc. (**Liquidia**)), related to the infusion devices used to administer Remodulin subcutaneously. We understand that generic treprostinil was initially launched by Sandoz/RareGen for use only by intravenous infusion. In May 2021, Sandoz/Liquidia Corporation announced that Sandoz's generic treprostinil was made available for subcutaneous use, following FDA clearance of a cartridge that can administer the product via the MS-3 pump. In addition, Liquidia has announced it is developing a new subcutaneous infusion system for its generic treprostinil product. See Note 14—*Litigation,* to our consolidated financial statements included in this Report.

Regulatory authorities in various European countries began approving generic versions of Remodulin in 2018, followed by pricing approvals and commercial launches in most of these countries in 2019 and 2020. As a result, our international Remodulin revenues have decreased compared to the period prior to generic launch, due to increased competition and a reduction in our contractual transfer price for Remodulin sold by certain international distributors for sales in countries in which the pricing of Remodulin is impacted by the generic competition.

Nebulized Tyvaso and Orenitram—Potential Future Generic Competition

We settled litigation with Watson Laboratories, Inc. (**Watson**) related to its ANDA seeking FDA approval to market a generic version of Nebulized Tyvaso before the expiration of certain of our U.S. patents. Under the settlement, Watson was permitted to market its generic version of Nebulized Tyvaso in the United States as early as January 2026, although, to date, they have not received FDA approval to do so.

We also settled litigation with Actavis Laboratories FL, Inc. (**Actavis**) and ANI Pharmaceuticals, Inc. (**ANI**) related to their ANDAs seeking FDA approval to market generic versions of Orenitram before the expiration of certain of our U.S. patents. Under the settlement agreements, Actavis and ANI can market their generic versions of Orenitram in the United States beginning in June 2027 and December 2027, respectively, although either or both of them may be permitted to enter the market earlier under certain circumstances.

Competition from these generic companies could reduce our net product sales and profits. See Note 14—*Litigation,* to our consolidated financial statements included in this Report.

Liquidia—Yutrepia

In May 2025, Liquidia obtained final FDA approval to market Yutrepia®, a dry powder formulation of treprostinil for inhalation, to treat PAH and PH-ILD. Liquidia announced that it launched sales of Yutrepia in June 2025. The Yutrepia NDA was submitted under the 505(b)(2) regulatory pathway with Nebulized Tyvaso as the reference listed drug. Yutrepia competes directly with Tyvaso DPI, Nebulized Tyvaso, and our other treprostinil-based products.

We are engaged in patent litigation with Liquidia concerning Yutrepia. Specifically, we allege that Yutrepia infringes a patent we own covering the treatment of PH-ILD to improve exercise capacity in patients suffering from PH-ILD by inhaling treprostinil at specific dosages. If we are successful in this litigation, we believe Liquidia will be required to remove PH-ILD as a labeled indication for Yutrepia until the expiration of our patent in February 2042. We are also engaged in litigation with Liquidia alleging trade secret misappropriation. In this case, we allege that a former executive of ours misappropriated trade secrets related to Tyvaso when he utilized them as an executive of Liquidia to aid in the development of Yutrepia. Finally, we are engaged in separate litigation against Liquidia alleging that Yutrepia infringes a patent that claims a method of treating pulmonary hypertension using inhaled treprostinil delivered in a specified dosage using a specified dosage regimen. This patent expires in May 2027.

Liquidia has also sued us, alleging infringement of a patent with claims directed to the treatment of pulmonary hypertension by administering specified amounts of treprostinil via a dry powder inhaler in a specified number of breaths. That case is currently stayed pending developments in the trade secret misappropriation litigation described above.

For further details regarding these and other litigation matters involving Liquidia and Yutrepia, please see Note 14—*Litigation*, to our consolidated financial statements.

General

We intend to vigorously enforce our intellectual property rights related to our products. However, we may not prevail in defending our patent rights, and additional challenges from other ANDA filers or other challengers may 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 or filer of a 505(b)(2) NDA for a branded treprostinil product were to receive approval to sell its treprostinil product and/or prevail in any patent litigation, our affected product(s) would become subject to increased competition. Patent expiration, patent litigation, and competition from generic or other branded treprostinil manufacturers could have a significant, adverse impact on our treprostinil-based product revenues, our profits, and our stock price. These potential effects are inherently difficult to predict. For additional discussion, see the risk factor entitled, *Our intellectual property rights may not effectively deter competitors from developing competing products that, if successful, could have a material adverse effect on our revenues and profits*, contained in *Part I*, *Item 1A—Risk Factors* included in this Report.

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. 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 a patent expiry in November 2017. As a result, we are required to make milestone payments to Lilly equal to $325,000 for each $1.0 million in net product sales, plus a royalty equal to ten percent of our net product sales. The current term of our Adcirca license agreement expires December 31, 2026. Following expiration of the agreement, we will remain obligated to refund the purchase price of any Adcirca that we previously sold to distributors that expires unsold. For additional discussion, see our *Adcirca* product description included 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

Approval of our BLA for Unituxin conferred a 12-year data exclusivity period through March 2027, during which the FDA may not approve a biosimilar for Unituxin. Our orphan drug exclusivity in the United States for Unituxin expired in March 2022. Under a non-exclusive license agreement with The Scripps Research Institute, we pay a royalty of one percent of Unituxin net product sales. We have no patents covering the Unituxin drug product.

DEKA Agreements

In December 2014, we entered into an exclusive agreement with DEKA to develop a semi-disposable system for subcutaneous delivery of Remodulin, which we refer to as the Remunity and RemunityPRO Pumps. Our agreement with DEKA expires on the last to occur of 25 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 pumps. Under the terms of the agreement, we funded the development costs related to the Remunity and RemunityPRO Pumps and will continue to fund any further development costs associated with new versions. We pay product fees and a single-digit royalty to DEKA based on commercial sales of the Remunity and RemunityPRO Pumps, and the Remodulin drug product sold for use with the 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. In November 2019, we entered into a supply agreement with an affiliate of DEKA to manufacture and supply the Remunity Pump, and later amended it to provide for manufacture and supply of the RemunityPRO Pump. Under this supply agreement, we are responsible for all costs associated with manufacturing the Remunity and RemunityPRO Pumps. The Remunity and RemunityPRO Pumps are 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.

Tyvaso DPI and the MannKind Agreement

In September 2018, we entered into a worldwide, exclusive license and collaboration agreement with MannKind for the development and commercialization of Tyvaso DPI for the treatment of PAH. The agreement became effective on October 15, 2018.

Under our agreement with MannKind, we are responsible for global development, regulatory, and commercial activities related to Tyvaso DPI, and we share manufacturing responsibilities with MannKind. The agreement also requires us to pay MannKind a ten percent royalty on our net sales of Tyvaso DPI, subject to certain reductions. 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 $40.0 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. In August 2025, we exercised this option and amended our agreement with MannKind to include development and commercialization of a second investigational molecule utilizing MannKind's dry powder technology.

In December 2023, MannKind entered into a royalty purchase agreement with Sagard Healthcare Funding Partners Borrowers 2 SPE, LP, with our consent, to sell ten percent of the royalties payable under the license agreement (i.e., one percentage point of the ten percent royalty) in exchange for $150.0 million up-front, plus up to an additional $50.0 million if net sales of Tyvaso DPI meet certain thresholds. Based on the up-front purchase price alone, the implied net present value of future Tyvaso DPI net revenues at the time of the transaction was $15.0 billion.

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 device, 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. For additional detail concerning these patents, see *Tyvaso DPI*, *Nebulized Tyvaso*, *Remodulin*, *and Orenitram Proprietary Rights* above.

In August 2021 we entered into a commercial supply agreement with MannKind (as amended, the **Supply Agreement**). Pursuant to the Supply Agreement, MannKind is responsible for manufacturing and supplying Tyvaso DPI to us. Unless earlier terminated, the initial term of the Supply Agreement continues until December 31, 2031, and will thereafter be renewed automatically for additional, successive two-year terms unless we give 24 months' written notice of non-renewal, or MannKind gives 48 months' written notice of non-renewal, prior to the end of the initial term or any additional renewal term. In addition, each party has customary termination rights, including termination for the other party's material breach that is not cured within a specific timeframe or in the event of liquidation, bankruptcy, or insolvency of the other party.

Ralinepag and the Arena Agreement

On November 15, 2018, we entered into an exclusive license agreement with Arena Pharmaceuticals, Inc. (**Arena**) related to ralinepag. 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, IND No. 109021 (related to ralinepag), and non-clinical, preclinical, 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. Under our license agreement, we are obligated to 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 United Kingdom, 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. Under our license agreement with Arena, we have an exclusive license to a variety of granted and pending patents and patent 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. In March 2022, Arena was acquired by Pfizer Inc. Based on potential patent term extensions and additional patent filings, we believe that U.S. patent protection for ralinepag will likely last through at least the mid-2030s.

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 synthesize treprostinil, the active ingredient in Tyvaso DPI, Nebulized Tyvaso, and Remodulin, and treprostinil diolamine, the active ingredient in Orenitram, at our facility in Silver Spring, Maryland. We produce dinutuximab, the active ingredient in Unituxin, at our Silver Spring facility. We manufacture drug product for Nebulized Tyvaso, Remodulin, and Unituxin at our Silver Spring facility. We manufacture Orenitram drug product, and we package, warehouse, and distribute Tyvaso DPI, Nebulized Tyvaso, Remodulin, Orenitram, and Unituxin, at our facilities in RTP.

We maintain, at a minimum, a two-year inventory of Nebulized Tyvaso, Remodulin, and Orenitram based on expected demand, and we contract with third-party contract manufacturers to supplement our capacity for some products, to mitigate the risk that we might not be able to manufacture internally sufficient quantities to meet patient demand. For example, Simtra BioPharma Solutions (formerly known as 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 Woodstock Sterile Solutions to serve as an additional manufacturer of Nebulized Tyvaso drug product. We currently rely entirely on MannKind to manufacture Tyvaso DPI finished drug product and inhalers. We have initiated efforts to qualify a contract manufacturer as a second manufacturing source for dinutuximab, the active ingredient in Unituxin. We have no plans to develop a redundant manufacturing source for finished Tyvaso DPI, Orenitram, or Unituxin drug product, or Tyvaso DPI inhalers.

We rely on Forj Medical and Phillips-Medisize Corp. to manufacture the nebulizer used in our Tyvaso Inhalation System and various third parties to manufacture the monthly disposable device accessories for the Tyvaso Inhalation System. We rely entirely on Lilly to manufacture Adcirca. We currently rely on third-party contract manufacturers to produce ralinepag. We are in the process of qualifying our RTP facility to produce our primary commercial supply of ralinepag, if and when it is approved by the FDA.

We rely entirely on third parties to supply pumps and other supplies necessary to administer Remodulin. ICU Medical discontinued manufacturing the MS-3 system used to administer subcutaneous Remodulin, and specialty pharmacy distributors informed us that supplies of MS-3 pumps are exhausted, although a limited number of refurbished pumps may be available for use with generic treprostinil. ICU Medical has also discontinued manufacturing and distribution of the CADD-Legacy system used to administer intravenous Remodulin. Historically, these were the pumps primarily used to administer Remodulin to patients in the United States. In 2021, we launched the Remunity Pump to administer subcutaneous Remodulin, and in 2022 ICU Medical made an alternative pump, the CADD-Solis, available for intravenous Remodulin. We rely entirely on DEKA and its affiliates to manufacture the Remunity and RemunityPRO Pumps for us. In June 2023, our third-party contract manufacturer obtained FDA clearance for a cartridge to be used with the MS-3 pump for subcutaneous infusion of Remodulin. This clearance enables us to help ensure continuity of cartridge supplies to existing patients using the MS-3 pump. We are also engaged in further efforts to develop alternative pumps to administer Remodulin. There are additional ancillary supplies used with these pumps, and there are a limited number of manufacturers that supply them.

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, 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, development, and commercialization of products to treat cardiopulmonary diseases, pulmonary diseases, and cancer. For the treatment of PAH, we compete with many approved products in the United States and the rest of the world. In the U.S., these competitive therapies include oral ERAs (Letairis® (ambrisentan), Opsumit® (macitentan), Tracleer® (bosentan), generic bosentan, and generic ambrisentan); prostacyclin-class therapies Uptravi® (oral selexipag), Veletri® (intravenous epoprostenol), Ventavis® (inhaled iloprost), Yutrepia® (treprostinil inhalation powder), generic intravenous epoprostenol, and generic treprostinil injection; PDE-5 inhibitors (Revatio® (sildenafil), generic sildenafil, and generic tadalafil); an SGC stimulator Adempas® (riociguat); an activin pathway inhibitor Winrevair (sotatercept-csrk) delivered via subcutaneous injection; and an oral combination product known as Opsynvi®, comprised of tadalafil and macitentan. Some of these therapies are manufactured and marketed by large pharmaceutical companies such as Johnson & Johnson, Gilead Sciences, Inc., Bayer Schering Pharma AG, GSK plc, and Merck, as well as a variety of large generic drug manufacturers. In the fourth quarter of 2025, the manufacturer of Flolan® (intravenous epoprostenol) discontinued manufacture of the product.

Merck's Winrevair was approved by the FDA to treat PAH in March 2024. A majority of patients enrolled in the *STELLAR* pivotal clinical trial of Winrevair were on background prostacyclin-class therapies such as treprostinil, and to date we have not seen a material impact on the use of our treprostinil-based therapies. However, some physicians may choose to prescribe Winrevair prior to initiating prostacyclin therapy, which could negatively impact our revenues, and Merck has completed clinical studies that could result in an earlier use of Winrevair for treating PAH.

In May 2025, Liquidia received final FDA approval to market Yutrepia, a dry powder formulation of treprostinil, to treat PAH and PH-ILD. Yutrepia competes directly with our treprostinil-based products, including in particular Nebulized Tyvaso and Tyvaso DPI. We have litigation pending which could, if successful, result in the removal of PH-ILD as a labeled indication for Yutrepia. See Note 14—*Litigation*, to our consolidated financial statements included in this Report, for additional details.

Nebulized Tyvaso, Tyvaso DPI, and Yutrepia are currently the only FDA-approved inhaled prostacyclin analogues available in the United States for newly diagnosed patients.

There are a wide variety of investigational PAH therapies in development. Therapies in registration-phase studies, or which have completed registration-phase studies, include the following:

- *L606*, an inhaled, liposomal form of treprostinil currently being developed by Pharmosa Biopharm Inc. (**Pharmosa**) and Liquidia for treatment of PAH and PH-ILD, intended to be dosed twice daily. In June 2023, Liquidia announced it had entered into an exclusive licensing agreement with Pharmosa for development and commercialization of L606 in North America, and that the product is the subject of an upcoming phase 3 clinical trial in patients with PH-ILD, with the intent of obtaining approval for the treatment of both PAH and PH-ILD via the 505(b)(2) regulatory pathway, with Nebulized Tyvaso as the reference listed drug. On October 2, 2024, Liquidia and Pharmosa announced that they amended the licensing agreement to expand Liquidia's licensed territory to include Europe, Japan, and elsewhere, and to include rights to Pharmosa's nebulizers for use with L606.
- *Seralutinib (GB002)*, a small molecule tyrosine kinase inhibitor being developed by Gossamer Bio, Inc. (**Gossamer**) as a dry powder inhaled product for PAH and PH-ILD. In February 2026, Gossamer announced that a phase 3 study in PAH failed to meet its primary endpoint with statistical significance, but that the company will continue its efforts to seek approval for PAH. In addition, Gossamer initiated a phase 3 study in PH-ILD during the fourth quarter of 2025.
- *TPIP (INS1009)*, an inhaled dry powder formulation of treprostinil palmitil intended to be dosed once per day, being developed by Insmed Incorporated. In January 2026, the Office of Orphan Products Development of the FDA granted orphan drug designation to TPIP for the treatment of patients with PAH on the basis of plausible clinical superiority to approved versions of treprostinil. The company has indicated that they plan to initiate a phase 3 study of TPIP in PAH

patients in the first half of 2026. In addition, the company initiated a phase 3 study in PH-ILD in the fourth quarter of 2025, and disclosed that they plan to initiate additional phase 3 studies in PPF and IPF in the second half of 2026.

Additional therapies being studied for PAH include the following, among others: Cereno Scientific AB's valproic acid (CS1) (phase 2b planned for 2026); Boston Scientific's TIVUS™ (pivotal trial); Respira Therapeutics' vardenafil (RT234) (phase 2b); Chugai Pharmaceutical Co., Ltd's satralizumab (phase 2); Regeneron's REGN13335 (phase 2); Apollo Therapeutics, APL-9796 (phase 2); Pfizer's PF-07868489 (phase 1/2); and Tiakis Biotech's tiprelestat (phase 2). In addition, Infusyn Therapeutics has indicated it is developing an implantable pump to deliver intravenous iloprost for PAH.

Oral non-prostacyclin therapies (such as PDE-5 inhibitors and ERAs) are commonly prescribed as first-line treatments for less severely ill PAH patients. As patients progress in their disease severity, additional advanced approved therapies, such as inhaled prostacyclin analogues (including Tyvaso DPI and Nebulized Tyvaso) or infused prostacyclin analogues (including Remodulin) are then commonly added. Orenitram was the first approved oral prostacyclin-class therapy for PAH in the United States, and offers a more convenient alternative therapy to Remodulin and Nebulized 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, and will compete with a generic version of Uptravi which is expected to launch in 2026. Orenitram's initial indication was limited to the improvement of exercise capacity, which may have led physicians to prescribe Uptravi instead of Orenitram. 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. Given the progressive nature of PAH, many patients initiate Orenitram or another one of our treprostinil-based therapies after their disease progresses while taking Uptravi. In August 2018, we announced the results of our *FREEDOM-EV* clinical study, which demonstrated that Orenitram delays time to clinical worsening, demonstrated improvement across key clinical measures, and, at study closure, indicated a positive impact on survival rates. In October 2019, the FDA approved a supplement to our Orenitram NDA expanding the Orenitram label to indicate that it also delays disease progression, in addition to improving exercise capacity. We believe that these clinical results and updated labeling have resulted in increased use of Orenitram. We are developing a next-generation IP receptor agonist called ralinepag, for PAH. If approved by the FDA, we believe ralinepag will have a competitive advantage against Uptravi (and generic selexipag, if launched) due to its once-daily dosing profile, whereas Uptravi is dosed twice daily.

We have faced generic competition for Adcirca since the launch of generic tadalafil in the United States in August 2018, which has significantly reduced our Adcirca revenues. We have also faced generic competition for Remodulin in the United States and certain European countries since 2019. Finally, we have entered into settlement agreements with Actavis and ANI permitting them to launch generic versions of Orenitram in the United States in June 2027 and December 2027, respectively, or earlier under certain circumstances. We have also entered into a settlement agreement with Watson permitting it to launch a generic version of Nebulized Tyvaso in the United States as early as January 2026, although to date Watson has not received FDA approval to do so. 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 and Challenges to our Intellectual Property Rights*.

Aside from Tyvaso DPI, Nebulized Tyvaso, and Yutrepia, there are currently no approved therapies indicated to treat PH-ILD. Several PAH drug candidates are also being developed for PH-ILD (*e.g.,* L606, seralutinib, TPIP, and Cereno Scientific AB's CS014). In addition, Foresee Pharmaceuticals is developing mirivadelgat for PH-ILD (phase 2), and Pulmovant is developing mosliciguat for PH-ILD (phase 2). Other companies are now developing, or may in the future develop, other therapies to treat PH-ILD. In addition, the use of antifibrotic therapies to treat underlying lung disease (such as the IPF therapies discussed below) could delay the onset of group 3 pulmonary hypertension.

If the *TETON* program(s) are successful, we anticipate seeking IPF and PPF indications for Nebulized Tyvaso. There are currently only three branded therapies that are approved by the FDA to treat IPF: Ofev® (nintedanib) and Jascayd® (nerandolimast), which are marketed by Boehringer Ingelheim International GmbH, and Esbriet® (pirfenidone), which is marketed by F. Hoffman-La Roche Ltd. (**Roche**). Ofev and Jascayd are also approved to treat PPF. A generic version of Esbriet is also available to treat IPF. There are potentially competing therapies in advanced clinical development for IPF. These therapies include, but are not limited to: Bristol Myers Squibb Company's admilparant (BMS-986278) (phase 3); Avalyn Pharma's AP01 (inhaled pirfenidone) (phase 2b) and AP02 (inhaled nintedanib) (planning phase 2); Calliditas Therapeutics' setanaxib (phase 2); Cumberland Pharmaceuticals' Vasculan® (ifetroban) (phase 2); Daewoong Pharmaceutical's bersiporocin (DWN12088) (phase 2); Endeavor Biosciences' taladegib (NV-101) (phase 2a); Roche/Genentech's vixarelimab (phase 2); GSK's GSK3915393 (phase 2); Insilico Medicine's ISM001_055 (phase 2); PureTech Health's deupirfenidone (LYT-100) (phase 3 ready); Redx Pharma's zelasudil (phase 2); Syndax Pharmaceuticals' Niktimvo® (axatilimab-csfr) (phase 2); Calluna Pharma (Cal101) (phase 2); GRI Bio's GRI-0621 (phase 2); Amgen's Tezepelumab-ekko (phase 2); Lilly's MTX-463 (phase 2); and Vicore Pharma's buloxibutid (phase 2). Some or all of these therapies may also be developed as treatments for PPF. As noted above, Insmed has also announced plans to study TPIP for IPF and PPF.

Unituxin may face competition from Qarziba® (dinutuximab beta), an antibody product developed by Apeiron Biologics AG that is approved in Europe to treat high-risk neuroblastoma but is not approved in the United States. In October 2016, EUSA Pharma (UK) Ltd. (which was acquired by Recordati Group in 2022) announced it had acquired global commercialization rights to Qarziba. In addition, Y-mAbs Therapeutics, Inc. (**Y-mAbs**), is developing several GD-2 targeting drug candidates, and

in November 2020 obtained FDA approval for Danyelza® (naxitamab-gqgk) to treat pediatric and adult patients with relapsed and refractory (second line) high-risk neuroblastoma in bone or bone marrow. Y-mAbs launched commercial sales of Danyelza in 2021. Y-mAbs is also conducting studies of naxitamab for frontline high-risk neuroblastoma.

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. Some 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 and requirements by the FDA in the United States, the EMA in the European Union (**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 IND; (3) clinical studies, including well-controlled clinical trials, in healthy volunteers and patients to establish safety, efficacy, and dose-response characteristics for each drug indication; (4) submission of an NDA or BLA to the FDA; and (5) FDA acceptance, review, and approval of the NDA or BLA.

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.

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 1* 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 2* 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 3* 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 4* studies are often conducted following marketing approval, in order to meet regulatory requirements or to provide additional data related to drug use.

FDA Approval Process

After successful completion of the required clinical testing, an NDA is typically submitted to the FDA in the United States, and a marketing authorization application 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 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. Most applications for non-priority drugs are reviewed within ten to twelve months. Special expedited 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 an NDA, but do not guarantee that a product will receive FDA approval.

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. In addition, before approving an NDA, the FDA will typically inspect one or more clinical sites to assess 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 post-marketing testing, including phase 4 clinical studies, and/or a risk evaluation and mitigation strategy (**REMS**) to help ensure that the benefits of the drug outweigh the potential risks. 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: restrictions on the marketing or manufacturing of the product; fines, warning letters, or holds on post-approval clinical trials; refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals; product seizure or detention, or refusal to permit the import or export of products; or 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 that the FDA 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, or for which there is no reasonable expectation that U.S. sales will be sufficient to recoup the development and production costs. 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).

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 has been shown through bioequivalence testing to be therapeutically equivalent to the approved drug, which is known as the reference listed drug (**RLD**). 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.

NDA applicants are required to identify each patent with claims that cover the drug (drug substance or drug product) or FDA-approved method of using the drug. 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 make one of several certifications to the FDA with regard to each Orange Book listed patent for the RLD. A Paragraph III certification states that the ANDA applicant seeks approval after the patent expires. A Paragraph IV certification asserts that the patent does not block approval of the ANDA, either because the patent is invalid or unenforceable or because the patent, even if valid, is not infringed by the new product. If the applicant does not challenge the listed patents, the ANDA will not be approved until all the listed patents claiming the referenced product have expired. Alternatively, for a method of use 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.

An ANDA 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.

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 may vary widely from country to country. In most cases, our distribution partners are entirely responsible for obtaining marketing approvals outside the United States.

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. 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 small-molecule 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 created an abbreviated approval pathway for biological products shown to be "biosimilar" to an FDA-licensed reference 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.

A reference biologic is granted 12 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. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

Cell-Based 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).

Regulation of Medical Devices

We currently do not hold any stand-alone medical device authorizations, but we do hold FDA authorization for the inhaler and nebulizer system as part of the drug-device combination NDAs for Tyvaso DPI and Nebulized Tyvaso, respectively. In addition, our business partners have the medical device clearances required to deliver our drugs, including, for example, the Remunity and RemunityPRO Pumps and the cartridge used with the MS-3 pump. 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 adverse medical events; truthful and non-misleading labeling; and promotion of the device consistent 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 (**PMA**).

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. To be substantially equivalent, the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device.

Devices deemed by the FDA to pose the greatest risks, such as life-sustaining, life-supporting, or some implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally-marketed device, are placed in Class III, requiring approval of a PMA application. A PMA generally requires data from clinical trials that establish the safety and effectiveness of the device.

The FDA also allows the submission of a direct *de novo* petition. This procedure allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA.

The 510(k), *de novo*, and PMA processes can be expensive, lengthy, and unpredictable. The FDA's 510(k) clearance process usually takes from three to 12 months, but can last longer. The process of obtaining a PMA approval is much more costly and uncertain than the 510(k) clearance process and generally takes from one to three years, or even longer, from the time the application is filed with the FDA. In addition, a PMA approval generally requires the performance of one or more clinical trials. Despite the time, effort, and cost invested by a sponsor, a device may not be approved or cleared by the FDA.

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. During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping requirements, and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims about them. The clinical investigators in the clinical study are also subject to FDA regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements. Additionally, after a trial begins, the sponsor, the FDA, or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include requirements pertaining to registration and device listing; QSR manufacturing requirements; labeling regulations and promotional restrictions; and reporting of device malfunctions and death and serious injuries that may have been caused by the device. The FDA has authority to order product recalls and to require post-market surveillance. In addition, certain product modifications to 510(k)-cleared and PMA-approved devices require further clearance and approval.

The FDA has broad regulatory and enforcement powers with respect to medical devices, similar to those for drugs and biologics. The FDA enforces these regulatory requirements through, among other means, periodic unannounced inspections. The Food and Drug Omnibus Reform Act gives the FDA authority to request medical device facility records in advance of, or in lieu of, inspections. Any failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, which may include sanctions such as:

- adverse publicity, warning letters, untitled letters, it has come to our attention letters, fines, injunctions, consent decrees, and civil penalties;
- repair, replacement, refunds, recall, or seizure of products;

- operating restrictions, partial suspension, or total shutdown of production;
- denial of requests for regulatory clearance or PMA approval of new products or services, new intended uses, or modifications to existing products or services;
- withdrawal of regulatory clearance or PMA approvals that have already been granted; or
- 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. Medical devices are CE marked and placed on the market in the EU at the discretion and on the liability of their manufacturer following a conformity assessment process that may include the participation of a notified body. 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.

Combination Products

A combination product is a product that combines two or more FDA-regulated product components or products, e.g., a drug-device or a device-biologic. A combination product can take a variety of forms, such as a single item 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 of the product, based on which constituent part 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. 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 FDA center may consult or collaborate with other FDA centers.

Organ Manufacturing and Organ Alternatives

Our manufactured organ and organ alternative programs present unique regulatory challenges, relative to our more traditional drugs and biologic products. For example, our xenotransplantation products are regulated by the FDA's Center for Biologics Evaluation and Research (**CBER**) as biologics. However, edits to the genome of pigs are subject to a separate FDA approval process as new animal drugs, which falls within the purview of the FDA's Center for Veterinary Medicine. In 2020, the FDA approved our new animal drug application (**NADA**) for the genetic modification to the GalSafe lineage of pigs that are intended for use as a source of human food consumption and as a source for potential therapeutic products. The GalSafe pig is the source of our development-stage UThymoKidney product. We also plan to seek NADA approval for the pig lineage containing ten genetic modifications that we are using to generate our development-stage UKidney and UHeart products. In addition, production of xenografts intended for xenotransplantation must take place in DPF facilities that meet both cGMP requirements and unique requirements designed to ensure that our pigs are free of designated pathogens.

Our Miromatrix subsidiary is developing manufactured organ alternatives based on porcine scaffolds, but these products are not regulated as xenotransplantation products because they do not contain or require *ex vivo* contact with live cells, tissues, or organs from a nonhuman animal source. Miromatrix products contain human cells and are therefore subject to regulation as human cell- and tissue-based products. We anticipate that Miromatrix products will each be regulated as a combination product consisting of a device (a porcine-derived extracellular matrix) and a biologic (the human cells used to cellularize the extracellular matrix). We expect that CBER will have primary jurisdiction as the lead FDA review center for Miromatrix products because human cells provide the fundamental mode of action in these products, and that each product will require a BLA. Because these products use cell- and tissue-based components, we anticipate that Miromatrix products will be required to be manufactured in accordance with both cGTP and cGMP standards.

We believe our 3D printed, regenerative medicine, and bio-artificial organ alternative products will be subject to similar regulatory requirements as the Miromatrix products, and will necessitate BLA approvals in the U.S.

Our CLES EVLP service utilizes an acellular organ perfusate (STEEN™ solution) that is regulated by the FDA as a medical device. As such, we submitted a PMA to the FDA for approval of the CLES technology.

In many cases, our manufactured organ and organ alternative products will involve seeking regulatory approval for categories of products that have never been approved by the FDA before, and therefore, our anticipated regulatory approach is subject to change as regulators issue new guidance, and as our discussions with the FDA and other agencies progress.

Government Reimbursement of Pharmaceutical Products

In the United States, many independent third-party health plans, and government health care programs, such as Medicaid and Medicare, pay for patient use of our commercial products. A material portion of our product sales are reimbursed under

these government programs. The availability of adequate government reimbursement for our products is subject to regulatory changes and controls affecting these programs.

Medicaid is a joint federal and state program that benefits low-income and disabled individuals. It is administered by the states and CMS, the federal agency that also administers the Medicare program. We participate in the Medicaid Drug Rebate Program, pursuant to which, as a condition of having federal funds made available for our drugs under Medicaid and Medicare Part B, we are required to pay a rebate to each state Medicaid program for each unit of our covered outpatient drugs dispensed to Medicaid beneficiaries and reimbursed by a state Medicaid program. Medicaid rebates are based on pricing data we report on a monthly and quarterly basis to CMS. If we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data to CMS for up to three years after those data originally were due.

Medicare is a federal program that is administered by CMS that provides covered health care benefits to individuals aged 65 or over and to certain disabled and chronically ill persons. Specifically, Medicare Part A covers inpatient hospital benefits, Medicare Part B covers physician-administered drugs (as well as physician services and outpatient care), and Medicare Part D covers self-administered drugs. We are required to provide average sales price information on a quarterly basis to CMS for our products that are payable under Medicare Part B.

Our drugs are covered under Medicaid and Medicare as follows:

- Tyvaso DPI, Orenitram, and Adcirca are reimbursed under Medicare Part D, and we pay rebates to Part D plans that cover these products.
- Remodulin and Nebulized Tyvaso are reimbursable under Medicare Part B. The Medicare Part B contractors who administer the program cover Remodulin and Nebulized Tyvaso under local coverage determinations and provide reimbursement according to statutory guidelines.
- Medicaid also covers Remodulin, Tyvaso DPI, Nebulized Tyvaso, Adcirca, Orenitram, and Unituxin, and, as noted above, we must pay Medicaid rebates on this utilization.
- Unituxin is administered entirely as an in-patient therapy and would typically be reimbursed under Medicare Part A. However, because Unituxin is indicated for the treatment of a pediatric cancer, Medicare is unlikely to cover treatment, but Medicaid may cover pediatric patients requiring care.

As discussed under the risk factor entitled, *Government healthcare reform and other reforms could adversely affect our revenue, costs, and results of operations,* the Inflation Reduction Act (**IRA**) enacted in 2022, regulations proposed by the Trump administration (referred to as **GLOBE** and **GUARD**), and other federal measures, if finalized or enacted, will likely have significant impacts on prices and reimbursement rates, particularly in Medicare. Individual U.S. states have also enacted, or are considering enacting, legislation to limit the growth of healthcare costs, including the cost of prescription drugs. We continue to evaluate the possible impacts on our commercial and pipeline products.

Federal law requires that any company that participates in the Medicaid Drug Rebate Program also participate in the Public Health Service's 340B drug pricing program (the **340B program**), in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program, which is administered by the Health Resources and Services Administration (**HRSA**), requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients.

In order to be eligible to have our products paid for with federal funds under Medicaid and Medicare Part B and purchased by certain federal agencies and grantees, we also participate in the U.S. Department of Veterans Affairs (**VA**) Federal Supply Schedule (**FSS**) pricing program. Under this program, we are obligated to make our products available for procurement under an FSS contract under which we must comply with standard government terms and conditions and charge a price to certain federal agencies that is no higher than the statutory federal ceiling price. We also participate in the Tricare Retail Pharmacy program, under which we pay quarterly rebates on utilization of innovator products that are dispensed through the Tricare Retail Pharmacy network to Tricare beneficiaries.

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.

The False Claims Act (**FCA**) prohibits any person from, among other things, presenting, or causing to be presented, a false or fraudulent claim for payment of government funds, or making, or causing to be made, a false statement material to a false or fraudulent claim. 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.

The federal Physician Payments Sunshine Act, implemented as the Open Payments Program, requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments and other transfers of value to various healthcare professionals, including physicians, physician assistants, nurse practitioners, and clinical nurse specialists, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

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

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.

Outside the U.S., interactions between pharmaceutical companies and physicians are also governed by strict laws, regulations, industry self-regulation codes of conduct, and physicians' codes of professional conduct. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order, or use of medicinal products, which is prohibited in the EU, is governed by the national anti-bribery laws of the EU member states. Violation of these laws could result in substantial fines and imprisonment. Certain EU member states, or industry codes of conduct, require that payments made to physicians be publicly disclosed. Moreover, agreements with physicians must often be the subject of prior notification and approval by the physician's employer, his/her competent professional organization, and/or the competent authorities of the individual EU member states. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines, or imprisonment.

State Pharmaceutical and Medical Device Marketing Laws

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 disclosure of information related to drug pricing and 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.

Privacy Laws

We must comply with numerous federal, state, and non-U.S. laws that govern the privacy and security of health and other personal information. In the U.S., numerous federal and state laws and regulations govern the collection, use, disclosure, and protection of health related and other personal information. Many of these laws differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Compliance with these laws is difficult, constantly evolving, and time consuming. Federal regulators, state attorneys general, and plaintiffs' attorneys, including class action attorneys, have been and will likely continue to be active in this space.

The Health Insurance Portability and Accountability Act of 1996 (**HIPAA**) imposes privacy, security, and breach reporting obligations, including mandatory contractual terms, with respect to safeguarding the privacy and security of individually-identifiable health information upon covered entities subject to the rule. We could be subject to criminal penalties if we knowingly obtain, use, or disclose individually-identifiable health information maintained by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA.

In addition, we are required to comply with the California Consumer Privacy Act (**CCPA**). The CCPA became effective in 2020 and establishes certain requirements for data use and sharing transparency, and provides California residents certain rights concerning the use, disclosure, and retention of their personal data. The obligations to comply with the CCPA and evolving legislation require us, among other things, to update our notices and develop new processes internally and with our partners. We may be subject to fines, penalties, or private actions in the event of non-compliance with these laws.

Outside the U.S., the legislative and regulatory landscape for privacy and data security continues to evolve. There has been increased attention to privacy and data security issues that could potentially affect our business, including the EU General Data Protection Regulation (**GDPR**), which became effective in 2018 and imposes potential penalties up to the greater of €20 million or four percent of annual global revenue for failure to comply with its requirements. In addition, the CCPA and laws and regulations enacted in the United States, Europe, Asia, and Latin America, increase potential enforcement and litigation activity.

Because we enroll EU subjects in certain of our clinical trials, we are subject to additional privacy restrictions, including restrictions relating to the collection, use, storage, transfer, and other processing of personal data, including personal health data, regarding individuals in the European Economic Area (**EEA**) as governed by the GDPR. The GDPR imposes several

requirements on companies that process personal data, strict rules on the transfer of personal data out of the EEA, including to the U.S., and fines and penalties for failure to comply with the requirements of the GDPR and the related national data protection laws of the EU member states. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with any European activities.

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 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.

Environmental Matters

We are subject to laws and regulations that require compliance with federal, state, and local regulations for the protection of the environment. We believe that our operations comply in all material respects with such applicable laws and regulations. Our compliance with these requirements did not change during the past year, and is not expected to have a material effect upon our capital expenditures, cash flows, earnings, or competitive position.

Human Capital

We are united by our commitment to developing innovative therapies for unmet needs and our dedication to be responsible citizens that have a positive impact on patients, the environment, and society. Our employees, whom we call **Unitherians**, are mission critical to these commitments because they share the same passion and dedication to meeting our purpose. As of December 31, 2025, we had approximately 1,400 employees working across our 15 locations worldwide. None of our employees are covered by a collective bargaining agreement and we believe our overall relations with our employees are good.

Our people mission focuses on five key commitments, providing Unitherians with:

- Challenging, innovative work
- Opportunities for career advancement
- Autonomy to do their best work
- Inspiring work environment allowing for work/life integration
- Competitive pay and benefits

In 2025, we achieved approximately $2.25 million in revenue per employee, which ranks near the top of our industry peer group. We believe this level of productivity is driven by a sustained focus on our people and our commitment to fostering engagement, motivation, and alignment with our strategic objectives. The Compensation Committee of our Board of Directors (**Board**) oversees our human capital management priorities, which are driven by the five key commitments noted above.

Our "Unitherian" Culture. We are intentional in our effort to maintain our entrepreneurial culture. We believe this instills a greater sense of ownership, meaning, and commitment in Unitherians, motivating them to go above and beyond to achieve our ambitious goals. Moreover, we are confident that our culture provides us with a competitive advantage by enabling us to attract the best talent to drive innovation and excellence in pursuit of our key strategic objectives. United Therapeutics is proud to be an equal opportunity employer, and does not discriminate based on race, religion, national origin, gender, age, marital status, disability, pregnancy, sexual orientation, gender identity or expression, military and veteran status, or any other basis protected by applicable law. We have a policy that prohibits all forms of unlawful harassment and retaliation, and we provide training to all Unitherians on their responsibilities and protections under this policy.

PBC Conversion. In 2021, we converted United Therapeutics into a public benefit corporation, becoming the first publicly traded company in our industry to do so. As a public benefit corporation, our Board is now obligated to balance the interests of its patient-focused public benefit purpose, the financial interests of shareholders, and the interests of other stakeholders who are materially impacted by our conduct, such as Unitherians. We believe that this conversion has helped further underscore our commitment to Unitherians, as well as our mission-driven public benefit purpose of creating a brighter future for patients.

Talent Acquisition, Retention, and Talent Development. We strive to hire and retain exceptionally talented people who are passionately committed to our goals and who will thrive in our unique culture. We provide Unitherians with a variety of personal and professional development opportunities for them to grow and thrive. We believe that our talent acquisition, talent management, and talent development efforts are key factors in our low turnover compared to our industry peer group, which historically has trended well below the industry average. In 2025, we continued that trend with our voluntary turnover at 3.5 percent, well below industry average of 10 percent (based on June 1, 2024 through June 1, 2025 data from Aon's *Turnover Study for the Life Sciences/Biotech/Pharma Sector*, published December 2025).

Inclusion and Belonging. We are proud of our diverse, engaged workforce, and we firmly believe that being a great place to work means cultivating a workplace that drives innovation, performance, and results through diverse perspectives and a culture of inclusion, with a commitment to providing equal employment opportunity for all. At United Therapeutics, inclusion is one of our five core values, deeply integrated into our employee experience.

Employee Development and Engagement. We seek to foster employee development and engagement by cultivating a culture of continuous growth and learning. We provide meaningful professional development opportunities, including leadership training, and actively encourage employees to pursue ongoing education, certifications, and skill enhancement through a variety of programs, including our education assistance program which enables full-time employees to pursue external coursework aligned with both business and individual career goals. Our commitment to quality and integrity is reinforced through required training on our Code of Conduct and other key organizational content. Employee input is central to our culture. We actively seek and value employee feedback, encouraging open dialogue and the sharing of ideas and concerns so we can take informed action. We believe our regular town hall meetings – featuring executive and business updates as well as patient-focused sessions – create meaningful connections between employees, leadership, and the patient experience. We also provide an internal social digital platform to strengthen connections across teams and functions. The effectiveness of these efforts is reflected in a recent external engagement survey conducted by Great Place to Work, where 94 percent of respondents indicated that they consider United Therapeutics "a great place to work." We have consistently maintained this high level of engagement, with 90 percent or more of respondents from 2018 to 2025 affirming their positive experience with our organization.

Health and Safety. We are committed to providing and maintaining a safe, healthy, and secure workplace for all Unitherians. We have an environmental health and safety program. We routinely provide training on workplace safety and security to all Unitherians.

A Holistic Approach to Total Rewards and Employee Wellness. Our success depends on an exceptionally talented workforce. Because Unitherians are central to achieving our strategic goals, we invest in robust people programs that reflect the high value we place on their financial, mental, and physical wellbeing. Our comprehensive total rewards offering includes a competitive base salary, short-term cash incentive compensation, stock awards, and an employee stock purchase plan – enabling all full-time employees to share directly in the company's financial success. For example, all full-time domestic Unitherians are eligible to receive minimum annual compensation of $75,000, including salary and bonus. We offer market-leading benefit programs, including a 401(k) savings plan with a company match, as well as health and welfare benefits such as flexible spending accounts, generous paid time off, parental bonding leave, adoption and surrogacy assistance, employee assistance programs, flexible work arrangements, tuition assistance, and more. We seek to consider the needs of Unitherians at all life stages, offering benefits like elder care support, tutoring/college coaching, pet care, and pet wellness benefits. We offer competitive medical, dental, vision, and prescription coverage that is available to both part-time and full-time Unitherians. Our inspiring work environments include several employee-focused amenities, such as on-site cafeterias, childcare centers, and state-of-the-art fitness centers.

Board Oversight. Our Board, through its Compensation Committee, oversees our human capital management strategies, including our focus on inclusion and belonging; workplace environment and culture; and talent development and retention. These topics are reviewed and discussed regularly at meetings of both the Compensation Committee and of the full Board.

Corporate Website

Our Internet website address is *https://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*.

INFORMATION ABOUT OUR EXECUTIVE OFFICERS

The following is a list, as of February 25, 2026, 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 Rothblatt, Ph.D., J.D., M.B.A.	71	Chairperson and Chief Executive Officer
Michael Benkowitz	54	President and Chief Operating Officer
James C. Edgemond	58	Chief Financial Officer and Treasurer
Paul A. Mahon, J.D.	62	Executive Vice President, General Counsel, and Corporate Secretary

Martine Rothblatt, Ph.D., J.D., M.B.A., founded United Therapeutics in 1996 and has served as Chairperson and Chief Executive Officer since its inception. Previously, she created the satellite radio company SiriusXM. She is an inventor or co-inventor on ten U.S. patents, with additional patents pending. Her pioneering book, *Your Life or Mine: How Geoethics Can Resolve the Conflict Between Private and Public Interests in Xenotransplantation*, anticipated the need for both global virus bio-surveillance and a greatly expanded supply of transplantable organs. Dr. Rothblatt has a Ph.D. in medical ethics from the University of London.

Michael Benkowitz joined United Therapeutics in 2011 as our Executive Vice President, Organizational Development, and was promoted to President and Chief Operating Officer in 2016. He is responsible for all of our sales, marketing, market access, patient relations, manufacturing, medical affairs, and corporate compliance activities, most company-wide administrative functions, including human resources and information technology, many of our business development efforts, and several of our key business alliances and partnerships.

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.

Item 1A. Risk Factors

Investing in our securities involves uncertainty and risk due to a variety of factors. You should carefully consider each of the following risks and all of the other information contained in this Report and in other documents that we file with, or furnish to, the SEC before making any investment decision with respect to our securities. Statements in this section are based on our beliefs and opinions regarding matters that could materially adversely affect us in the future and are not representations as to whether such matters have or have not occurred previously. Further, the risks and uncertainties described below are not the only ones we face and should not be considered a complete statement of all potential risks or uncertainties that we face or may face in the future. Additional risks not presently known to us or that we currently deem immaterial may also materially affect our business.

Risks Related to Our Products and Our Operations

We rely heavily on sales of our treprostinil-based therapies to generate revenues and support our operations.

Sales of our treprostinil-based therapies – Tyvaso DPI, Nebulized Tyvaso, Remodulin, and Orenitram – comprise the vast majority of our revenues. Substantially decreased sales of any 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 materially decline, or to grow more slowly than expected. Our net revenues could also be negatively impacted by pricing pressure as a result of competitive challenges, the IRA, and other drug price reduction initiatives. The availability of generic versions of our products has negatively impacted our revenues, and these and additional generic products launched in the future may continue to do so. The approval and launch of new therapies may materially negatively impact sales of our current and potential new products. Sales may decrease if any third party that manufactures, markets, distributes, or sells our commercial products cannot do so satisfactorily, or we cannot manage our internal manufacturing processes. Finally, if demand for our Tyvaso products does not meet our expectations, 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 sell those products.

To obtain approvals from the FDA and international regulatory agencies to sell new products, to expand the product labeling for our existing products, or to launch new delivery devices for our existing products, we must conduct clinical trials demonstrating that our products are safe and effective. Regulators have substantial discretion over the approval process. Regulators may require us to amend ongoing trials or perform additional trials, which have in the past and could in the future result in significant delays and additional costs and may be unsuccessful. Delays and costs associated with regulatory requirements to change or add trials have sometimes caused us to discontinue efforts to develop a particular product, and may do so again in the future. If our clinical trials are not successful, or we fail to address identified deficiencies adequately, we will not obtain required approvals to market the new product or new indication. We cannot predict with certainty how long it will take, or how much it will cost, to complete necessary clinical trials or obtain regulatory approvals of our current or future products. The time and cost needed to complete clinical trials and obtain regulatory approvals varies by product, indication, and country. In addition, failure to obtain, or delays in obtaining, regulatory approval has in the past and could in the future require us to recognize impairment charges.

Our clinical trials have been and in the future may be discontinued, delayed, canceled, or disqualified for various reasons, including: (1) pandemics; (2) manufacturing and supply chain disruptions; (3) the drug is unsafe or ineffective, or physicians and/or patients believe that the drug is unsafe or ineffective, or that other therapies are safer, more effective, better tolerated, or more convenient; (4) patients do not enroll in or complete clinical trials at the rate we expect, due to the availability of alternative therapies, the enrollment of competing clinical trials, or other reasons; (5) we, or clinical trial sites or other third parties, do not adhere to trial protocols and required quality controls under GCP regulations; (6) patients experience severe side effects during treatment or die during our trials because of adverse events; and (7) the results of clinical trials conducted in a particular country are not acceptable to regulators in other countries.

We may not compete successfully with established or newly developed drugs or products.

Competition could negatively impact our operating results. 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. Some of these competitors have substantially greater financial, marketing, manufacturing, sales, distribution, and technical resources, and a larger number of approved products, than we do. Some of these competitors also possess greater experience in areas critical to our success, such as research and development, clinical trials, sales and marketing, and regulatory matters.

Numerous treatments compete with our commercial therapies. For example, for the treatment of PAH, we compete with over fifteen branded and generic drugs. Sales of a generic version of Adcirca launched in August 2018 have had a material adverse impact on our sales of Adcirca. The availability of generic treprostinil injection in the United States could materially impact our revenues, and generic competition materially impacted our Remodulin revenues outside the United States. Our

competitors are also developing numerous new products that may compete with ours, including products intended to treat PAH and/or PH-ILD. For example, Merck commercially launched Winrevair (sotatercept-csrk) in the United States in March 2024, which competes with our treprostinil-based products. In addition, in June 2025 Liquidia launched U.S. sales of Yutrepia for PAH and PH-ILD, which now competes with our treprostinil-based products. Additional treatments, such as Insmed Incorporated's TPIP, are in late-stage clinical trials for treatment of PAH and/or PH-ILD. Each of these products could potentially materially adversely affect our revenues. There are also three therapies approved for the treatment of IPF, including Boehringer Ingelheim's Jascayd® (nerandomilast), which was approved by FDA in October 2025 for IPF, and later for PPF. A wide variety of additional therapies are being developed by our competitors for the treatment of IPF. Existing and future approved IPF therapies would compete with Tyvaso DPI and Nebulized Tyvaso if either or both of them is ultimately approved for that indication. The introduction of lower-priced competing products may reduce both the price that we are able to charge for our products and the volume of products we sell.

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. 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 our products, and use of these competing therapies often delays or prevents initiation of our therapies.

The successful commercialization of our products depends on the availability of coverage and adequacy of reimbursement from third-party payers, including governmental authorities and private health insurers. Pharmaceutical pricing and reimbursement pressures may negatively impact our sales.

The commercial success of our products depends, in significant part, on coverage by governmental payers such as Medicare and Medicaid, and private insurance companies. 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. Government and commercial payers are increasingly attempting to limit the price of medicinal products and frequently challenge the pricing of new or expensive drugs. 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. Financial pressures may cause United States government payers and/or private health insurers to implement policies that would reduce reimbursement rates for our products, limit future price increases, cap reimbursement rates for pharmaceuticals to rates paid internationally, require the automatic substitution of generic products, demand more rigorous requirements for initial coverage for new products, implement step therapy policies that require patients to try other medicines, including generic products, before using our products, or take other similar steps that could make it more difficult for patients to access our products. See, for example, the discussion of the IRA and the proposed GLOBE and GUARD regulations in the risk factor below entitled *Government healthcare reform and other reforms could adversely affect our revenue, costs, and results of operations*.

Our prostacyclin analogue products (Tyvaso DPI, Nebulized Tyvaso, Remodulin, and Orenitram) and our oncology product (Unituxin) are expensive therapies. Specialty pharmacy distributors may not be able to obtain adequate reimbursement for our products from commercial and government payers to motivate them to support our products. Third-party payers may reduce the amount of reimbursement for our products based on changes in pricing of other therapies for the same disease or the development of new payment methodologies to cover and reimburse treatment costs, such as the use of cost-effectiveness research or value-based payment contracts. Third-party payers often encourage the use of less-expensive generic alternative therapies, which has materially impacted our Adcirca revenues and which may materially impact our Remodulin revenues and revenues from our other products if and when generic competitors come to market. Similarly, pricing and rebating strategies for competitive therapies could put pressure on us to reduce the prices of our products and/or offer increased rebates to third-party payers. If commercial or government payers do not cover our products or limit payment rates, patients and physicians could choose competing products or products with lower out-of-pocket costs.

Our manufacturing strategy exposes us to significant risks.

We must be able to manufacture sufficient quantities of our commercial products to satisfy demand. We manufacture Nebulized Tyvaso drug product, Remodulin, Orenitram, and Unituxin, including the active ingredient in each of these products (and in Tyvaso DPI), at our own facilities and rely on third parties for additional manufacturing capacity for Nebulized Tyvaso and Remodulin. We also rely on third parties for our manufacturing, sometimes exclusively, as detailed under the risk factor below entitled, *We rely in part on third parties to perform activities that are critical to our business*. If any of our internal or third-party manufacturing and supply arrangements are interrupted, we may not have sufficient inventory to meet future demand. Changes 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.

Our internal manufacturing process subjects us to risks as we engage in increasingly complex manufacturing processes. We manufacture our entire supply of Orenitram and Unituxin without an FDA-approved back-up manufacturing site. We do not plan to engage a third party to manufacture Orenitram; however, we have initiated efforts to qualify a third party to manufacture Unituxin drug substance, which will take multiple years and may not succeed. Our manufactured organ and organ alternative 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, and we may never be able to do so successfully. Additional risks of our manufacturing strategy include the following:

- We, our third-party manufacturers, and other third parties involved in the manufacturing process, such as third parties that operate testing and storage facilities, are subject to the cGMP requirements of the FDA and its international counterparts, as applicable, current good tissue practices, and similar international regulatory standards, and other quality standards related to device manufacturing. Our ability to exercise control over regulatory compliance by our third-party manufacturers is limited.
- We and our third-party manufacturers may need to increase our respective manufacturing capacity by constructing new facilities, and/or expanding existing facilities, in order to continue meeting anticipated demand for our products. These efforts are often costly and time-consuming, and must meet rigorous regulatory requirements. These efforts could be unsuccessful or take longer or cost more than we anticipate, due to a variety of factors including the lead time needed to procure, install, and qualify the highly specialized equipment necessary to manufacture the product.
- We may experience difficulty designing and implementing processes and procedures to comply with applicable regulations as we develop manufacturing operations for new products.
- Our primary manufacturing facilities are located in rapidly growing biopharmaceutical manufacturing hubs. Competition for experienced technical and entry level operations personnel is intense, and we may experience difficulty in staffing both our existing and future manufacturing facilities, which could limit the capacity of our facilities and/or delay startup of new facilities.
- Unituxin is a chimeric monoclonal antibody that has stringent quality control and stability requirements. The drug substance manufacturing process involves a complex, multi-step cell culture and purification process. Many biologic products, including Unituxin, are particularly sensitive to the conditions under which they are manufactured. Supplier-driven changes to any of the raw materials or components used in the manufacture of Unituxin, such as discontinuation or alteration, could have unintended impacts on the quality and shelf life of Unituxin and may inhibit or prevent our ability to supply acceptable finished product in sufficient quantities or at all. Batches of Unituxin that fail to meet certain release specifications cannot be sold into the market. We have a limited capacity to produce batches of Unituxin. If a sufficient number of batches fail to meet release specifications, we could face a shortage of drug product. During 2025 we encountered limitations on our ability to supply Unituxin to our distributor in Japan, which caused our distributor to delay starting new patients on this therapy in Japan. Our efforts to proactively engage with the FDA to adjust certain manufacturing specifications for Unituxin to reduce the risk of a shortage in the United States may prove unsuccessful. Furthermore, Unituxin has a limited shelf life, which impacts our ability to stockpile inventory at comparable levels to our other commercial products.
- Natural and man-made disasters (such as fires, contamination, power loss, hurricanes and other forms of severe weather, earthquakes, flooding, terrorist attacks, and acts of war), some of which could be exacerbated by climate change, disease outbreaks, and pandemics such as COVID-19 impacting our internal and third-party manufacturing and warehousing sites could cause a supply disruption.
- The chemical, microbiological, and physical quality attributes of our products could be substandard and such products could not be sold or used or could be subject to recalls.
- The FDA and its international counterparts could require new testing and compliance inspections of new manufacturers of our products, or new manufacturing facilities we operate.
- If we produce products that do not meet FDA-approved specifications and we fail to detect these issues prior to distribution of these products, our products may be the subject of safety alerts, product recalls, or other corrective actions, and we may be charged in product liability claims and lawsuits which, regardless of their ultimate outcome, could have a material adverse effect on our business and reputation and on our ability to attract and retain customers.
- Regulatory agencies may not be able to timely inspect our facilities, or those of our third-party manufacturers, which could result in delays in obtaining necessary regulatory approvals for our products.
- We may be unable to contract with needed manufacturers on satisfactory terms or at all.
- The supply of materials and components necessary to manufacture and package our products may become scarce or unavailable, which in the past has delayed, and in the future 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 can be sold.
- Manufacturers of the devices used to administer our inhaled and infused therapies are subject to medical device requirements of the FDA and its international counterparts, as applicable. Any non-compliance, recall, or enforcement action issued against them could adversely impact our sales and operations.
- The infrastructure of our internal manufacturing facilities, along with certain facilities of our third-party manufacturers, is aging. These facilities have highly sophisticated and complex utility systems and manufacturing equipment. If any of these systems or equipment require long-term repair or replacement, the impacted facility may not be able to manufacture product for a substantial period of time.

- We and our third-party manufacturers rely upon local municipalities to supply our facilities with clean water, which is subsequently processed into high purity water and used as a key ingredient for several of our commercial drug products. If local municipalities are unable to supply water that meets relevant quality standards, we and our third-party manufacturers may be unable to manufacture these products until such a situation is remediated.
- We and our third-party manufacturers rely upon utility companies to supply our facilities with electrical power. The U.S. power grid is aging and demand for electrical power is rapidly increasing, partially driven by the construction of data centers in certain regions. If utility companies are not able to reliably supply electrical power, we and our third-party manufacturers may be unable to operate our facilities at full capacity.
- Our supply chain for raw materials and consumables extends worldwide and is complex. Suppliers based in China, India, and Taiwan play a role in our supply chain to support our second- and third-tier suppliers. Political unrest or trade disputes involving China, India, Taiwan, or other countries in our supply chain could impact our ability and the ability of our third-party manufacturers to source raw materials and consumables. We also have limited visibility into the supply chains on which our primary suppliers rely; as such, we rely on our primary suppliers to have robust risk mitigation strategies to detect issues and prevent supply disruption. Our commercial active pharmaceutical ingredient and all of our finished commercial product is manufactured in the United States.
- We are closely monitoring global military conflicts including those involving Ukraine and Israel. Although we do not directly source any raw materials or consumables from the directly impacted countries, our international suppliers and service providers in these regions could be impacted by extended conflicts or an escalation of these conflicts into neighboring countries.
- The cost of many key raw materials and consumables used in the manufacture of our products has increased due to significant inflationary pressure, and could increase further as a result of tariffs enacted by the Trump administration. Should the prices of raw materials and consumables further increase as a result of inflation or tariffs, we could see higher than average year-over-year increases in cost of goods sold. Tariffs and other trade barriers could also cause a substantial increase in the material costs associated with our construction activities.
- Any of our third-party manufacturers could undergo a change of control, causing a change in our business relationship with the relevant manufacturer. Such a change could impact our long-term supply outlook and cause us to seek alternatives that could require a lengthy regulatory approval process. Alternative suppliers may not be readily available, causing us to rely solely on internal capabilities to meet future demand.
- In 2024 we completed a DPF to produce our xenotransplantation products for human clinical studies. This facility houses gene-edited pigs in a highly controlled containment environment. This facility is a first of its kind, and unforeseen operational issues or disease outbreak amongst its herd could significantly impact the clinical development timelines for our xenotransplantation products. We are constructing two additional DPF facilities to mitigate operational risk and increase capacity. We will need to construct additional DPF facilities at significant expense in order to support the development and commercialization of our xenotransplantation products. If development of our xenotransplantation products fails or demand is significantly less than anticipated, we will not recoup our significant investment in these unique facilities as they would be difficult to repurpose. Conversely, prior to approval of our xenotransplantation products, we may not construct the number of facilities that we believe will ultimately be required to meet patient demand, which may delay our ability to meet demand when and if our xenotransplantation products are approved.
- Unituxin and Tyvaso DPI both require cold chain transportation since these products must be maintained at 2-8°C while in transit. As a result, these products have an elevated risk of quality-control incidents compared to our other commercial products, which may be transported under room temperature conditions. We use third party logistics companies that specialize in cold chain transportation for high-value products; however, should a temperature excursion occur, it may cause loss of some or all product in the particular shipment.

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 or lost revenues. 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.

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 and product complaint activities, including handling and reporting of adverse effects (including adverse events and product complaints); (5) obtaining medical device clearances and approvals for the devices used to administer our drugs; and (6) marketing and distributing our products. Any disruption in the ability of third parties to continue to perform these critical activities could materially adversely impact our business and results of operations. Any change in service providers could interrupt the manufacture and distribution of our products and services, and impede the progress of our clinical trials, commercial launch plans, and related revenues.

We rely on various distributors to market, distribute, and sell our commercial products. If they are unsuccessful in, or reduce or discontinue, 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. In the United States, we derive substantially all our treprostinil-based revenues from sales to two distributors, Accredo and CVS Specialty. If either of these two distributors places significantly larger or smaller orders in a given time period, our revenues can be impacted in a way that does not reflect patient demand.

We rely entirely on third parties to supply pumps and other supplies necessary to administer Remodulin. There are a limited number of pumps and other supplies 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. Smiths Medical (which has since been acquired by ICU Medical) discontinued manufacturing the MS-3 system used to administer subcutaneous Remodulin, and specialty pharmacy distributors informed us that supplies of new MS-3 pumps are fully exhausted, although a limited number of refurbished pumps may be available for use with generic treprostinil. In 2022, ICU Medical discontinued manufacturing and distribution of the CADD-Legacy system used to administer intravenous Remodulin. Historically, these were the pumps primarily used to administer Remodulin to patients in the United States. In 2021, we launched the Remunity Pump to administer subcutaneous Remodulin, and in 2022 ICU Medical made an alternative pump, the CADD-Solis, available for intravenous Remodulin. We rely entirely on DEKA and its affiliates to manufacture the Remunity and RemunityPRO Pumps. Additional ancillary supplies are used with these pumps, and a limited number of manufacturers that supply them.

Lilly manufactures and supplies Adcirca for us. 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.

We rely on two contract manufacturers — Forj Medical and Phillips-Medisize Corp. — to manufacture the Tyvaso Inhalation System for Nebulized Tyvaso. As Nebulized Tyvaso is a drug-device combination product, we cannot sell Nebulized Tyvaso without the Tyvaso Inhalation System. We also rely on various third parties to supply the monthly disposable device accessories that are used with the Tyvaso Inhalation System. We rely entirely on MannKind to manufacture Tyvaso DPI finished drug product and inhalers for us, with no plans to develop an alternate or backup supply arrangement. If MannKind is unable to manufacture Tyvaso DPI in sufficient quantities for us for any reason, our commercial sales of Tyvaso DPI could be materially and adversely impacted.

We also rely on various sole-source suppliers for manufacturing activities related to ralinepag. We are in the process of qualifying our RTP facility to produce our primary commercial supply of ralinepag if and when it is approved by the FDA. This effort could be unsuccessful or take longer or cost more than we anticipate, in which case we may be more reliant on our existing third-party contract manufacturers.

Finally, we rely entirely on Sanner GmbH to manufacture cartridges that were cleared by the FDA for use with the MS-3 pump to administer Remodulin. For a further discussion of risks created by the use of third-party contract manufacturers, see the risk factor above entitled, *Our manufacturing strategy exposes us to significant risks*.

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. Third-party failure to conduct or assist us in conducting clinical trials in accordance with study protocols, quality controls, GCP, or other applicable requirements or to submit associated regulatory filings, could limit or prevent our ability to rely on results of those trials in seeking regulatory approvals.

Reports of actual or perceived side effects and other adverse effects associated with our products could cause our sales to decrease or regulatory approvals to be revoked.

Reports of adverse effects (including side effects and other adverse events, as well as product complaints) associated with our products could affect a physician's decision to prescribe or a patient's willingness to use our products, which may have a significant adverse impact on sales of our products. An example of a known risk associated with the pump system used for intravenous Remodulin is sepsis, which is a serious and potentially life-threatening infection of the bloodstream caused by a wide variety of bacteria. In addition, Unituxin is associated with severe side effects, and its label contains a boxed warning related to potential infusion reactions and neurotoxicity. We are required to report certain adverse effects to the FDA and its international counterparts. Development of new products, and new formulations, indications, and delivery devices for existing products, could result in new side effects and other adverse effects which may be serious in nature. If the use of our products harms patients or is perceived to harm patients, regulatory approvals could be revoked or otherwise negatively impacted.

Negative attention from special interest groups may impair our business.

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 organ manufacturing 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 or manufacturing activities could impede the operation of our business.

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 losses significantly exceed our liability insurance coverage, we may experience financial hardship or potentially be forced out of business. Clinical testing and eventual marketing and sale of new products, reformulated versions of existing products, or use of existing products in new indications could expose us to new product liability risks that are not covered by our existing policies.

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, Chairperson 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. 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 retain qualified scientific and technical personnel. Competition for such personnel in our industries is intense. If we fail to attract and retain such employees, we may not be successful in developing and commercializing new therapies.

Risks Related to Legal Compliance

We must comply with extensive laws and regulations in the United States and other countries. Failure to obtain approvals on a timely basis or to comply with these requirements could delay, disrupt, or prevent 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, the U.S. Department of Agriculture, and their international counterparts, as applicable. The process of obtaining and maintaining regulatory approvals for new drugs, biologics, and medical devices is lengthy, expensive, and uncertain. The regulatory approval process is particularly uncertain for our organ manufacturing program. Once approved, the manufacture, distribution, advertising, and marketing of our products are subject to extensive regulation, including requirements related to product labeling, pharmacovigilance and adverse effect reporting and processing (including both adverse events and product complaints), storage, distribution, and record-keeping. Our product candidates have in the past and may in the future fail to receive regulatory approval. 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 effects subsequent to commercial introduction. Our ability to obtain regulatory approvals for our products has been, and in the future may be, materially impacted by the outcome and quality of our clinical trials and other data submitted to regulators, as well as the quality of our manufacturing operations and those of our third-party contract manufacturers and contract laboratories. In addition, third parties may submit citizen petitions to the FDA seeking to delay approval of, or impose additional approval conditions for, our products. Citizens petitions have in the past, and may in the future, significantly delay or prevent approval of our products.

In April 2025, the Trump administration announced a reduction in force at the U.S. Department of Health and Human Services, including layoffs at the FDA. These and other efforts to reduce the size of the FDA or its funding, combined with changes in FDA leadership, have begun to result in slower FDA response times and/or longer review periods. Future government shutdowns, funding disputes, reorganizations, furloughs, or reductions in resources or changes in priorities or focus may result in further delays. If response and review delays persist and/or worsen, they could potentially impact our ability to timely progress our pipeline efforts or obtain regulatory approval for new products and new indications for existing products.

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. Regulatory approval is also required for new formulations and new indications for an approved product. While physicians may 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 and its international counterparts. Failure to follow applicable rules and guidelines related to promotion and advertising can result in the adverse regulatory actions by the FDA and its international counterparts — such as warning letters, enforcement actions, civil lawsuits, or criminal prosecution.

We must comply with various laws in jurisdictions around the world that restrict certain marketing practices.

Our business activities may be subject to challenge under laws in jurisdictions around the world restricting marketing practices, such as:

- Anti-kickback and false claim statutes, the Foreign Corrupt Practices Act, and the United Kingdom Bribery Act. In the United States, the Federal Anti-Kickback Statute prohibits, among other activities, knowingly and willfully offering, paying, soliciting, or receiving remuneration (i.e., anything of value) 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 healthcare program like Medicare or Medicaid. This statute is interpreted broadly to apply to arrangements between pharmaceutical manufacturers and prescribers, purchasers, specialty pharmacies, formulary managers, patients, and others. Our practices may not always qualify for safe harbor protection under this statute.
- The Federal False Claims Act, which prohibits any person from knowingly presenting or causing to be presented a false or fraudulent claim for payment of government funds, or making or causing a false statement material to a false or fraudulent claim. Pharmaceutical and health care companies have faced liability under this law for causing false claims to be submitted because they marketed a product for unapproved and non-reimbursable uses.
- Analogous state laws and regulations, including anti-kickback and false claims laws, which apply to items and services reimbursed under Medicaid or, in several states, regardless of the payer, including private payers.

We are also subject to numerous other laws and regulations that, while not specific to the healthcare industry, apply to the healthcare industry in important ways. For example, we are subject to antitrust regulations with respect to interactions with other participants in the markets we currently serve or may serve in the future. These antitrust laws are vigorously enforced in the U.S. and in other jurisdictions in which we operate.

Compliance with these and similar laws on a state-by-state basis is difficult, time consuming, and requires substantial resources. Any investigation, inquiry, or other legal proceeding under these laws related to our operations, even if we successfully defend against it, or any penalties imposed upon us for failure to comply, could have a material adverse effect on our business and financial condition or reputation. Sanctions under these federal and state laws may include treble civil monetary penalties, payment of damages, fines, exclusion of our products from reimbursement under federal health care programs, imprisonment, and the curtailment or restructuring of our operations.

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

Our industry is highly regulated and changes in law or government health care programs, like Medicaid or Medicare, may adversely impact our business, operations, or financial results. We cannot predict how future federal or state legislative or administrative changes related to healthcare reform will affect our business.

Political, economic, and regulatory developments may lead to fundamental changes in the U.S. healthcare industry, particularly given the persistent criticism of prescription drug costs in the U.S. We expect there will continue to be legislative and regulatory proposals to change the healthcare system in ways that could adversely impact our ability to commercialize and to sell our products profitably. Even proposals or executive actions that ultimately are deemed unlawful or otherwise repealed could negatively impact the U.S. pharmaceutical sector and our business.

Among other things, there have been several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things: bring more transparency to drug pricing; reduce the cost of prescription drugs under government payer programs; review the relationship between pricing and manufacturer patient programs; and reform government program reimbursement methodologies for drugs.

The IRA was enacted in 2022. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare, with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); redesigns the Medicare Part D benefit (beginning in 2024); and replaces the Medicare Part D coverage gap discount program with a new manufacturer discounting program (beginning in 2025). CMS has published the negotiated prices for the initial ten drugs, which went into effect in January 2026, and the subsequent 15 drugs, which will first be effective in 2027. The IRA permits the Secretary of the Department of Health and Human Services (**HHS**) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has issued guidance, and is expected to continue to issue guidance, even while multiple lawsuits challenging the IRA negotiation requirement remain pending. While the impact of the IRA on the pharmaceutical industry cannot yet be fully determined, it is likely to be significant.

Under the Medicare Part D manufacturer discounting program that became effective January 1, 2025 pursuant to the IRA, manufacturers must give a 10 percent discount on Part D drugs in the initial coverage phase, and a 20 percent discount on Part D drugs in the so-called "catastrophic phase" (the phase after the patient incurs costs above the initial phase out-of-pocket threshold, which is $2,000 beginning in 2025). The IRA allows the 10 and 20 percent discounts to be phased in over time for certain drugs for "specified small manufacturers." In April 2024, CMS informed us that we are deemed to be a specified small manufacturer.

Orenitram and Tyvaso DPI are both reimbursed under Medicare Part D, and the reimbursement amount will be impacted by the 10 and 20 percent discounts under the new manufacturer discounting program. These increased discounts will impact Tyvaso DPI and Orenitram revenues, while also having an industry-wide impact on the cost of Part D drugs. The impact on

Tyvaso DPI and Orenitram revenues could be offset because the IRA's Part D redesign, which went into effect in 2025 and resulted in an increase in the number of patients able to afford these therapies. The amount of the offset, if any, is inherently uncertain and difficult to predict.

The manner in which CMS has implemented the manufacturer discounting program will also increase financial obligations of Part D prescription drug plans with respect to beneficiaries in the catastrophic coverage phase. This may incentivize Part D prescription drug plans to seek greater price concessions from us in order to include our products on their formularies.

More recently, the One Big Beautiful Bill Act, which was enacted in July 2025, significantly reduced funding of the Medicaid program. Such reductions are expected to decrease the number of persons enrolled in Medicaid and reduce the services covered by Medicaid, which could adversely affect our sales of our commercial products.

The Trump administration is pursuing a two-fold strategy to reduce drug costs in the U.S. On the one hand, the Trump administration has threatened to impose significant tariffs on pharmaceutical manufacturers that do not adopt pricing policies such as most favored nation pricing, which would tie the price for drugs in the U.S. to the lowest price in a group of other countries. In response, multiple manufacturers have entered into confidential pricing agreements with the federal government. On the other hand, the Trump administration is pursuing traditional regulatory pathways to impose drug pricing policies and published two proposed regulations in December 2025, referred to as GLOBE and GUARD. If finalized and adopted, these regulations would implement mandatory payment models under which manufacturers of eligible drugs would be required to pay rebates to the federal government on a portion of the units of their drugs that are reimbursed by Medicare, with the rebate amount based on most favored nation pricing. Imposing a rebate in the U.S. that is based on drug prices outside the U.S. would mark a drastic and unprecedented shift in the U.S. pharmaceutical market. While it is unclear whether and how the Trump administration proposals will be implemented, the Trump administration policies are likely to have a significant negative impact on the pharmaceutical industry and may negatively affect our ability to receive revenues from sales of our commercial products. Even regulatory proposals or executive actions that ultimately are deemed unlawful or otherwise repealed could negatively impact the U.S. pharmaceutical sector and our business.

Individual U.S. states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement limitations, marketing cost disclosure, and transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing. A number of states have either implemented or are considering implementation of drug price transparency legislation. Requirements of pharmaceutical manufacturers under such laws include advance notice of planned price increases; reporting price increase amounts and factors considered in taking such increases; wholesale acquisition cost information disclosure to prescribers, purchasers, and state agencies; and new product notice and reporting. Other legislation establishes so-called prescription drug affordability boards that could impose price caps on specific drugs, and at least one state board is imposing an upper payment limit. States are also seeking to implement general, across-the-board price caps for pharmaceuticals, or are seeking to regulate drug distribution. These state legislative measures could limit the price or payment for certain drugs or could complicate the distribution of drugs. A number of states are authorized to impose civil monetary penalties or pursue other enforcement mechanisms against manufacturers who fail to comply with state law requirements, including the untimely, inaccurate, or incomplete reporting of drug pricing information under transparency obligations. Additional legislation in these areas imposing additional requirements on manufacturers, as well as penalties for noncompliance, could be introduced in the future. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs.

In October 2020, HHS and the FDA issued a final rule and guidance concerning two new pathways for importing lower-cost drugs into the United States. The final rule allows certain prescription drugs to be imported from Canada, and the guidance describes procedures for drug manufacturers to facilitate the importation of FDA-approved drugs and biologics manufactured abroad and originally intended for sale in a foreign country into the United States. In January 2024, the FDA approved Florida's drug importation plan. In November 2025, the FDA granted a six-month extension for Florida to begin implementing its plan.

The IRA and other healthcare reform measures that may be adopted in the future may result in additional downward pressure on the payment that we receive for any approved product, and may adversely impact our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payment from commercial payers. Further state and federal healthcare reform measures adopted in the future could limit the amounts that state and federal governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

It is difficult to predict the impact, if any, that future federal or state legislation, or executive actions, might have on the use of and reimbursement for our products in the United States, such as the potential for the importation of generic versions of our products, for price caps under state laws, or for increased difficulties and costs related to the distribution of our products.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions, and fines, which could adversely impact our business, financial condition, results of operations, and prospects.

We participate in, and have certain price reporting obligations to, the Medicaid Drug Rebate program and other governmental programs that require us to pay rebates or offer discounts on our products. Certain programs, such as the

340B program, impose limits on the price we are permitted to charge certain entities for our products or for any future products for which we receive regulatory approval. Changes to these programs could negatively affect the coverage and reimbursement by these programs of our products or any future products for which we receive regulatory approval and could negatively impact our results of operations. Our failure to comply with these price reporting, rebate payment, or pricing requirements could adversely impact our financial results. Applicable laws and regulations, including the IRA, could affect our obligations in ways we cannot anticipate.

Pricing and rebate calculations vary among products and programs. The calculations are complex and are often subject to interpretation by us, governmental or regulatory agencies, and the courts. If we must restate or recalculate information provided under these programs, our costs of compliance could increase. We could be held liable for errors in the submissions we are required to make with regards to governmental drug pricing program, including retroactive rebates and program refunds. We may incur significant civil monetary penalties if we are found to have knowingly provided false information to the government or to have charged 340B covered entities more than the statutorily mandated ceiling price, and resolution of any claims that we violated these provisions could be costly. Certain failures to timely submit required data also could result in a civil monetary penalty for each day the information is late. We could also become subject to allegations under the False Claims Act and other laws and regulations. In addition, misreporting and failure to timely report data to CMS also can be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid Drug Rebate program. If CMS terminates our rebate agreement, no federal payments would be available under Medicaid or Medicare Part B for our covered outpatient drugs.

CMS, the VA, the Office of Inspector General of the Department of Health and Human Services (**OIG**), and other governmental agencies have pursued manufacturers that were alleged to have failed to report data to the government in a timely manner. Governmental agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. We cannot assure you that any submissions we are required to make under governmental drug pricing programs will not be found to be incomplete or incorrect.

Similar political, economic, and regulatory developments are occurring in other countries and may affect our profitability. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles that may increase operating costs. Healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines and medical devices by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval or certification of our product candidates, restrict or regulate post-approval activities, and affect our ability to commercialize our product candidates, if approved or certified. In markets outside of the United States and EU, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

We may be subject to enforcement action or penalties in connection with the contract pharmacy policy we have implemented pursuant to the 340B program.

We participate in the 340B program and have implemented a policy regarding the distribution of our drugs at 340B ceiling prices through third-party pharmacies that contract with 340B covered entities, known as "340B contract pharmacies". Under our 340B contract pharmacy policy, which we adopted to address program integrity risks, our drugs are only shipped at the 340B ceiling price to those 340B contract pharmacies that meet certain criteria. Our policy has no impact on 340B purchases by 340B covered entities themselves. Our contract pharmacy policy preserves patient access, while addressing compliance and integrity concerns resulting from the proliferation of contract pharmacies. Nonetheless, HHS, in a non-binding (and now-retracted) Advisory Opinion, stated that manufacturers in the 340B program are obligated to sell their covered outpatient drugs at the 340B ceiling price to all contract pharmacies acting as agents of a covered entity. Certain covered entities have expressed the view that participating manufacturers are obligated to sell their covered outpatient drugs to all contract pharmacies of a covered entity.

We and certain other manufacturers initiated litigation challenging the Advisory Opinion and HRSA's position on contract pharmacies generally. HHS subsequently withdrew the Advisory Opinion, but HRSA issued letters to manufacturers, including us, threatening enforcement action if the manufacturers do not abandon their 340B contract pharmacy policies. We filed suit against HHS and HRSA in June 2021 in the U.S. District Court for the District of Columbia. In September 2021, HRSA sent to us, along with the other manufacturers challenging HRSA's 340B interpretation, letters stating that HRSA was referring this issue to the OIG for potential enforcement action. We have not had any communication from the OIG regarding our 340B contract pharmacy policy. In November 2021, the court granted our motion for summary judgment, ruling that the letters threatening enforcement action "contain legal reasoning that rests upon an erroneous reading of Section 340B." HRSA appealed, and the appellate court affirmed the lower court's decision in our favor.

If HRSA develops a new theory of liability, we may face enforcement action or penalties as well as adverse publicity. Such an outcome may also prompt other parties to challenge our policies. It is also possible that covered entities could bring an action against us under the administrative dispute resolution pathway. We expect the compliance of policies like ours will continue to be litigated. We may also face enforcement action under the laws of certain states that are seeking to impose their own 340B contract pharmacy requirements. Such actions could, if determined adversely to us, result in penalties and other sanctions that could have a negative impact on our business. If we are unable to curb the proliferation of abuses caused by 340B contract pharmacies, we could see increased sales at 340B ceiling prices, which could have a material adverse impact on our revenues.

Patient assistance programs for pharmaceutical products have come under increasing scrutiny by governments, legislative bodies, enforcement agencies, and other third parties. These activities may result in actions that effectively reduce prices or demand for our products, harm our business or reputation, or subject us to fines or penalties.

Company-sponsored patient assistance programs, including insurance premium and co-pay assistance programs and manufacturers' donations to third-party charities that provide such assistance, are subject to heightened scrutiny. The Department of Justice (**DOJ**) has taken enforcement action against pharmaceutical companies alleging violations of the Federal False Claims Act and other laws in connection with patient assistance programs. We have been, and may in the future, be subject to DOJ investigations with respect to our support of non-profit patient assistance programs, which can result in sanctions, fines, or other payments and agreements with respect to our compliance programs. As discussed in Note 14—*Litigation*, to our consolidated financial statements, we have been sued by Humana Inc., United Healthcare Services, Inc., and various parties in the *MSP Recovery* litigation for allegedly violating RICO and various state laws in connection with our donations to a charity. These lawsuits, or other lawsuits in the future, could result in significant monetary judgments and the imposition of other penalties against us.

Members of Congress have called upon the OIG to issue revised guidance about patient assistance programs. Actions taken by the OIG, the DOJ, or other agencies as a result of this industry-wide inquiry could reduce demand for our products and/or coverage of our products by federal and state health care. If any or all these events occur, our business, prospects, and stock price could be materially and adversely affected.

Payers and pharmacy benefit managers have developed mechanisms to limit the benefits patients receive under co-pay assistance programs through imposing so-called co-pay accumulator or maximizer programs. These programs do not allow a patient using co-pay assistance to count the manufacturer's co-payment contribution toward their annual out-of-pocket payment maximum/deductible. Once the co-pay benefit has been exhausted, patients are faced with paying the full out-of-pocket maximum/deductible. Some states have passed legislation to limit the use of co-pay accumulator programs, while some other states have indicated that these programs should be allowed to limit cost of care and encourage patients to use lower cost generics. In addition, some states have imposed restrictions on manufacturer co-pay programs when therapeutic equivalents are available. Growing use of such programs, or new laws limiting manufacturer ability to provide co-pay assistance, could affect patient access to our products and limit product utilization, which may, in turn, adversely affect our business, prospects, and stock price.

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. We are expanding these activities in both scale and location. 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. The risk of accidental contamination or injury from these materials cannot be eliminated. Once chemical and hazardous materials leave our facilities, we cannot control the manner in which such hazardous waste is disposed of by our contractors. We could be liable for substantial civil damages or costs associated with the cleanup of the release of hazardous materials and such liability could have a material adverse effect on our business.

The increasing use of social media platforms and artificial intelligence-based software 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. For example, patients and others may use social media channels to comment on the effectiveness of a product or to report alleged adverse effects, such as adverse events and product complaints. When such disclosures occur, we may fail to monitor and comply with applicable adverse effect 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 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.

Additionally, artificial intelligence-based software is increasingly being used in our business and in the biopharmaceutical industry generally. As with many developing technologies, artificial intelligence-based software presents risks and challenges that could affect its further development, adoption, and use, and therefore our business. For example, algorithms employed by such software may be flawed; data sets may be insufficient, of poor quality, or contain biased information; and inappropriate or controversial data practices could impair the accuracy and usefulness of the results. If our analyses assisted by artificial intelligence applications are deficient or inaccurate, we could be subject to competitive harm, potential legal liability, and brand or reputational harm. Furthermore, use of artificial intelligence-based software may lead to the inadvertent release of confidential information which may impact our ability to realize the benefit of our intellectual property and expose us to liability and brand or reputational harm.

Risks Related to Our Intellectual Property and Data Privacy

If any of the agreements under which we license or acquired intellectual property rights are breached or terminated, we could lose our rights to continue to develop, manufacture, and sell the products covered by such agreements.

Our business depends upon our continuing ability to exploit our intellectual property rights acquired from third parties under product license and purchase agreements covering drugs or other products 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 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 the 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 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. Our patents related to our individual treprostinil-based products expire at various times through 2042. We entered into settlement agreements with certain generic drug companies permitting them to launch generic versions of Remodulin in the United States and other companies to launch generic versions of Nebulized Tyvaso and Orenitram in the United States. In some instances, the FTC has brought actions against brand and generic companies that have entered into such agreements, alleging that they violate antitrust laws. Even in the absence of an FTC challenge, other governmental or private litigants may assert antitrust or other claims against us relating to such agreements. We have been sued by Sandoz for violating our settlement agreement with them and we have accrued a liability of $74.1 million in connection with such suit, reflecting the final judgment and post-judgment interest accrued through the end of 2025, although our ultimate liability may be greater. Other actions against us in the future could result in significant monetary judgments and the imposition of other penalties against us. 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 the Unituxin drug product. For further details, see *Part I, Item 1—Business—Patents and Other Proprietary Rights, Strategic Licenses, and Market Exclusivity—Generic Competition and Challenges to our Intellectual Property Rights.*

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. When our patents expire, competitors may develop generic versions of our products and market them at a lower price. 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 United States' laws.

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 offices, or other means. For example, Liquidia is challenging various patents related to Nebulized Tyvaso and our other treprostinil-related products, and has successfully challenged some of them.

Patent litigation can be time consuming, distracting, and costly, and the outcome may be difficult to predict and unfavorable to us. If we are unsuccessful in the defense of our patents, our business could be negatively impacted.

We also rely on trade secrets to protect our proprietary know-how and other confidential technological advances. Our confidentiality agreements with our employees and others to whom we disclose trade secrets and confidential information may not necessarily prevent our trade secrets from being used or disclosed without our authorization, as we allege happened in our lawsuit against Liquidia and Dr. Rosciigno. These agreements may be difficult, time-consuming, and expensive to enforce or may not provide an adequate remedy in the event of unauthorized disclosure. If our trade secrets were 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, and our business and competitive position could be harmed.

Third parties have alleged, and may in the future allege, that our products or services infringe their patents and other intellectual property rights, which could result in the payment of royalties that negatively affect our profits, subject us to costly and time-consuming litigation, or cause us to lose the ability 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. For 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; if not, 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 may incur significant costs to defend ourselves against the claims made in the action and our management's attention could be diverted from our day-to-day business operations, whether or not the action has merit. An adverse judgment or settlement resulting from the action could require us to pay substantial amounts in damages for infringement or to obtain a license to continue to use the intellectual property that is the subject of the infringement claim, or could result in injunctive relief limiting our ability to develop, manufacture, or sell our products. In April 2025, Liquidia initiated litigation against us alleging that Tyvaso DPI infringes a patent assigned to Liquidia. While we believe we have meritorious defenses and will vigorously defend against these claims, this litigation could be time consuming and ultimately may not be resolved in our favor, in which case, we could be required to pay substantial damages.

Cybersecurity incidents and other disruptions impacting our networks, systems, or data may have a material adverse effect on our business.

We are increasingly dependent on information technology systems and infrastructure, much of which is outsourced to third parties including in cloud-based platforms. We collect, store, and use sensitive or confidential data, including intellectual property, our proprietary business information and that of our suppliers, patients, healthcare providers, and business partners, and personally identifiable information. We recently launched a new patient relations program, United Therapeutics Cares, which has increased our access to sensitive information about our patients. Actual or alleged cybersecurity incidents, including those caused by employee error, malfeasance, system failures, malware, ransomware, viruses, distributed denial of services attacks, credential harvesting, social engineering, and other forms of unauthorized access or disclosure to, or disrupting the operation of, our networks and systems or those of our customers, suppliers, vendors, and other service providers, can cause the loss, destruction, or unauthorized access or disclosure of data, including personal information of employees or confidential or proprietary information, disruption of our manufacturing and other operations, and damage to our reputation and competitive position, any of which could be costly to address and remediate and adversely affect our business, financial condition, or results of operations. We are also 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. Therefore, cybersecurity incidents could expose us to significant civil and/or criminal penalties, as well as private litigation, all of which could adversely affect our business, financial condition, or results of operations.

In the past we have experienced, and in the future we may again experience, data security incidents. The preventive actions we take to reduce exposure to, and the risks associated with, cybersecurity incidents may be insufficient to prevent or mitigate the effects of material cybersecurity incidents in the future. Because the tools and methods – including those deploying artificial intelligence technology – used by threat actors to damage or obtain unauthorized access to networks, systems, and data change frequently, and are often not known until used against a target, we may be unable to anticipate these tools or methods or implement adequate preventative measures. It is impossible to eliminate all cybersecurity threats and exposure to cybersecurity incidents, and thus our networks and systems, as well as those of our service providers, suppliers, customers and other third parties, remain potentially vulnerable to known or unknown threats.

Risks Related to Our Financing Capacity, Indebtedness, and Investments

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. Our credit agreement (the **2025 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.

Our portfolio of investments is subject to market, interest, operational, and credit risk that may reduce its value.

We maintain a portfolio of investments that includes: (1) corporate debt securities; (2) strategic investments in publicly-traded equity securities; and (3) strategic equity investments in privately-held companies. These investments are subject to general economic conditions, volatility in the financial marketplace, market- and industry-wide dynamics, the current elevated interest rate environment and changes in interest rates, industry- and company-specific developments impacting the business, prospects, and credit ratings of the issuer of the securities, and other factors, each of which has affected, and may in the future affect, the income that we receive from our investments, the net realizable value of our investments, and our ability to sell them. These factors have caused, and could in the future cause, us to: (a) experience a decline in our investment income; (b) record impairment charges to reduce the carrying value of our investment portfolio; or (c) sell investments for less than our acquisition cost; each of which in turn could negatively impact our liquidity and our earnings. Our efforts to mitigate these risks through diversification of our investments and monitoring of our portfolio's overall risk profile may not be successful and the value of our investments may decline. The privately-held companies we have invested in may be particularly susceptible to the factors described above as these companies are typically in the early stages of developing technologies or products that may never materialize, which could result in a loss of all or a substantial part of our investment in these companies.

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

We seek to expand our business in part through acquisitions of complementary businesses, products, and technologies. The success of this strategy will depend on our ability to identify, and the availability of, suitable acquisition candidates. We may incur costs related to an acquisition but may be unable or unwilling to consummate the proposed transaction. Acquisitions involve numerous risks, including: the ability to realize anticipated synergies and manage 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; potential disruptions in ongoing operations during integration; risks inherent in entering markets and sectors in which we have limited or no direct experience; and the potential loss of key employees, customers, or vendors and other business partners of the acquired companies. External factors, such as compliance with law, may also impact the successful integration of an acquired business. Acquisitions could involve dilutive issuances of equity securities, the incurrence of debt, one-time write-offs of goodwill (or in-process research and development assets), 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. The terms of financing we obtain 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 limit our ongoing operations or require us to divest assets.

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, significant price and volume fluctuations in the market may not relate to operating performance. The price of our common stock could decline sharply due to general market conditions as well as the following factors, among others:

- quarterly and annual financial results and any failure to meet our expectations or those of securities analysts;
- timing of enrollment and results of our clinical trials;
- announcements regarding generic or other challenges to the intellectual property related to our products, the launch and successful commercialization of generic versions of our products or other competitive products, and the impact of competition from generic and other products on our revenues;
- announcements regarding litigation matters, including our ongoing litigation with Liquidia, among others;
- announcements regarding our efforts to obtain regulatory approval of, and to launch commercial sales of, new products;
- 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 laws and regulations affecting reimbursement of, our therapeutic products by government payers, changes in reimbursement policies of private insurance companies, including the implementation and impacts of the IRA and other governmental efforts to reduce drug prices, 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 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 other activity which could be viewed as being dilutive to our shareholders;

- rumors 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 domestic or international regulatory approvals;
- 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; and
- 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.

Provisions of Delaware law, our charter, bylaws 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, our restated certificate of incorporation, and bylaws 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, as a result of our conversion to a PBC, our Board is required to consider and balance the financial interests of shareholders, the interests of stakeholders materially affected by our conduct, and the pursuit of our specific public benefit purpose when evaluating takeover offers. This requirement of Delaware law may make our company a less attractive takeover target than a traditional for-profit corporation.

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 accelerate the vesting of outstanding stock options, and restricted stock units. Any increase in our stock price resulting from the announcement of a change of control, and our broad-based change of control severance program, under which our employees may be entitled to severance benefits if they are terminated without cause (or they terminate their employment for good reason) following a change of control, could make an acquisition of our company significantly more expensive to the purchaser.

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 the 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 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 and MannKind have the right to terminate our license agreements related to Adcirca and Tyvaso DPI, 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.

Our shareholders must rely on stock appreciation for any return on their investment in us.

We have never paid, and do not intend to pay, cash dividends. The terms of our current or future debt arrangements we may enter into may restrict us from doing so. As a result, the return on an investment in our common stock depends entirely upon the future appreciation, if any, in the price of our common stock.

Our exclusive forum bylaw may limit our shareholders' ability to bring a claim in a forum that they find favorable for disputes with us or our directors, officers, or other employees.

Our bylaws provide that, to the fullest extent permitted by law, unless we agree in writing to an alternative forum, (1) the Delaware Court of Chancery (or, if such court does not have, or declines to accept, jurisdiction, another state court or a federal court located in Delaware) will be the exclusive forum for any complaint asserting any internal corporate claims, including claims in the right of the corporation based upon a violation of a duty by a current or former director, officer, employee, or shareholder in such capacity, or as to which the Delaware General Corporation Law confers jurisdiction upon the Court of Chancery; and (2) the federal district courts will be the exclusive forum for any complaint asserting a cause of action arising under the Securities Act of 1933, as amended. The choice of forum provision may limit our shareholders' ability to bring a claim in a forum that they find favorable for disputes with us or our directors, officers, or other employees, and may discourage such lawsuits. There is uncertainty as to whether a court would enforce this provision. If a court ruled the choice of forum provision was inapplicable or unenforceable in an action, we may incur additional costs to resolve such action in other jurisdictions. Our choice of forum provision is intended to apply to the fullest extent permitted by law to the above-specified types of actions and proceedings, including any derivative actions asserting claims under state law or the federal securities laws. Our shareholders will not be deemed, by operation of the choice of forum provision, to have waived our obligation to comply with all applicable federal securities laws and the rules and regulations thereunder.

In 2021, we converted to a Delaware PBC. Conversion may not result in the benefits that we anticipate, requires our directors to balance the interest of shareholders with other interests, and may subject us to additional litigation and other risks.

We may not be able to achieve our public benefit purpose or realize the expected positive impacts from being a PBC.

One of the primary distinctions between a PBC and a traditional Delaware for-profit corporation is that, in making decisions, the directors of a PBC have an obligation to balance the financial interests of shareholders, the interests of stakeholders materially affected by the PBC's conduct, and the pursuit of the corporation's specific public benefit purpose. The application of this balancing obligation may allow our directors to make decisions that they could not have made pursuant to the fiduciary duties applicable prior to PBC conversion. There is no guarantee that our Board will resolve conflicts among the financial interests of our shareholders, our public benefit purpose, or stakeholders materially affected by our conduct, in favor of our shareholders' financial interests. For instance, in a sale of control transaction, our Board would be required to consider and balance the factors listed above and might choose to accept an offer that does not maximize short-term shareholder value due to its consideration of other factors. This requirement of Delaware law may make our company a less attractive takeover target than a traditional for-profit corporation.

A Delaware PBC must also provide its shareholders with a statement, at least every other year, as to the PBC's assessment of the success of its efforts to promote its public benefit purpose and the best interests of those materially affected by the PBC's conduct. If the public perceives that we are not successful in promoting our public benefit purpose, or that our pursuit of our public benefit purpose is having a negative effect on the financial interests of our shareholders, that perception could negatively affect our reputation, which could adversely affect our business, results of operations, and stock price. In addition, Delaware's PBC statute may be amended to require more explicit or burdensome reporting requirements that could increase the time and expense required to comply.

As a Delaware PBC, we may be subject to increased litigation risk.

Shareholders of a Delaware PBC (if they, individually or collectively, own the lesser of (1) two percent of the PBC's outstanding shares; or (2) shares with a market value of $2 million or more on the date the lawsuit is instituted) can file a derivative lawsuit claiming the directors failed to balance shareholder and public benefit interests. Traditional Delaware for-profit corporations are not subject to this potential liability. As a PBC, we may be subject to increased derivative litigation, which may be costly and require management's attention, which may adversely affect our financial condition and results of operations. In addition, there is currently limited case law involving PBCs (including case law interpreting and applying the balancing obligation of PBC directors), which may expose us to additional litigation risk generally until additional case law develops or additional legislative action is taken.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

We have implemented a cybersecurity program consistent with industry practices to assess, identify, and manage risks from cybersecurity threats that may result in adverse effects on the confidentiality, integrity, and availability of our networks, systems, and data.

Governance

Board of Directors

Our board of directors exercises its oversight role through its Audit Committee, which has primary responsibility for overseeing risks related to cybersecurity matters. Our Audit Committee regularly receives reports and presentations on data privacy and security, which address relevant cybersecurity issues, and which can span a wide range of topics, including but not limited to, recent developments, evolving standards, vulnerability assessments, review of risks from third parties such as customers, service providers, and suppliers, and the current threat environment. These reports and presentations are provided by senior personnel with responsibility for IT security, including our Security, Risk and Compliance Senior Director (**SRC Senior Director**) and our Chief Information Officer. Our board, through its interactions with our Audit Committee chair and our SRC Senior Director and Chief Information Officer receives periodic updates regarding cybersecurity risk matters and prompt and timely information regarding significant cybersecurity incidents and our response to such incidents.

Management

At the management level, our Corporate Crisis Management Team (**CCMT**) is comprised of senior representatives from all key business functions, including finance, operations, and legal, and has broad oversight of our risk management processes, including management of cybersecurity risks. The CCMT has global responsibility for corporate crisis management, policy guidance, and training for employees involved in crisis management at all levels. Additional information on cybersecurity risks we face is discussed in *Part I, Item 1A–Risk Factors*, which should be read in conjunction with this *Item 1C–Cybersecurity*.

Internal Cybersecurity Team

Our Incident Management Team (**IMT**) is led by our SRC Senior Director, who serves as the point of contact for all IT security related matters within our company, and also includes our Chief Information Officer. Our IMT is responsible for the implementation, monitoring, and maintenance of the cybersecurity and data protection practices across our company. Our SRC Senior Director is responsible for ensuring the regular review and maintenance of the Computer Security Incident Response Plan (**CSIRP**) and the execution of all procedures within it. Our SRC Senior Director has technical leadership experience and cybersecurity expertise gained from over 25 years of experience, including security leadership, program development, strategy formulation, data protection, and IT risk management within the health care, pharmaceutical, and biotechnology industries. Our Chief Information Officer has over ten years of experience with our company, and an extensive background in security technology and operations, compliance, data privacy, business continuity, and disaster recovery.

The security professionals in the IMT have cybersecurity backgrounds and expertise relevant to their roles, including, in certain circumstances, relevant industry certifications. In addition to our internal cybersecurity capabilities, we also have engaged outside experts to assist with assessing, identifying, and managing cybersecurity risks. The IMT meets as necessary to discuss, investigate, and respond to any cybersecurity incidents, to allocate resources to respond to incidents, and to confirm incidents are appropriately documented. We have protocols by which the IMT escalates certain cybersecurity incidents within our company and, where appropriate, the IMT will notify appropriate stakeholders and our Audit Committee and provide updates on the status of such incidents. Experienced employees responsible for various parts of our business and a team of trained cybersecurity professionals assist our SRC Senior Director and the IMT. Internal teams, including our Operations Infrastructure Team, Operations End User Computer Team, Operations Engineering Team, Security, Risk and Compliance Team, Operational Technology Team, and Application Administrators and certain external vendors (together, the **Incident Response Team Members**), collectively with the IMT, form the Incident Response Team (**IRT**), which investigates and responds to privacy or cybersecurity incidents.

Risk Management and Strategy

We operate in the biotechnology sector, which is subject to various cybersecurity risks that could adversely impact our business, financial condition, and results of operations, including intellectual property theft; fraud; extortion; harm to employees, patients, or healthcare providers; violation of privacy laws and other litigation and legal risk; and reputational risk. We have implemented a risk-based approach to identify and assess the cybersecurity threats that could affect our business and information systems, and we manage cybersecurity risks through a robust enterprise risk management process. These policies and practices are aligned with industry best practices and standards, such as the National Institute of Standards and Technology (**NIST**) cybersecurity framework. Our cybersecurity program encompasses the IMT and its policies, platforms, procedures, and processes for assessing, identifying, and managing risks from cybersecurity threats, including third-party risk from vendors and suppliers. Our program includes various policies, procedures, and plans related to cybersecurity, including the CSIRP, Corporate Crisis Management Plan, Crisis Communications Response Plan, Organizational Resiliency Governance Policy and Framework, and Business Continuity Plans. These plans outline a coordinated approach for protecting information security, managing vulnerabilities, and assessing, identifying, and managing risks from cybersecurity threats, including identifying and responding to cybersecurity incidents, and processes for categorizing incidents, reporting findings, and keeping senior management, our Audit Committee, and other key stakeholders informed and involved as appropriate.

The CSIRP applies to all company employees and workforce members and provides processes and procedures to properly identify and handle incidents that may affect the safety and/or security of company resources. The CSIRP covers all potential or realized privacy or security incidents, and is applicable to all company campuses, divisions, business units, systems, devices, and materials.

In general, our incident response process involves five phases:

- *Identify*– in which we gather an understanding of how to manage our cybersecurity risks to our systems, assets, data and capabilities, including through threat modeling, cybersecurity threat intelligence from industry-recognized forums and sources, internal audits, third-party reviews and assessments, vulnerability scans and penetration tests;
- *Protect*– in which we implement controls and safeguards to protect or deter cybersecurity threats, including through firewalls, VPNs, identity and access management and intrusion prevention systems;
- *Detect*– in which we engage in continuous monitoring to provide proactive and real-time alerts of cybersecurity-related events;

- *Respond*– in which any threats are timely reported to responsible teams, and triaged for purposes of preliminary classification and escalation, and assessment for possible notification and disclosure requirements; and
- *Recover*– in which business continuity plans are implemented, vulnerabilities are identified and mitigated, legal obligations and risks are identified, and our systems are returned to operational readiness.

We have developed a Testing, Training, & Exercise (**TT&E**) program in accordance with NIST Special Publication 800-84, in which all members of the IRT are required to participate, to sustain and refine our ability to handle computer security incidents in accordance with best practices. The TT&E program includes testing of procedures, systems, and plans, training for the IRT, and tabletop exercises. We also conduct required periodic phishing simulation tests for all employees.

For the response phase of an incident, after our SRC Senior Director or the designated alternate IRT leader receives notification of any potential or realized privacy or security incident, our SRC Senior Director or the designated alternate IRT leader makes an initial severity classification and determines if it is appropriate to convene the IRT, the members of which will be based on the nature and severity of the incident. The IMT has general authority and responsibility for incident response, which includes allocating resources to respond to incidents and providing the appropriate reports and statuses to senior management through the office of the CIO. The Incident Response Team Members support the IMT in these efforts.

We also employ processes designed to identify and reduce the potential impact of a security incident at a third-party vendor or otherwise implicating the third-party technology and systems we use.

We maintain a cyber liability insurance plan underwritten by multiple insurance companies, which provides protection against certain potential losses arising from cybersecurity incidents.

Impact of Cybersecurity Risk

To date, we have not been subject to any cybersecurity incidents that, individually or in the aggregate, have had a material impact to our operations or financial condition, although we recognize that cyberattacks impacting our networks or systems may have a material adverse effect on our operations in the future, as discussed in our *Part I, Item 1A–Risk Factors*. Our business depends on the availability, reliability, and security of our information systems, networks, data, and intellectual property. However, we do not have reason to believe that risks from cybersecurity threats, including as a result of any previous cybersecurity incidents, are reasonably likely to materially affect our business, reputation, operations, or revenue over the long term.

Item 2. Properties

North Carolina–We own a total of 279 acres and have active operations in approximately 630,000 square feet at our co-headquarters campus in RTP. Our clinical research and development, commercialization, manufacturing, warehousing and logistics hub, and our ULobe research and development laboratory, all operate within this campus. We manufacture Orenitram drug product and we package, warehouse, and distribute Nebulized Tyvaso, Tyvaso DPI, Remodulin, Orenitram, and Unituxin at this location. If the FDA approves ralinepag, we plan to transfer manufacturing of this product to our RTP campus following commercial launch. We also have an additional capacity for future growth and expansion at this campus. Additionally, we lease approximately 21,000 square feet of office space in Morrisville, North Carolina to house our United Therapeutics Cares patient support program.

Maryland–We own a 415,000 square foot combination laboratory and office building campus in Silver Spring, Maryland that serves as our co-headquarters, is used to manufacture certain of our products, and houses one of our *ex vivo* lung perfusion centers. Manufacturing activities at this campus include the synthesis of treprostinil, the active ingredient in Tyvaso DPI, Nebulized Tyvaso, and Remodulin, and treprostinil diolamine, the active ingredient in Orenitram, as well as dinutuximab, the active ingredient in Unituxin. We also manufacture Nebulized Tyvaso drug product, Remodulin drug product, and Unituxin drug product at our Silver Spring campus. We plan to produce manufactured lung alternatives for clinical studies at our Silver Spring campus.

Minnesota–Our Miromatrix subsidiary leases a 42,300 square foot office and laboratory facility in Eden Prairie, Minnesota, where it produces manufactured kidney and liver products for research and development purposes and clinical trials. We are constructing a 65,000 square foot clinical-scale DPF facility in Stewartville, Minnesota where we intend to produce porcine hearts and kidneys for use in xenotransplantation clinical trials and to support eventual commercial production of our xeno-organs following FDA approval.

Florida–We own a 75,000 square foot building on land we lease on the Mayo Clinic campus in Jacksonville, Florida, which houses one of our *ex vivo* lung perfusion centers. We also own a 14,000 square foot building in Melbourne, Florida, which houses a call center.

New Hampshire–We lease a 74,500 square foot office and laboratory facility in Manchester, New Hampshire, where we conduct our 3D organ alternative bioprinting research and development activities.

Texas—We are constructing a 65,000 square foot clinical scale DPF facility in Houston, Texas, where we intend to produce porcine hearts and kidneys for use in xenotransplantation clinical trials, and to support eventual commercial production of our xeno-organs following FDA approval.

Virginia—We own and operate a 65,000 square foot clinical-scale DPF facility in Christiansburg, Virginia where we produce porcine hearts and kidneys for use in xenotransplantation clinical trials, and where we intend to support eventual commercial production of our xeno-organs following FDA approval. We also lease a laboratory and farm in Blacksburg, Virginia that support our xenotransplantation research and development efforts.

Quebec—We own a 23,000 square foot facility in Bromont, Quebec, Canada, which is dedicated to the development of sustainable aircraft for the delivery of manufactured organs and organ alternatives.

Massachusetts—Our IVIVA subsidiary leases a 23,500 square foot office and laboratory facility in Medford, Massachusetts, where it produces manufactured kidney alternative products for research and development purposes and clinical trials. In 2025, we purchased a 50,000 square foot facility in Lexington, Massachusetts, which is intended to serve as a cGMP site for clinical production of manufactured organs.

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 the aggregate, have a material adverse effect on our business, financial condition, or operating results. See Note 14—*Litigation*, to our consolidated financial statements, which is incorporated herein by reference.

Item 4. Mine Safety Disclosures

Not applicable.

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 18, 2026, there were approximately 24 holders of record of our common stock.

Dividend Policy

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

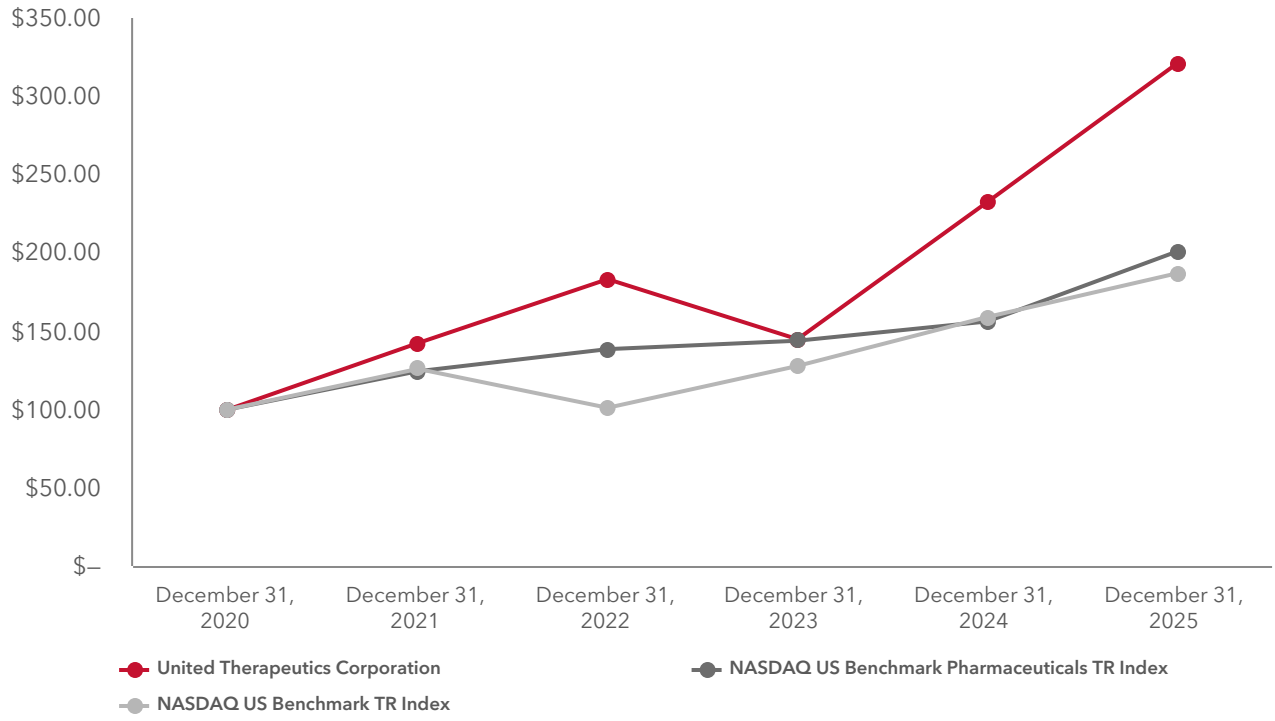
Issuer Purchases of Equity Securities

Period	Total Number of Shares (or Units) Purchased	Average Price Paid Per Share (or Unit)	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	Approximate Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs
October 1, 2025 - October 31, 2025	–	$ –	–	$ –
November 1, 2025 - November 30, 2025[(1)]	3,882	391.18	3,882	–
December 1, 2025 - December 31, 2025	–	–	–	–
Total	**3,882**	**$ 391.18**	**3,882**	**$ –**

(1) As announced on July 30, 2025, our Board of Directors approved a share repurchase program authorizing up to $1.0 billion (plus the amount of any customary contingent settlement obligations that may arise upon the expiration or early termination of an accelerated share repurchase contract) in aggregate repurchases of our common stock, which program expires on March 31, 2026. Pursuant to this authorization, we entered into two accelerated share repurchase agreements (the **2025 ASR agreements**), comprised of a $500.0 million uncollared stock repurchase agreement (the **Uncollared ASR**) and a $500.0 million collared stock repurchase agreement (the **Collared ASR**), with Citibank, N.A. (**Citi**) on August 1, 2025 to repurchase $1.0 billion of our common stock. We made an aggregate upfront payment of $1.0 billion to Citi and received initial deliveries of 1,274,296 and 849,531 shares of our common stock on August 4, 2025, representing approximately 75 percent and 50 percent of the total shares that would be repurchased under the Uncollared ASR and Collared ASR, respectively, measured based on the closing price of our common stock on August 1, 2025. Upon completion of an agreed-upon hedging period and the subsequent determination of the minimum and maximum share amounts to be repurchased under the Collared ASR, we received an additional 514,789 shares of our common stock on August 25, 2025. The final settlement of the Uncollared ASR occurred in November 2025, and we received an additional 3,882 shares of our common stock upon settlement. The average price paid per share was based on the daily volume-weighted average price per share of our common stock during the repurchase period under the Uncollared ASR, less a discount. The final settlement of the Collared ASR occurred in January 2026, and we received no additional shares of our common stock upon settlement as a result of a collar provision that established the minimum and maximum number of shares to be repurchased, as well as other adjustments. In total, we repurchased 2,642,498 shares of our common stock under the 2025 ASR agreements that we currently hold as treasury stock in our consolidated balance sheets.

Comparison of Five-Year Total Cumulative Shareholder Return

The following chart shows the performance from December 31, 2020 through December 31, 2025 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 U.S. Benchmark Pharmaceuticals TR Index, assuming the investment of $100 at the beginning of the period and the reinvestment of dividends, if any.



Item 6. [Reserved]

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. All statements in this filing are made as of the date this Report is filed with the SEC. We undertake no obligation to publicly update or revise these statements, whether as a result of new information, future events, or otherwise.

The following Management's Discussion and Analysis of Financial Condition and Results of Operations and other sections of this Report contain forward-looking statements made pursuant to the safe harbor provisions of Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. These statements, which are based on our beliefs and expectations about future outcomes and on information available to us through the date this Report on Form 10-K is filed with the SEC, include, among others, statements related to the following:

- Expectations of revenues, expenses, profitability, cash flows, and growth in the number of patients being treated with our products, including continued growth in sales of Tyvaso DPI, and anticipated growth in the number of patients with PH-ILD being treated with our Tyvaso products;
- The sufficiency of our cash on hand to support operations;
- Our ability to obtain and maintain domestic and international regulatory approvals;
- Our ability to maintain attractive pricing and reimbursement levels for our products, in light of increasing competition, including from generic products, and pressure from government and other payers to decrease the costs associated with healthcare, including the potential impact of the IRA on our business and the Trump administration's most favored nation pricing initiatives;
- The expected volume and timing of sales of our commercial products, as well as potential future commercial products, including the anticipated effect of various research and development efforts on sales of these products;
- The timing and outcome of clinical studies, other research and development efforts, and related regulatory filings and approvals;
- The outcome of pending and potential future legal and regulatory actions by the U.S. Food and Drug Administration (**FDA**) and other regulatory and government enforcement agencies related to our products and potential competitive products;
- The timing and outcome of ongoing litigation, including the lawsuit filed against us by Sandoz and Liquidia PAH, LLC (formerly known as RareGen); our patent and trade secret litigation with Liquidia related to Yutrepia; Liquidia's patent lawsuit against us related to Tyvaso DPI; and our litigation with Humana Inc., United Healthcare Services, Inc., MSP Recovery Claims, Series LLC, and related entities;
- The impact of competing therapies on sales of our commercial products, including the impact of generic versions of Remodulin; established therapies such as Uptravi®; and newer therapies such as Merck's Winrevair and Liquidia's Yutrepia;
- 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 (including our plans to expand manufacturing capacity for Tyvaso DPI);
- Expectations regarding the amount and timing of capital expenditures to construct new facilities to support our product development and commercialization efforts, including our xenotransplantation-related facilities;
- Expectations regarding the timing and impact of our business development efforts;
- 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;
- Any statements that include the words "believe," "seek," "expect," "anticipate," "forecast," "project," "intend," "estimate," "should," "could," "may," "will," "plan," or similar expressions; and
- Other statements contained or incorporated by reference in this Report that are not historical facts.

We caution you that these statements are not guarantees of future performance and are subject to numerous evolving risks and uncertainties that we may not be able to accurately predict or assess, and that may cause our actual results to differ materially from anticipated results, including the risks and uncertainties we describe in *Part I, Item 1A–Risk Factors* of this Report and risks and uncertainties described in other cautionary statements, cautionary language, and risk factors set forth in our other filings with the SEC.

Overview of Marketed Products

We market and sell the following commercial products:

- *Tyvaso DPI*, a dry powder inhaled formulation of the prostacyclin analogue treprostinil, approved by the FDA in May 2022 to improve exercise ability in patients with PAH and PH-ILD.
- *Nebulized Tyvaso,* a nebulized liquid inhaled formulation of treprostinil, approved by the FDA to improve exercise ability in patients with PAH. Nebulized Tyvaso was also approved by the FDA in March 2021 to improve exercise ability in patients with PH-ILD. Nebulized Tyvaso has also been approved with respect to PAH and/or PH-ILD in various countries outside of the United States.
- *Remodulin*, a continuously-infused formulation of treprostinil, approved by the FDA for subcutaneous and intravenous delivery to diminish symptoms associated with exercise in patients with PAH. Remodulin has also been approved in various countries outside of the United States. In February 2021, we launched U.S. sales of the Remunity Pump, a next-generation subcutaneous infusion system for Remodulin developed under an exclusive development and license agreement with DEKA. In September 2025, we launched a new patient-filled version of the Remunity Pump, called RemunityPRO, which is intended to improve the patient experience by making the pump easier to use.
- *Orenitram*, an oral extended-release tablet form of treprostinil, approved by the FDA to delay disease progression and improve exercise capacity in PAH patients.
- *Unituxin*, an infused monoclonal antibody approved in the United States and Canada for the treatment of high-risk neuroblastoma and approved in Japan for the treatment of neuroblastoma after high-dose chemotherapy.
- *Adcirca*, an oral immediate-release tablet form of the PDE-5 inhibitor tadalafil, approved by the FDA to improve exercise ability in PAH patients. We sell Adcirca under an in-license from Lilly that expires December 31, 2026.

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

Research and Development

We are engaged in research and development of new indications and delivery devices for our existing products. We are studying Nebulized Tyvaso in patients with IPF and PPF (the *TETON* studies).

In addition, we are developing a new product to treat PAH, ralinepag. We are also heavily engaged in research and development of organ transplantation-related technologies including xenotransplantation, regenerative medicine, and *ex vivo* lung perfusion. For additional detail regarding our research and development programs, see *Part I, Item 1—Business—Research and Development*.

Revenues

Our total revenues consist primarily of sales of the commercial products noted above, including the delivery devices (in the case of Tyvaso DPI, Nebulized Tyvaso, and Remodulin). We have entered into separate, non-exclusive distribution agreements with Accredo and CVS Specialty to distribute Tyvaso DPI, Nebulized Tyvaso, Remodulin, the Remunity and RemunityPRO Pumps, and Orenitram in the United States, and we have entered into an exclusive distribution agreement with Cencora Global Procurement Ltd. to distribute Unituxin in the United States. We also sell Nebulized Tyvaso, Remodulin, and Unituxin 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. We also derive revenues from the sale of commercial *ex vivo* lung perfusion services, which are presented under *Other* within Note 13—*Segment Information* to our consolidated financial statements included in this Report.

We require our specialty pharmaceutical distributors to maintain reasonable levels of inventory reserves for our treprostinil-based therapies because the interruption of these therapies can be life threatening. Our specialty pharmaceutical distributors typically place monthly or semi-monthly orders based on current utilization trends and contractual minimum and maximum inventory requirements. As a result, sales of our treprostinil-based therapies can vary depending on the timing and magnitude of these orders and do not precisely reflect changes in patient demand. The information we have about patient demand, the number of patients using our products, and inventory held by our distributors, is based upon our review of patient utilization and inventory data provided to us by our specialty pharmaceutical distributors.

Operating Expenses

We devote 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 costs described below.

Cost of Sales

Our cost of sales primarily includes costs to manufacture our products, royalty and sales-based milestone payments under license agreements granting us rights to sell related products, direct and indirect distribution costs incurred in the sale of our 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.

Research and Development

Our research and development expenses primarily include costs associated with the research and development of new products, new indications for existing products, and various post-marketing research activities. 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 payments to third-party contract manufacturers before FDA approval of the relevant product. Expenses also include costs for third-party arrangements, including upfront fees and milestone payments required under license arrangements for therapies under development. We do not track fully-burdened research and development expenses by individual product candidate.

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, including share-based compensation and salary-related expenses. Selling expenses include product marketing and sales operations costs, as well as other costs incurred to support our sales efforts. General and administrative expenses include the core corporate support functions such as human resources, finance, and legal, and associated external costs to support those functions.

Share-Based Compensation

Currently, we grant stock options and restricted stock units under the United Therapeutics Corporation Amended and Restated 2015 Stock Incentive Plan (as amended to date, the **2015 Plan**), which provides for the issuance of up to 14,770,000 shares of our common stock, including the 950,000 shares added pursuant to an amendment and restatement of the 2015 Plan approved by our shareholders in June 2025. In February 2019, our Board of Directors approved the 2019 Inducement Stock Incentive Plan (the **2019 Inducement Plan**), which provides for the issuance of up to 99,000 shares of our common stock pursuant to awards granted to newly-hired Unitherians. Currently, we grant equity-based awards to Unitherians and members of our Board of Directors in the form of stock options and restricted stock units under the 2015 Plan, and we may grant restricted stock units to newly-hired Unitherians under the 2019 Inducement Plan. The grant date fair values of stock options and restricted stock units are recognized as share-based compensation expense ratably over their vesting periods. Historically, we granted awards under our Share Tracking Awards Plan (the **STAP**). Issuance of awards under this plan was discontinued in 2015 and all remaining outstanding STAP awards were exercised during the first quarter of 2025.

The fair value of stock options is 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.

Future Prospects

We anticipate that revenue growth over the near-term will be driven primarily by: (1) continued growth in sales of Tyvaso DPI; (2) continued growth in the number of PH-ILD patients prescribed Tyvaso DPI and Nebulized Tyvaso; (3) continued growth in the number of patients prescribed Orenitram; and (4) modest price increases for some of our products. We believe that additional revenue growth in the medium- and longer-term will be driven by new products, new indications for existing products, and new devices to deliver our existing products, as described above under *Part I, Item 1—Business—Research and Development*.

Our ability to achieve our 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 approval applications 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 net price of our products and the reimbursement of our products by public and private health insurance organizations, including the impact on such net prices and reimbursement amounts as a result of the IRA and other government initiatives focused on drug pricing, and as a result of additional payer rebates; (5) the competition we face within our industry, including competition from generic companies, the recent launch of Yutrepia, and the potential launch of new therapies for PAH, PH-ILD, IPF, and/or PPF; (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 have budgeted approximately $400 million for capital expenditures during 2026 and through the end of 2028 to construct additional facilities to support the development and commercialization of our products and technologies. This amount is primarily dedicated to construction of a new manufacturing facility in RTP; and construction of clinical-scale DPF facilities in Stewartville, Minnesota and Houston, Texas. We plan to fund these capital expenditures using cash on hand.

We anticipate our existing DPF facility in Virginia and the two planned DPF facilities in Minnesota and Texas will provide an initial commercial supply of our xeno-organ products if and when they are approved by the FDA. However, if our xeno-organ products are approved by the FDA, we likely will need to continue building additional DPF facilities to satisfy demand for these products. Additional DPF facilities will be very capital-intensive, but we expect they will be executed in stages, which will enable us to adjust the schedule (and anticipated cost) of construction depending on the progress of our clinical and regulatory activities.

We operate in a highly competitive market in which several large pharmaceutical companies control many of the available PAH therapies, including Merck, which received FDA approval for Winrevair (sotatercept-csrk) to treat PAH in March 2024. These pharmaceutical companies are well established in the market and possess greater financial, technical, and marketing resources than we do. In addition, Yutrepia was approved by the FDA in May 2025 for treatment of PAH and PH-ILD, and the product was launched commercially in June 2025. While we have not seen a material impact on our net revenues as a result of Winrevair or Yutrepia's launch to date, our net revenues could be materially impacted if either or both of these products gain significant market share or cause material price erosion for our existing products.

Results of Operations

This section of this Report generally discusses 2025, 2024, and 2023 items and year-to-year comparisons between 2025 and 2024. Discussions of year-to-year comparisons between 2024 and 2023 that are not included in this Report can be found in *Part II, Item 7–Management's Discussion and Analysis of Financial Condition and Results of Operations–Results of Operations* of our Form 10-K filed on February 26, 2025 (our **2024 Annual Report**).

Revenues

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

	Year Ended December 31,			Dollar Change		Percentage Change	
	2025	2024	2023	2025 v. 2024	2024 v. 2023	2025 v. 2024	2024 v. 2023
Net product sales:							
Tyvaso DPI	$1,292.5	$1,033.6	$ 731.1	$ 258.9	$ 302.5	25 %	41 %
Nebulized Tyvaso	585.7	586.8	502.6	(1.1)	84.2	– %	17 %
Total Tyvaso	1,878.2	1,620.4	1,233.7	257.8	386.7	16 %	31 %
Remodulin[(1)]	526.8	538.1	494.8	(11.3)	43.3	(2)%	9 %
Orenitram	496.9	434.3	359.4	62.6	74.9	14 %	21 %
Unituxin	226.8	238.7	198.9	(11.9)	39.8	(5)%	20 %
Adcirca	30.0	23.8	28.9	6.2	(5.1)	26 %	(18)%
Other	24.0	22.1	11.8	1.9	10.3	9 %	87 %
Total revenues	**$3,182.7**	**$2,877.4**	**$ 2,327.5**	**$ 305.3**	**$ 549.9**	**11 %**	**24 %**

(1) Net product sales include sales of infusion devices, including the Remunity and RemunityPRO Pumps.

Total Tyvaso net product sales grew 16 percent to $1,878.2 million in 2025, compared to $1,620.4 million in 2024, driven by growth in Tyvaso DPI net product sales. Tyvaso DPI net product sales increased in 2025, as compared to 2024, primarily due to an increase in quantities sold of $268.5 million. The increase in quantities sold was primarily due to continued growth in the number of patients following the product's launch and, to a lesser extent, increased commercial utilization following the implementation of the Medicare Part D benefit redesign under the IRA.

Orenitram net product sales increased in 2025, as compared to 2024, primarily due to an increase in quantities sold of $46.0 million. The increase in quantities sold was driven, at least in part, by increased commercial utilization following the implementation of the Medicare Part D benefit redesign under the IRA.

The table below presents the breakdown of total revenues between the United States and rest-of-world (**ROW**) (in millions):

	Year Ended December 31,								
	2025			2024			2023		
	U.S.	ROW	Total	U.S.	ROW	Total	U.S.	ROW	Total
Net product sales:									
Tyvaso DPI	$1,291.8	$ 0.7	$1,292.5	$1,033.2	$ 0.4	$1,033.6	$ 731.1	$ –	$ 731.1
Nebulized Tyvaso	531.9	53.8	585.7	545.5	41.3	586.8	477.1	25.5	502.6
Total Tyvaso	1,823.7	54.5	1,878.2	1,578.7	41.7	1,620.4	1,208.2	25.5	1,233.7
Remodulin[(1)]	448.9	77.9	526.8	464.2	73.9	538.1	414.6	80.2	494.8
Orenitram	496.9	–	496.9	434.3	–	434.3	359.4	–	359.4
Unituxin	214.7	12.1	226.8	219.6	19.1	238.7	181.3	17.6	198.9
Adcirca	30.0	–	30.0	23.8	–	23.8	28.9	–	28.9
Other	22.8	1.2	24.0	19.1	3.0	22.1	9.8	2.0	11.8
Total revenues	$3,037.0	$ 145.7	$3,182.7	$2,739.7	$ 137.7	$2,877.4	$2,202.2	$ 125.3	$2,327.5

(1) Net product sales include sales of infusion devices, including the Remunity and RemunityPRO Pumps.

Gross-to-Net Deductions

We recognize revenues net of: (1) rebates and chargebacks; (2) prompt pay discounts; (3) allowance for sales returns; and (4) distributor fees. These are referred to as gross-to-net deductions and are primarily based on estimates reflecting historical experiences as well as contractual and statutory requirements. We currently estimate our allowance for sales returns using reports from our distributors. The tables below present a reconciliation of the liability accounts associated with these deductions (in millions):

	Year Ended December 31, 2025				
	Rebates & Chargebacks	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, January 1, 2025	$ 140.8	$ 5.1	$ 2.2	$ 11.6	$ 159.7
Provisions attributed to sales in:					
Current period	521.6	74.0	0.9	41.7	638.2
Prior periods	0.7	0.1	–	(0.5)	0.3
Payments or credits attributed to sales in:					
Current period	(296.6)	(67.7)	–	(30.1)	(394.4)
Prior periods	(127.6)	(5.2)	(1.7)	(11.0)	(145.5)
Balance, December 31, 2025	**$ 238.9**	**$ 6.3**	**$ 1.4**	**$ 11.7**	**$ 258.3**

	Year Ended December 31, 2024				
	Rebates & Chargebacks	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, January 1, 2024	$ 108.4	$ 5.3	$ 1.9	$ 10.4	$ 126.0
Provisions attributed to sales in:					
Current period	356.0	64.4	1.9	41.8	464.1
Prior periods	(10.6)	–	(1.0)	(0.9)	(12.5)
Payments or credits attributed to sales in:					
Current period	(215.8)	(59.3)	–	(30.4)	(305.5)
Prior periods	(97.2)	(5.3)	(0.6)	(9.3)	(112.4)
Balance, December 31, 2024	**$ 140.8**	**$ 5.1**	**$ 2.2**	**$ 11.6**	**$ 159.7**

	Year Ended December 31, 2023				
	Rebates & Chargebacks	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, January 1, 2023	$ 81.3	$ 4.4	$ 3.3	$ 10.9	$ 99.9
Provisions attributed to sales in:					
Current period	278.0	52.5	1.3	40.7	372.5
Prior periods	(2.5)	(0.1)	(1.9)	(0.9)	(5.4)
Payments or credits attributed to sales in:					
Current period	(169.8)	(47.3)	–	(30.3)	(247.4)
Prior periods	(78.6)	(4.2)	(0.8)	(10.0)	(93.6)
Balance, December 31, 2023	**$ 108.4**	**$ 5.3**	**$ 1.9**	**$ 10.4**	**$ 126.0**

Cost of Sales

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

	Year Ended December 31,			Dollar Change		Percentage Change	
	2025	2024	2023	2025 v. 2024	2024 v. 2023	2025 v. 2024	2024 v. 2023
Category:							
Cost of sales	$ 380.5	$ 304.3	$ 255.1	$ 76.2	$ 49.2	25 %	19 %
Share-based compensation expense[1]	3.9	5.4	2.4	(1.5)	3.0	(28)%	125 %
Total cost of sales	**$ 384.4**	**$ 309.7**	**$ 257.5**	**$ 74.7**	**$ 52.2**	**24 %**	**20 %**

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

Cost of sales, excluding share-based compensation. The increase in cost of sales for the year ended December 31, 2025, as compared to the same period in 2024, was primarily due to increases in: (1) royalty expense resulting from a growth in revenues; (2) inventory reserve expense; and (3) the cost of products and services sold.

Research and Development

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

	Year Ended December 31,			Dollar Change		Percentage Change	
	2025	2024	2023	2025 v. 2024	2024 v. 2023	2025 v. 2024	2024 v. 2023
Category:							
External research and development[1]	$ 245.8	$ 217.5	$ 192.0	$ 28.3	$ 25.5	13 %	13 %
Internal research and development[2]	212.3	183.6	146.6	28.7	37.0	16 %	25 %
Share-based compensation expense[3]	32.3	29.1	15.6	3.2	13.5	11 %	87 %
Other[4]	59.6	50.8	53.8	8.8	(3.0)	17 %	(6)%
Total research and development expense	**$ 550.0**	**$ 481.0**	**$ 408.0**	**$ 69.0**	**$ 73.0**	**14 %**	**18 %**

(1) *External research and development* primarily includes fees paid to third parties (such as clinical trial sites, contract research organizations, and contract laboratories) for preclinical and clinical studies and payments to third-party contract manufacturers before regulatory approval of the relevant product.

(2) *Internal research and development* primarily includes salary-related expenses for research and development functions, internal costs to manufacture product candidates before regulatory approval, and internal facilities-related expenses, including depreciation, related to research and development activities.

(3) See *Share-Based Compensation* section below for discussion.

(4) *Other* primarily includes upfront fees and milestone payments to third parties under license agreements related to development-stage products, adjustments to the fair value of our contingent consideration obligations, and costs to acquire certain in-process research and development (**IPR&D**) assets. During the year ended December 31, 2025, we recorded (a) $42.2 million in expense related to milestone payments for drug delivery device and formulation technologies; and (b) $10.8 million in expense related to adjustments to the fair value of contingent consideration obligations for manufactured organ and organ alternative projects.

During the year ended December 31, 2024, we recorded $40.2 million and $8.0 million in expense related to upfront non-refundable licensing payments for drug delivery device technologies and *ex vivo* lung perfusion technology, respectively. During the year ended December 31, 2023, we recorded $46.0 million in IPR&D expense in connection with the acquisition of IVIVA.

Research and development, excluding share-based compensation. The increase in research and development expense for the year ended December 31, 2025, as compared to the same period in 2024, was primarily due to: (1) increased expenditures related to manufactured organ and organ alternative projects; and (2) increased expenditures for drug delivery device and formulation technologies.

Selling, General, and Administrative

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

	Year Ended December 31,			Dollar Change		Percentage Change	
	2025	2024	2023	2025 v. 2024	2024 v. 2023	2025 v. 2024	2024 v. 2023
Category:							
General and administrative[1]	$ 501.0	$ 432.8	$ 374.2	$ 68.2	$ 58.6	16 %	16 %
Impairment of property, plant, and equipment (**PP&E**)	21.7	–	–	21.7	–	NM[3]	NM[3]
Litigation accrual	3.0	71.1	–	(68.1)	71.1	(96)%	NM[3]
Sales and marketing	118.6	96.3	81.8	22.3	14.5	23 %	18 %
Share-based compensation expense[2]	111.5	109.5	21.1	2.0	88.4	2 %	419 %
Total selling, general, and administrative expense	**$ 755.8**	**$ 709.7**	**$ 477.1**	**$ 46.1**	**$ 232.6**	**6 %**	**49 %**

(1) Excluding impairment of PP&E and litigation accrual. See *Impairment of PP&E* and *Litigation accrual* sections below.

(2) See *Share-Based Compensation* section below for discussion.

(3) Calculation is not meaningful.

General and administrative, excluding impairment of PP&E, litigation accrual, and share-based compensation. The increase in general and administrative expense for the year ended December 31, 2025, as compared to the same period in 2024, was primarily due to increases in: (1) personnel expense due to growth in headcount; and (2) legal expenses related to litigation matters.

Impairment of PP&E. During the second quarter of 2025, we recorded a $21.7 million impairment charge to write down the carrying value of certain PP&E.

Litigation accrual. During the years ended December 31, 2025 and 2024, we recorded accruals of $3.0 million and $71.1 million, respectively, related to ongoing litigation with Sandoz. We currently do not expect that the amount of any loss in excess of this accrual would be material to our financial results; however, the amount ultimately payable, if any, could be higher or lower than this amount depending on the amount of post judgment interest and the outcome of appeals, as discussed in Note 14–*Litigation*, to our consolidated financial statements. The litigation accrual is included within *selling, general, and administrative* in our consolidated statements of operations.

Sales and marketing, excluding share-based compensation. The increase in sales and marketing expense for the year ended December 31, 2025, as compared to the same period in 2024, was primarily due to increases in: (1) personnel expense due to growth in headcount; and (2) marketing expenses.

Share-Based Compensation

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

	Year Ended December 31,			Dollar Change		Percentage Change	
	2025	2024	2023	2025 v. 2024	2024 v. 2023	2025 v. 2024	2024 v. 2023
Category:							
Stock options	$ 42.3	$ 29.8	$ 15.4	$ 12.5	$ 14.4	42 %	94 %
Restricted stock units	103.1	79.7	52.4	23.4	27.3	29 %	52 %
STAP awards	(0.8)	32.3	(30.7)	(33.1)	63.0	(102)%	205 %
Employee stock purchase plan	3.1	2.2	2.0	0.9	0.2	41 %	10 %
Total share-based compensation expense	**$ 147.7**	**$ 144.0**	**$ 39.1**	**$ 3.7**	**$ 104.9**	**3 %**	**268 %**

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

	Year Ended December 31,			Dollar Change		Percentage Change	
	2025	2024	2023	2025 v. 2024	2024 v. 2023	2025 v. 2024	2024 v. 2023
Cost of sales	$ 3.9	$ 5.4	$ 2.4	$ (1.5)	$ 3.0	(28)%	125 %
Research and development	32.3	29.1	15.6	3.2	13.5	11 %	87 %
Selling, general, and administrative	111.5	109.5	21.1	2.0	88.4	2 %	419 %
Total share-based compensation expense	**$ 147.7**	**$ 144.0**	**$ 39.1**	**$ 3.7**	**$ 104.9**	**3 %**	**268 %**

The increase in share-based compensation expense for the year ended December 31, 2025, as compared to the same period in 2024, was primarily due to: (1) an increase in restricted stock unit expense due to a greater number of outstanding performance-based restricted stock units during the year ended December 31, 2025, as compared to the same period in 2024; and (2) an increase in stock option expense due to a greater number of unvested and outstanding performance-based stock options during the year ended December 31, 2025, as compared to the same period in 2024, partially offset by a decrease in STAP expense, as all remaining STAP awards were exercised during the first quarter of 2025. See Note 8—*Share-Based Compensation*, to our consolidated financial statements for more information.

Other Income (Expense), Net

The change in *other income (expense), net* for the year ended December 31, 2025, as compared to the same period in 2024, was primarily due to net unrealized gains on equity securities. See Note 4—*Investments* and Note 5—*Fair Value Measurements,* to our consolidated financial statements for more information.

Income Tax Expense

Income tax expense was $379.2 million for the year ended December 31, 2025, as compared to $343.9 million for the same period in 2024. Our effective income tax rate was approximately 22 percent for the years ended December 31, 2025 and 2024. For additional details, see Note 10—*Income Taxes* to our consolidated financial statements.

2025 Share Repurchase

In August 2025, we entered into the 2025 ASR agreements with Citi, comprised of a $500 million Uncollared ASR and a $500 million Collared ASR. Under the 2025 ASR agreements, we made an aggregate upfront payment of $1.0 billion to Citi and received initial deliveries of 1,274,296 and 849,531 shares of our common stock on August 4, 2025, representing approximately 75 percent and 50 percent of the total shares that would be repurchased under the Uncollared ASR and Collared ASR, respectively, measured based on the closing price of our common stock on August 1, 2025. Upon completion of an agreed-upon hedging period and the subsequent determination of the minimum and maximum share amounts to be repurchased under the Collared ASR, we received an additional 514,789 shares of our common stock on August 25, 2025. The final settlement of the Uncollared ASR occurred in November 2025, and we received an additional 3,882 shares of our common stock upon settlement. The final settlement of the Collared ASR occurred in January 2026, and we received no additional shares of our common stock upon settlement as a result of a collar provision that established the minimum and maximum number of shares to be repurchased, as well as other adjustments. In total, we repurchased 2,642,498 shares of our common stock under the 2025 ASR agreements that we currently hold as treasury stock in our consolidated balance sheets.

2024 Share Repurchase

In March 2024, we entered into an accelerated share repurchase agreement (the **2024 ASR agreement**) with Citi. Under the 2024 ASR agreement, we made an aggregate upfront payment of $1.0 billion to Citi and received an aggregate initial delivery of 3,275,199 shares of our common stock on March 27, 2024, which represented approximately 80 percent of the total shares that would be repurchased under the 2024 ASR agreement, measured based on the closing price of our common stock on March 25, 2024.

The share repurchase under the 2024 ASR agreement was divided into two tranches, resulting in upfront payments of $300 million and $700 million, respectively. The final settlement of the $300 million tranche occurred in June 2024, and we received an additional 181,772 shares of our common stock upon settlement. The final settlement of the $700 million tranche occurred in September 2024, and we received an additional 90,403 shares of our common stock upon settlement. In total, we repurchased 3,547,374 shares of our common stock under the 2024 ASR agreement that we currently hold as treasury stock in our consolidated balance sheets.

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 sources of liquidity are sufficient to fund ongoing operations and future business plans as we expect aggregate growth in revenues from our commercial products. Furthermore, our customer base remains stable, and we believe that 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 April 2025, we entered into the 2025 Credit Agreement, which provides for an unsecured revolving credit facility of up to $2.5 billion. Our outstanding balance under the 2025 Credit Agreement, which matures in 2030, was zero as of December 31, 2025. See *Unsecured Revolving Credit Facilities* below for further details.

For information regarding the fluctuation explanations between 2024 and 2023, see our 2024 Annual Report.

Cash and Cash Equivalents and Marketable Investments

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

	Year Ended December 31,		Dollar Change	Percentage Change
	2025	2024	2025 v. 2024	2025 v. 2024
Cash and cash equivalents	$ 1,557.1	$ 1,697.2	$ (140.1)	(8)%
Marketable investments–current	1,363.2	1,569.8	(206.6)	(13)%
Marketable investments–non-current	1,776.7	1,475.3	301.4	20 %
Total cash and cash equivalents and marketable investments	**$ 4,697.0**	**$ 4,742.3**	**$ (45.3)**	**(1)%**

Cash Flows

Cash flows comprise the following (dollars in millions):

	Year Ended December 31,			Dollar Change		Percentage Change	
	2025	2024	2023	2025 v. 2024	2024 v. 2023	2025 v. 2024	2024 v. 2023
Net cash provided by operating activities	$ 1,561.2	$ 1,327.1	$ 978.0	$ 234.1	$ 349.1	18 %	36 %
Net cash (used in) provided by investing activities	$ (551.3)	$ 417.2	$ (719.6)	$ (968.5)	$ 1,136.8	(232)%	158 %
Net cash used in financing activities	$ (1,150.0)	$ (1,254.8)	$ (11.9)	$ 104.8	$ (1,242.9)	8 %	NM[(1)]

(1) Calculation is not meaningful.

Operating Activities

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

The increase of $234.1 million in net cash provided by operating activities for the year ended December 31, 2025, as compared to the same period in 2024, was primarily due to an increase in net cash received due to the growth in sales of our commercial products.

Investing Activities

The increase of $968.5 million in net cash used in investing activities for the year ended December 31, 2025, as compared to the same period in 2024, was primarily due to: (1) a $682.6 million increase in cash used for total purchases, sales, and maturities of marketable investments; and (2) a $274.0 million increase in cash paid to purchase property, plant, and equipment.

Financing Activities

The decrease of $104.8 million in net cash used in financing activities for the year ended December 31, 2025, as compared to the same period in 2024, was primarily due to a $100.0 million decrease in net repayments on our line of credit.

Unsecured Revolving Credit Facilities

In March 2022, we entered into a credit agreement (the **2022 Credit Agreement**) with Wells Fargo, as administrative agent and a swingline lender, and various other lender parties, which provided for: (1) an unsecured revolving credit facility of up to $1.2 billion; and (2) a second unsecured revolving credit facility of up to $800.0 million.

On April 25, 2025, we terminated the 2022 Credit Agreement and entered into the 2025 Credit Agreement, which provides for an unsecured revolving credit facility of up to $2.5 billion in the aggregate. On April 25, 2025, we borrowed $200.0 million under the 2025 Credit Agreement and used the proceeds to repay all outstanding indebtedness under the 2022 Credit Agreement in connection with its termination. During the second quarter of 2025, we repaid the remaining $200.0 million balance under the 2025 Credit Agreement, which brought our aggregate outstanding balance to zero as of June 30, 2025. Our aggregate outstanding debt balance remained zero as of December 31, 2025 and February 25, 2026. See Note 7—*Debt—2025 Credit Agreement,* to our consolidated financial statements for additional information.

Contractual Obligations

As of December 31, 2025, 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	$ 37.6	$ 7.3	$ 14.1	$ 10.7	$ 5.5
Long-term debt obligations[1]	32.4	7.5	15.0	9.9	–
Obligations under the SERP[2]	63.4	26.0	13.0	–	24.4
Purchase obligations[3]	1,022.8	869.5	136.9	14.7	1.7
Total[4] [5]	**$ 1,156.2**	**$ 910.3**	**$ 179.0**	**$ 35.3**	**$ 31.6**

(1) We have contractual obligations to pay unused commitment fees under the 2025 Credit Agreement. As of December 31, 2025, our outstanding balance on the 2025 Credit Agreement was zero.

(2) Consists of actuarially derived, undiscounted, estimated future payouts of benefits. See Note 11—*Employee Benefit Plans—Supplemental Executive Retirement Plan* to our consolidated financial statements for further details.

(3) Purchase obligations primarily include: commitments related to research and development (including clinical trials) for new and existing products; 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 open purchase orders for the acquisition of goods and services in the ordinary course of business. The timing and amount of our obligations may differ based on certain future events.

(4) In addition to amounts in the table above, we are contractually obligated to make payments 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 in our consolidated balance sheets. See Note 12—*Commitments and Contingencies* to our consolidated financial statements for further details.

(5) As of December 31, 2025, our other non-current liabilities in our consolidated balance sheets includes a liability of $28.2 million for unrecognized tax benefits, including related interest and penalties. Due to the high degree of uncertainty on the timing of future events that could extinguish these unrecognized tax benefits, we are unable to estimate the period of settlement and therefore we have excluded these unrecognized tax benefits from the table above. See Note 10—*Income Taxes* to our consolidated financial statements for further details.

Obligations Under License Agreements and Acquisition Agreements

We pay a ten percent royalty on our net sales of Tyvaso DPI under our license agreement with MannKind. Under our agreement with Arena Pharmaceuticals, Inc., we will owe a low double-digit, tiered royalty on net product sales of ralinepag (for any route of administration), plus certain milestone payments upon defined regulatory events. We pay Lilly a royalty equal to ten percent of our net product sales of Adcirca, as well as milestone payments of $325,000 for each $1,000,000 in Adcirca 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 pay DEKA product fees and a single-digit royalty on net product sales of the Remunity and RemunityPRO Pumps and Remodulin for use with these pumps. We will owe former securityholders of Revivicor a five percent royalty on net product sales of UHeart, UKidney, and UThymoKidney, plus certain milestone payments upon defined regulatory events. We have entered into other license agreements 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 products covered by the license agreements. See Note 12—*Commitments and Contingencies* to our consolidated financial statements for further

details. In addition, we may owe additional earn-out consideration to the former securityholders of IVIVA, as described in Note 15–*Acquisitions–Asset Acquisition* to our consolidated financial statements.

Off-Balance Sheet Arrangements

We hold an interest in an unconsolidated variable interest entity (**VIE**). We determined that we are not the primary beneficiary of this entity. As a result, we do not consolidate this VIE. See Note 4–*Investments–Variable Interest Entities*. We do not have any other 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 commercial products: Tyvaso DPI, Nebulized Tyvaso, Remodulin, 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, see Note 2–*Summary of Significant Accounting Policies–Revenue Recognition* to our consolidated financial statements.

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

Rebates and Chargebacks

The most significant rebates we pay include rebates that relate to our participation in various government healthcare programs (including Medicare Part D inflationary rebates required under the IRA), contractual rebates to certain of our domestic distributors, and contractual rebates we pay 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. Inflationary rebates under Medicare Part D may follow a longer settlement timeline because they are calculated over applicable annual periods and invoiced by CMS following the end of those periods. Due to this time lag before notice of the rebate amount, we must estimate the amount of rebates and chargebacks to accrue. As of December 31, 2025 and 2024, we had a liability of $238.9 million and $140.8 million, respectively, related to rebates and chargebacks.

Estimates associated with our participation in government healthcare programs are particularly susceptible to adjustment given the time lag that may occur between our recording of an accrual and its ultimate invoicing. Because of the time lag in any particular quarter, adjustments to our rebates and chargebacks 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 total revenues for each of the years ended December 31, 2025, 2024, and 2023.

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

Recently Issued Accounting Standards

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

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Investment Risk

As of December 31, 2025, we have invested $3.1 billion in corporate debt securities and U.S. government and agency securities. 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. During the year ended December 31, 2025, we did not experience significant volatility in the value of these investments. 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, 2025 (dollars in millions):

	Expected Maturity		
	2026	**2027**	**2028**
Available-for-sale investments	$1,273.3	$1,101.7	$ 675.0
Weighted average interest rate	3.9 %	4.0 %	4.0 %

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 that we take prudent measures to mitigate investment related risks, such risks cannot be fully eliminated, as circumstances can occur that are beyond our control.

Item 8. Financial Statements and Supplementary Data

United Therapeutics Corporation
Index to Consolidated Financial Statements

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, 2025 and 2024, 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, 2025, 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, 2025 and 2024, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2025, 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, 2025, 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 25, 2026 expressed an unqualified opinion thereon.

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.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Revenue Deductions – Accounting for Rebates

Description of the Matter

As of December 31, 2025, accrued rebates and chargebacks were $238.9 million. As discussed in Note 2 to the consolidated financial statements, the Company recognizes revenues net of rebates, commonly referred to as "revenue deductions" or "gross-to-net deductions." Allowances for rebates include mandated discounts due to the Company's participation in various government health care programs (the **rebates**). The Company estimates accrued rebates on a product-by-product basis, considering actual revenue, historical payment experience, changes in product pricing and information regarding changes in program regulations and guidelines. The Company accrues for rebates in the same period the product is sold; however, third-party reporting and payment of the rebate amount occur on a time lag.

Auditing accrued rebates is complex due to the judgmental nature of the assumptions made in the accounting for accrued rebates due to the time lag and delay associated with third-party reporting of rebate amounts, and complexities of calculations in government pricing used to determine the rebate price and therefore rebate payments.

How We Addressed the Matter in Our Audit

We tested controls that address the risks of material misstatement relating to the measurement and valuation of accrued rebates. For example, we tested controls over management's review of the accrued rebates, including the significant assumptions and data provided by third parties.

To test accrued rebates, our audit procedures included, among others, evaluating the methodologies and assumptions and the underlying data used by the Company. We compared the assumptions used by management against historical trends, evaluated the change in estimated accruals from the prior periods, and assessed the historical accuracy of the Company's estimates against actual results. We performed substantive analytics by revenue deduction. We utilized government pricing specialists in evaluating the Company's government pricing methodology and calculations of government prices used to estimate rebates for a sample of the Company's products.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2003.
Tysons, Virginia
February 25, 2026

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, 2025, 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, 2025, based on the COSO criteria.

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, 2025 and 2024, 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, 2025 and the related notes and financial statement schedule listed in the Index at Item 15(a)(2) and our report dated February 25, 2026, 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 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 25, 2026

Consolidated Balance Sheets
(In millions, except share and per share data)

	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 1,557.1	$ 1,697.2
Marketable investments	1,363.2	1,569.8
Accounts receivable, no allowance for 2025 and 2024	350.2	279.3
Inventories, net	183.1	157.9
Other current assets	248.9	169.7
Total current assets	3,702.5	3,873.9
Marketable investments	1,776.7	1,475.3
Goodwill and other intangible assets, net	116.5	111.9
Property, plant, and equipment, net	1,729.7	1,222.4
Deferred tax assets, net	357.7	458.4
Other non-current assets	196.9	222.1
Total assets	**$ 7,880.0**	**$ 7,364.0**
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 488.0	$ 344.5
Line of credit	–	300.0
Other current liabilities	72.6	93.6
Total current liabilities	560.6	738.1
Other non-current liabilities	223.2	181.9
Total liabilities	783.8	920.0
Commitments and contingencies–Note 12		
Stockholders' equity:		
Preferred stock, par value $.01, 10,000,000 shares authorized, no shares issued	–	–
Common stock, par value $.01, 245,000,000 shares authorized, 76,452,253 and 74,997,896 shares issued, and 43,643,165 and 44,831,306 shares outstanding as of December 31, 2025 and 2024, respectively	0.8	0.8
Additional paid-in capital	2,798.0	2,698.9
Accumulated other comprehensive income (loss)	0.9	(3.4)
Treasury stock, 32,809,088 and 30,166,590 shares as of December 31, 2025 and 2024, respectively	(4,260.4)	(3,474.5)
Retained earnings	8,556.9	7,222.2
Total stockholders' equity	7,096.2	6,444.0
Total liabilities and stockholders' equity	**$ 7,880.0**	**$ 7,364.0**

See accompanying notes to consolidated financial statements.

Consolidated Statements of Operations
(In millions, except per share data)

	Year Ended December 31,		
	2025	**2024**	**2023**
Total revenues	$ 3,182.7	$ 2,877.4	$ 2,327.5
Operating expenses:			
Cost of sales	384.4	309.7	257.5
Research and development	550.0	481.0	408.0
Selling, general, and administrative	755.8	709.7	477.1
Total operating expenses	1,690.2	1,500.4	1,142.6
Operating income	1,492.5	1,377.0	1,184.9
Interest income	192.0	199.1	162.7
Interest expense	(19.5)	(42.9)	(59.3)
Other income (expense), net	48.9	5.8	(14.0)
Total other income, net	221.4	162.0	89.4
Income before income taxes	1,713.9	1,539.0	1,274.3
Income tax expense	(379.2)	(343.9)	(289.5)
Net income	**$ 1,334.7**	**$ 1,195.1**	**$ 984.8**
Net income per common share:			
Basic	**$ 30.13**	**$ 26.44**	**$ 21.04**
Diluted	**$ 27.86**	**$ 24.64**	**$ 19.81**
Weighted average number of common shares outstanding:			
Basic	**44.3**	**45.2**	**46.8**
Diluted	**47.9**	**48.5**	**49.7**

See accompanying notes to consolidated financial statements.

Consolidated Statements of Comprehensive Income (In millions)

	Year Ended December 31,		
	2025	2024	2023
Net income	$ 1,334.7	$ 1,195.1	$ 984.8
Other comprehensive income:			
Foreign currency translation loss included in net income	–	2.4	–
Defined benefit pension plan:			
Actuarial (loss) gain arising during period, net of tax	(3.7)	(0.3)	2.0
Actuarial gain and prior service cost included in net periodic pension cost and settlement, net of tax	(1.7)	(4.6)	(4.9)
Total defined benefit pension plan, net of tax	(5.4)	(4.9)	(2.9)
Available-for-sale debt securities:			
Unrealized gain arising during period, net of tax	10.5	10.8	45.6
Realized (gain) loss included in net income, net of tax	(0.8)	1.1	–
Total gain on available-for-sale debt securities, net of tax	9.7	11.9	45.6
Other comprehensive income, net of tax	4.3	9.4	42.7
Comprehensive income	**$ 1,339.0**	**$ 1,204.5**	**$ 1,027.5**

During the years ended December 31, 2025, 2024, and 2023, the tax (benefit) expense in other comprehensive income was $(0.2) million, $(0.4) million, and $(0.5) million, respectively, for the defined benefit pension plan and $3.2 million, $3.7 million, and $14.6 million, respectively, for the available-for-sale securities.

See accompanying notes to consolidated financial statements.

Consolidated Statements of Stockholders' Equity (In millions)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Treasury Stock	Retained Earnings	Stockholders' Equity
	Shares	Amount					
Balance, December 31, 2022	72.7	$ 0.7	$ 2,388.4	$ (55.5)	$ (2,579.2)	$ 5,042.3	$ 4,796.7
Net income	–	–	–	–	–	984.8	984.8
Other comprehensive income, net of tax	–	–	–	42.7	–	–	42.7
Shares issued under employee stock purchase plan (**ESPP**)	–	–	6.6	–	–	–	6.6
Common stock issued for restricted stock units (**RSUs**) vested	0.1	–	–	–	–	–	–
RSUs withheld for taxes	–	–	(13.8)	–	–	–	(13.8)
Exercise of stock options	0.9	–	98.0	–	–	–	98.0
Share-based compensation	–	–	69.8	–	–	–	69.8
Balance, December 31, 2023	**73.7**	**$ 0.7**	**$ 2,549.0**	**$ (12.8)**	**$ (2,579.2)**	**$ 6,027.1**	**$ 5,984.8**
Net income	–	–	–	–	–	1,195.1	1,195.1
Other comprehensive income, net of tax	–	–	–	9.4	–	–	9.4
Shares issued under ESPP	–	–	7.6	–	–	–	7.6
RSUs withheld for taxes	–	–	(12.2)	–	–	–	(12.2)
Share repurchase	–	–	(109.7)	–	(890.3)	–	(1,000.0)
Excise tax on net share repurchase	–	–	–	–	(5.0)	–	(5.0)
Common stock issued for RSUs vested	0.1	–	–	–	–	–	–
Exercise of stock options	1.2	0.1	152.5	–	–	–	152.6
Share-based compensation	–	–	111.7	–	–	–	111.7
Balance, December 31, 2024	**75.0**	**$ 0.8**	**$ 2,698.9**	**$ (3.4)**	**$ (3,474.5)**	**$ 7,222.2**	**$ 6,444.0**
Net income	–	–	–	–	–	1,334.7	1,334.7
Other comprehensive income, net of tax	–	–	–	4.3	–	–	4.3
Shares issued under ESPP	–	–	9.2	–	–	–	9.2
RSUs withheld for taxes	–	–	(16.6)	–	–	–	(16.6)
Share repurchase	–	–	(215.9)	–	(784.1)	–	(1,000.0)
Excise tax on net share repurchase	–	–	–	–	(1.8)	–	(1.8)
Common stock issued for RSUs vested	0.1	–	–	–	–	–	–
Exercise of stock options	1.4	–	173.9	–	–	–	173.9
Share-based compensation	–	–	148.5	–	–	–	148.5
Balance, December 31, 2025	**76.5**	**$ 0.8**	**$ 2,798.0**	**$ 0.9**	**$ (4,260.4)**	**$ 8,556.9**	**$ 7,096.2**

See accompanying notes to consolidated financial statements.

Consolidated Statements of Cash Flows
(In millions)

	Year Ended December 31,		
	2025	2024	2023
Cash flows from operating activities:			
Net income	$1,334.7	$1,195.1	$ 984.8
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	85.6	72.5	53.2
Share-based compensation expense	147.7	144.0	39.1
Impairments of property, plant, and equipment	21.7	–	3.6
Deferred income taxes	97.7	(64.1)	(64.4)
Other	(19.7)	(24.3)	(4.9)
Changes in operating assets and liabilities:			
Accounts receivable	(70.9)	(0.4)	(58.5)
Inventories	(52.6)	(46.9)	(13.6)
Accounts payable and accrued expenses	97.9	42.7	57.1
Other assets and liabilities	(80.9)	8.5	(18.4)
Net cash provided by operating activities	1,561.2	1,327.1	978.0
Cash flows from investing activities:			
Purchases of property, plant, and equipment	(520.5)	(246.5)	(230.4)
Acquired lease intangible assets	(5.5)	–	–
Deposits	(10.4)	(28.5)	(23.0)
Purchases of available-for-sale debt securities	(3,405.4)	(1,646.1)	(2,514.3)
Maturities of available-for-sale debt securities	1,583.9	1,537.0	2,137.3
Sales of available-for-sale debt securities	1,861.6	831.8	–
Purchases of investments in privately-held companies	(55.0)	(30.5)	–
Acquisitions, net of cash acquired	–	–	(89.2)
Net cash (used in) provided by investing activities	(551.3)	417.2	(719.6)
Cash flows from financing activities:			
Payments to repurchase common stock	(1,000.0)	(1,000.0)	–
Proceeds from line of credit	200.0	–	–
Repayment of line of credit	(500.0)	(400.0)	(100.0)
Excise tax paid on net share repurchase	(5.0)	–	–
Payments of debt issuance costs	(11.5)	(2.7)	(2.7)
Proceeds from the exercise of stock options	173.9	152.5	98.0
Proceeds from the issuance of stock under ESPP	9.2	7.6	6.6
RSUs withheld for taxes	(16.6)	(12.2)	(13.8)
Net cash used in financing activities	(1,150.0)	(1,254.8)	(11.9)
Net (decrease) increase in cash and cash equivalents	**$ (140.1)**	**$ 489.5**	**$ 246.5**
Cash and cash equivalents, beginning of year	1,697.2	1,207.7	961.2
Cash and cash equivalents, end of year	**$1,557.1**	**$1,697.2**	**$1,207.7**
Supplemental cash flow information:			
Cash paid for interest	**$ 13.5**	**$ 40.2**	**$ 56.0**
Cash paid for income taxes	**$ 313.3**	**$ 400.6**	**$ 332.5**
Non-cash investing and financing activities:			
Non-cash additions to property, plant, and equipment	**$ 116.3**	**$ 22.2**	**$ 18.4**
Measurement period adjustment to purchase price	**$ –**	**$ (1.4)**	**$ –**
Excise tax on net share repurchase	**$ 1.8**	**$ 5.0**	**$ –**
Receivable from maturity of available-for-sale debt securities	**$ –**	**$ –**	**$ 21.0**

See accompanying notes to consolidated financial statements.

Notes to Consolidated Financial Statements

1. Organization and Business Description

United Therapeutics Corporation is a biotechnology company focused on the development and commercialization of innovative products to address the unmet medical needs of patients with chronic and life-threatening conditions. In 2021, we converted to a Delaware public benefit corporation, with the express public benefit purpose *to provide a brighter future for patients through (a) the development of novel pharmaceutical therapies; and (b) technologies that expand the availability of transplantable organs*.

We have approval from the U.S. Food and Drug Administration (**FDA**) to market the following therapies: Tyvaso DPI® (treprostinil) Inhalation Powder (**Tyvaso DPI**), Tyvaso® (treprostinil) Inhalation Solution (**Nebulized Tyvaso**), Remodulin® (treprostinil) Injection (**Remodulin**), Orenitram® (treprostinil) Extended-Release Tablets (**Orenitram**), Unituxin® (dinutuximab) Injection (**Unituxin**), and Adcirca® (tadalafil) Tablets (**Adcirca**). We also derive revenues outside the United States from sales of Nebulized Tyvaso, Remodulin, and Unituxin, and within the United States from sales of commercial *ex vivo* lung perfusion services.

As used in these notes to our 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 consolidated 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. Certain prior year current liabilities previously presented separately in our consolidated balance sheets have been aggregated with *other current liabilities* to conform to the current year presentation. In the operating activities section of our consolidated statements of cash flows, we reclassified a portion of the prior period amount within *other assets and liabilities* to the line item *deferred income taxes* to conform with the current period presentation. This reclassification had no effect on previously reported net cash provided by operating activities.

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 our 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 the United Therapeutics Corporation Supplemental Executive Retirement Plan (**SERP**).

Fair Value Measurements

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

Assets and liabilities subject to fair value measurement disclosures are required to be classified according to a three-level fair value hierarchy with respect to the inputs (or assumptions) used to determine fair value. 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. See related disclosures in Note 5–*Fair Value Measurements*.

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. If we have both the positive intent and the ability to hold the securities until maturity, we have the option to classify the securities 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 the portion of the unrealized gains and losses that are not credit-related 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* in our consolidated balance sheets based on their contractual maturity dates.

We monitor our available-for-sale debt securities for impairment quarterly or more frequently if circumstances warrant. In the event that the amortized cost of a debt security exceeds its fair value, we evaluate whether any impairment is a result of credit loss or other factors. For investments in an unrealized loss position, we determine whether a credit loss exists by considering information about the collectability of the instrument, current market conditions, the investment issuer's financial condition and business outlook, and reasonable and supportable forecasts of economic conditions. An allowance for credit losses would be recorded in our consolidated statements of operations in the event the decline in the investment's fair value was a result of credit loss, and unrealized losses not related to credit losses would be recorded in *other comprehensive income (loss)*.

Our marketable investments also include investments in publicly-traded companies. The equity securities we own in these companies are recorded at fair value. Changes in the fair value of publicly-traded equity securities are recorded in our consolidated statements of operations within *other income (expense), net*.

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,	
	2025	2024
Raw materials	$ 30.6	$ 28.6
Work-in-progress	35.3	34.3
Finished goods	117.2	95.0
Total inventories	**$ 183.1**	**$ 157.9**

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. The impairment charge is limited to the amount of goodwill allocated to the reporting unit. We performed a qualitative assessment for our goodwill impairment testing for 2025, 2024, and 2023. During the years ended December 31, 2025, 2024, and 2023 our evaluation of goodwill did not result in any 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**) assets, which were measured at their estimated fair values as of their acquisition dates. There were no impairment losses related to indefinite-lived intangible assets during the years ended December 31, 2025, 2024, and 2023.

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. Amortization is recorded over the assets' useful lives on a straight-line basis. 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, 2025, 2024, and 2023 related to intangible assets subject to amortization.

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

	As of December 31, 2025			As of December 31, 2024		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Goodwill	$ 32.3	$ –	$ 32.3	$ 32.3	$ –	$ 32.3
Other intangible assets:						
In-process research and development	78.5	–	78.5	78.5	–	78.5
Other	13.5	(7.8)	5.7	8.0	(6.9)	1.1
Total	$ 124.3	$ (7.8)	$ 116.5	$ 118.8	$ (6.9)	$ 111.9

Related amortization expense for the years ended December 31, 2025, 2024, and 2023, was $0.9 million, $0.9 million and $0.3 million, respectively. As of December 31, 2025, aggregate amortization expense related to definite-lived intangible assets for each of the five succeeding years and thereafter is estimated to be less than $1.0 million per year.

Property, Plant, and Equipment (**PP&E**)

PP&E is recorded at cost and depreciated over its estimated useful life using the straight-line method. The estimated useful lives of PP&E 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

PP&E consists of the following (in millions):

	As of December 31,	
	2025	2024
Land and land improvements	$ 266.5	$ 181.9
Buildings, building improvements, and leasehold improvements	944.7	863.8
Buildings under construction	592.7	218.2
Furniture, equipment, and vehicles	493.6	449.7
Subtotal	2,297.5	1,713.6
Less–accumulated depreciation	(567.8)	(491.2)
PP&E, net	$1,729.7	$1,222.4

Depreciation expense for the years ended December 31, 2025, 2024, and 2023, was $84.7 million, $71.6 million, and $52.9 million, respectively.

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

In July 2025, we acquired approximately 60 acres of property containing five buildings located in Research Triangle Park, North Carolina (**RTP**) for future growth of our RTP campus. The total purchase price was $106.8 million, inclusive of taxes, closing costs, and other related expenses. The transaction was accounted for as an asset acquisition as substantially all of the fair value was concentrated in the land and buildings we acquired, which together comprise a single group of similar assets. We allocated the purchase price primarily to *land and land improvements* and *buildings, building improvements, and leasehold improvements*, which were recorded within *property, plant, and equipment, net* in our consolidated balance sheets as of December 31, 2025.

For the years ended December 31, 2025, 2024, and 2023, we recorded $21.7 million, zero, and $3.6 million of PP&E impairment charges in the aggregate, respectively, which were recorded within *selling, general, and administrative* in our consolidated statements of operations.

Investments in Privately-Held Companies

We measure our non-controlling equity investments in privately-held companies 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 monitor these investments individually for any observable price changes or impairment indicators. We 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 review of the attendant rights and obligations, such as voting rights, liquidation preferences, and protective provisions, is necessary to evaluate whether such a transaction is deemed to be a similar or identical investment. When a transaction is identified as similar or identical to our investment, we assess the fair value of our investment using various inputs, such as the discount rate, time to a liquidation event, and volatility, in a valuation model or analysis. We include our investments in privately-held companies within *other non-current assets* in 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 FASB Accounting Standards Codification (**ASC**) 820, *Fair Value Measurements*. At each reporting date, we review these investments individually for impairment by evaluating whether events or circumstances have occurred that may have a significant adverse effect on the fair value of the investments. If such events or circumstances have occurred, we will estimate the fair value of the investment. In such cases, we determine the estimated fair value of the investment using unobservable inputs including assumptions by the company's management.

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.

The Inflation Reduction Act of 2022 (**IRA**) imposes a one percent excise tax on net share repurchases that occur after December 31, 2022. For the years ended December 31, 2025 and 2024, we recorded $1.8 million and $5.0 million, respectively, in excise taxes imposed under the IRA, which amounts were included in *treasury stock* in our consolidated financial statements.

Revenue Recognition

We determine revenue recognition for our contractual arrangements with customers based on 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.

Revenues are generated from the sale of our commercially approved products: Tyvaso DPI, Nebulized Tyvaso, Remodulin, Orenitram, Unituxin, and Adcirca. We recognize revenue when we transfer control of our product to our distributors, which is generally when the product is shipped or delivered to the distributor.

See Note 13—*Segment Information*, for information on revenues disaggregated by commercial products and other, 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) allowance 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.

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 decrease in our net product sales of $0.3 million for the year ended December 31, 2025 and, aggregate increases in our net product sales of $12.5 million and $5.4 million for the years ended December 31, 2024 and 2023, respectively, related to changes in these estimates of revenue recognized from product sales in prior periods.

Rebates and chargebacks. Allowances for rebates include mandated discounts due to our participation in various government healthcare programs (including Medicare Part D inflationary rebates required under the IRA), contracted rebates to certain domestic distributors, and contracted discounts we pay managed care organizations covering Medicare Part D and commercial plans. 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. 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. Inflationary rebates under Medicare Part D may follow a longer settlement timeline because they are calculated over applicable annual periods and invoiced following the end of those periods. Our liability for rebates and chargebacks is included in *accounts payable and accrued expenses* and *other non-current liabilities* in our consolidated balance sheets. As of December 31, 2025 and 2024, our accrued rebates and chargebacks were $238.9 million and $140.8 million, respectively. In addition, during the years ended December 31, 2025, 2024, and 2023, we recognized $522.3 million, $345.4 million, and $275.5 million, respectively, in revenue deductions associated with rebates and chargebacks.

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 in 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 after the product's expiration date (generally 18 to 36 months after the initial sale). For Unituxin, we ship product with expiration dates that are generally nine to 14 months after the initial sale and customers have the right to return expired product for up to 12 months after the product's expiration date. For sales of our other commercial products, we do not offer our customers a general right of return. Our allowance for product returns for Adcirca and Unituxin for each of the years ended December 31, 2025 and 2024 was not material. We record our allowance for product returns in *other current* and *non-current liabilities* in our consolidated balance sheets.

Distributor fees. 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* in 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* in 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 expected credit losses, if deemed necessary, based on our assessment of the collectability of specific distributor accounts. We did not recognize any credit losses for accounts receivable for each of the years ended December 31, 2025 and 2024. 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 on our behalf. Specifically, Lilly handles all 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 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, amounts paid to third parties for services, and materials related to drug development and clinical trials.

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 IPR&D 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 costs, among others, 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 the applicable products, 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. Certain executives have stock options that vest over a service period and upon achievement of specific performance conditions. Share-based compensation expense for all stock option awards is recorded ratably over their vesting period, depending on the specific terms of the award and achievement of the specified performance conditions. Forfeitures are recognized as they occur. See Note 8—*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. Certain executives and certain other employees have restricted stock units that vest over a service period and upon achievement of specific performance conditions. Share-based compensation expense for restricted stock units is recorded ratably over their vesting period, depending on the specific terms of the award and achievement of any specified performance conditions.

We previously issued awards under the United Therapeutics Corporation 2011 Share Tracking Awards Plan (the **STAP**), which required cash settlement of awards issued under the STAP upon exercise of the awards. STAP awards were classified as a liability. Accordingly, the fair value of related cash-settled awards was re-measured at each reporting date until awards were exercised or otherwise no longer outstanding. Related changes in the fair value of outstanding cash-settled awards at each financial reporting date were recognized as adjustments to share-based compensation expense. We discontinued the issuance of STAP awards in June 2015 and all remaining outstanding STAP awards were exercised during the first quarter of 2025.

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

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 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.

We have elected to account for the tax on Global Intangible Low-Taxed Income as a component of tax expense in the period in which the tax is incurred.

Earnings Per Common Share

Basic earnings per common 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, adjusted for the potential dilutive effect of our outstanding stock options, outstanding RSUs, and shares issuable under the ESPP, as if the RSUs were vested, the stock options were exercised, and the shares expected to be issued under the ESPP at the end of the then-current offering period were issued. During periods in which we incur net losses, both basic and diluted loss per common share are 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 in our consolidated balance sheets.

3. Recently Issued Accounting Standards

Accounting Standards Adopted

In December 2023, the FASB issued Accounting Standards Update (**ASU**) 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, enhancing the required disclosures primarily related to the annual income tax rate reconciliation and income taxes paid. This ASU requires an entity's income tax rate reconciliation to provide additional information for reconciling items meeting a quantitative threshold, and to disclose certain selected categories within the income tax rate reconciliation. This ASU also requires entities to disclose the amount of income taxes paid, disaggregated by federal, state, and foreign taxes. This ASU is effective for this Annual Report on Form 10-K for the year ended December 31, 2025. The adoption of ASU 2023-09 expands our income tax disclosures, but has no impact on reported income tax expense or related tax assets or liabilities. We adopted the new standard on a retrospective basis for the annual period ended December 31, 2025, with no material impact on our consolidated financial statements. See Note 10–*Income Taxes*.

Accounting Standards Not Yet Adopted

In November 2024, the FASB issued ASU 2024-03, *Income Statement–Reporting Comprehensive Income–Expense Disaggregation Disclosures (Topic 220): Disaggregation of Income Statement Expenses*, which requires public business entities to disclose, on an annual and interim basis, disaggregated information about certain income statement expense line items in the notes to the financial statements. Public business entities are required to apply the guidance prospectively and may elect to apply it retrospectively. This ASU is effective for annual periods beginning after December 15, 2026, and interim periods beginning after December 15, 2027, although early adoption is permitted. We are evaluating the impact of adopting this guidance on our consolidated financial statements.

4. Investments

Marketable Investments

Available-for-Sale Debt Securities

Available-for-sale debt securities are recorded at fair value, with the portion of the unrealized gains and losses that are not credit-related included as a component of *accumulated other comprehensive income (loss)* in stockholders' equity, until realized. Available-for-sale debt securities consisted of the following (in millions):

As of December 31, 2025	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. government and agency securities	$ 2,433.0	$ 10.5	$ (0.3)	$ 2,443.2
Corporate debt securities	603.1	3.7	–	606.8
Total	$ 3,036.1	$ 14.2	$ (0.3)	$ 3,050.0
Reported under the following captions in our consolidated balance sheets:				
Cash and cash equivalents				$ 37.0
Current marketable investments				1,236.3
Non-current marketable investments				1,776.7
Total				$ 3,050.0

As of December 31, 2024	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. government and agency securities	$ 2,473.7	$ 3.1	$ (3.5)	$ 2,473.3
Corporate debt securities	568.0	1.9	(0.5)	569.4
Total	$ 3,041.7	$ 5.0	$ (4.0)	$ 3,042.7
Reported under the following captions in our consolidated balance sheets:				
Cash and cash equivalents				$ 21.5
Current marketable investments				1,545.9
Non-current marketable investments				1,475.3
Total				$ 3,042.7

The following tables present gross unrealized losses and fair value for those available-for-sale debt securities that were in an unrealized loss position as of December 31, 2025 and December 31, 2024, aggregated by investment category and length of time that the individual securities have been in a continuous loss position (in millions):

	Less than 12 months		12 months or longer		Total	
As of December 31, 2025	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
U.S. government and agency securities	$ 215.0	$ (0.3)	$ 3.5	$ –	$ 218.5	$ (0.3)
Corporate debt securities	19.6	–	–	–	19.6	–
Total	$ 234.6	$ (0.3)	$ 3.5	$ –	$ 238.1	$ (0.3)

	Less than 12 months		12 months or longer		Total	
As of December 31, 2024	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
U.S. government and agency securities	$ 947.3	$ (3.3)	$ 341.1	$ (0.2)	$ 1,288.4	$ (3.5)
Corporate debt securities	75.0	(0.2)	82.0	(0.3)	157.0	(0.5)
Total	$ 1,022.3	$ (3.5)	$ 423.1	$ (0.5)	$ 1,445.4	$ (4.0)

As of December 31, 2025 and December 31, 2024, we held 87 and 227 available-for-sale debt securities, respectively, that were in an unrealized loss position. In assessing whether the decline in fair value as of December 31, 2025 of any of these securities resulted from a credit loss, we consulted with our investment managers and reviewed the credit ratings for each security. We believe that these unrealized losses are a direct result of the current interest rate environment and do not represent an indication of credit loss. We do not intend to sell the investments in unrealized loss positions prior to their maturity and it is not more likely than not that we will be required to sell these investments before recovery of their amortized cost basis. There were no impairments due to credit loss on our available-for-sale debt securities during the years ended December 31, 2025 and 2024.

The following table summarizes the contractual maturities of available-for-sale debt securities (in millions). Actual maturities may differ from contractual maturities because the issuers of certain of these debt securities have the right to call the securities or prepay their obligations under the securities with or without penalties.

	As of December 31, 2025	
	Amortized Cost	Fair Value
Due within one year	$ 1,269.6	$ 1,273.3
Due in one to three years	1,766.5	1,776.7
Total	$ 3,036.1	$ 3,050.0

Investments in Equity Securities with Readily Determinable Fair Values

We held investments in equity securities with readily determinable fair values of $126.9 million and $23.9 million as of December 31, 2025 and 2024, respectively, which are included in *current marketable investments* in our consolidated balance sheets. One of the privately-held companies in which we invested became publicly traded in 2025. As a result, our investment in the equity securities of this company is recorded at fair value and included within *current marketable investments* in our consolidated balance sheets rather than measured as described below under *Investments in Privately-Held Companies*. Changes in the fair value of publicly-traded equity securities are recorded in our consolidated statements of operations within *other income (expense), net*. See Note 5—*Fair Value Measurements*.

During the years ended December 31, 2025, 2024, and 2023, we had no sales of equity securities with readily determinable fair values.

Investments in Privately-Held Companies

As of December 31, 2025 and 2024, we maintained non-controlling equity investments in privately-held companies of $53.8 million and $59.0 million, respectively, in the aggregate within *other non-current assets* in our consolidated balance sheets. We made payments of $55.0 million and $30.5 million for investments in privately-held companies during the years ended December 31, 2025 and December 31, 2024, respectively. No such payments were made during the year ended December 31, 2023.

When an observable price transaction occurs that is identified as similar or identical to our investment, we perform a valuation analysis to assess the fair value of our investment using various inputs, such as the discount rate, expected time to a liquidation event, and price volatility of peer company stocks. We adjust the fair value of our investment based on the valuation analysis and recognize the gain or loss in the period in which the observable price change occurred.

For non-controlling equity investments in privately-held companies in which we held an investment as of December 31, 2025, cumulative impairments and downward fair value adjustments were $5.3 million and cumulative upward fair value adjustments were $1.9 million.

Variable Interest Entities (**VIEs**)

We evaluate our interests in VIEs and will consolidate any VIE in which we have a controlling financial interest and are deemed to be the primary beneficiary. A controlling financial interest has both of the following characteristics: (1) the power to direct the activities of the VIE that most significantly impact its economic performance; and (2) the obligation to absorb losses of the VIE that could potentially be significant to the VIE or the right to receive benefits from the VIE that could be significant to the VIE. If both of the characteristics are met, we are considered to be the primary beneficiary and therefore will consolidate that VIE into our consolidated financial statements.

Unconsolidated VIE

In November 2019, we entered into a supply agreement with an affiliate of DEKA Research & Development Corporation (**DEKA**) to manufacture and supply the Remunity® Pump to us. The supply agreement was later amended to include supply of the RemunityPRO™ Pump. Under the terms of the supply agreement, we reimburse all the affiliate's costs to manufacture and supply the Remunity and RemunityPRO systems. We determined that the affiliate is a VIE as we are the primary customer of the affiliate and the affiliate currently relies on our reimbursement of its costs to sustain its operations. We have determined we are not the primary beneficiary of the affiliate as we do not have the power to direct or control its significant activities related to the manufacturing of medical devices. Accordingly, we have not consolidated the affiliate's results of operations and financial position with ours. As of December 31, 2025 and 2024, our consolidated balance sheets included $21.2 million and $13.8 million of assets, respectively, related to the supply agreement. As of December 31, 2025 and 2024, our consolidated balance sheets included a $3.2 million and $5.6 million liability, respectively, for our obligation to reimburse costs related to the supply agreement. While the terms of the supply agreement expose us to various future risks of loss given our responsibility to reimburse all costs incurred by the affiliate to manufacture and supply the Remunity and RemunityPRO

systems, we believe that our maximum exposure to loss as of December 31, 2025 as a result of our involvement with the affiliate is $21.2 million, the amount of assets related to the supply agreement noted above.

Consolidation of VIEs

In August 2019 and July 2022, we entered into operating agreements and trust agreements related to the contribution of assets to newly created trusts of which we are the beneficiary. The trusts were created for legal and administrative purposes and are not expected to make future purchases. As the operator of the assets, we are required to incur all future expenses related to the operation and maintenance of the assets. Accordingly, the trusts are deemed VIEs because they rely on our capital to sustain future operating expenses. We are deemed the primary beneficiary of the VIEs because we are the sole provider of financial support and can unilaterally remove the trustee without cause. Accordingly, we consolidate the VIE's balance sheet and results of operations.

As of December 31, 2025, our consolidated balance sheets included $55.7 million of assets due to the consolidation of these VIEs included within *property, plant, and equipment, net*. Upon consolidating the VIEs, which were not deemed a business as defined in ASC 805, *Business Combinations*, no gain or loss was recognized. These VIEs have no recourse against our assets and general credit, and the VIEs' assets cannot be used to settle the VIEs' liabilities. Our total risk of loss is the $55.7 million of assets we contributed, as noted above.

5. Fair Value Measurements

Assets and liabilities subject to fair value measurements are required to be disclosed within a fair value hierarchy. The fair value hierarchy ranks the quality and reliability of inputs used to determine fair value. Accordingly, assets and liabilities carried at, or permitted to be carried at, fair value are 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 classify these assets and liabilities within the fair value hierarchy. Our *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, 2025			
	Level 1	Level 2	Level 3	Balance
Assets				
Money market funds[1]	$ 753.1	$ –	$ –	$ 753.1
Time deposits[1]	–	–	–	–
U.S. government and agency securities[2]	–	2,443.2	–	2,443.2
Corporate debt securities[2]	–	606.8	–	606.8
Equity securities[3]	126.9	–	–	126.9
Total assets	**$ 880.0**	**$3,050.0**	**$ –**	**$3,930.0**
Liabilities				
Contingent consideration[4]	–	–	32.5	32.5
Total liabilities	**$ –**	**$ –**	**$ 32.5**	**$ 32.5**

	As of December 31, 2024			
	Level 1	Level 2	Level 3	Balance
Assets				
Money market funds[1]	$ 649.8	$ –	$ –	$ 649.8
Time deposits[1]	155.9	–	–	155.9
U.S. government and agency securities[2]	–	2,473.3	–	2,473.3
Corporate debt securities[2]	–	569.4	–	569.4
Equity securities[3]	23.9	–	–	23.9
Total assets	**$ 829.6**	**$3,042.7**	**$ –**	**$3,872.3**
Liabilities				
Contingent consideration[4]	–	–	24.7	24.7
Total liabilities	**$ –**	**$ –**	**$ 24.7**	**$ 24.7**

(1) Included in *cash and cash equivalents* in our consolidated balance sheets.

(2) Included in *cash and cash equivalents* and *current* and *non-current marketable investments* in our consolidated balance sheets. See Note 4–*Investments–Marketable Investments–Available-for-Sale Debt Securities* for further information. The fair value of these securities is principally measured or corroborated by trade data for identical securities for 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 *current marketable investments* in our consolidated balance sheets. The fair value of these securities is based on quoted market prices for identical instruments in active markets. During the years ended December 31, 2025 and 2024, we recorded $43.0 million and $9.0 million of net unrealized gains in the aggregate, respectively, on these securities. We recorded these gains and losses in our consolidated statements of operations within *other income (expense), net*. See Note 4–*Investments–Marketable Investments–Investments in Equity Securities with Readily Determinable Fair Values*.

(4) Included in *other current liabilities* and *other non-current liabilities* in our consolidated balance sheets. The fair value of our contingent consideration obligations is 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. The fair value of our contingent consideration liabilities increased by $7.8 million from December 31, 2024 to December 31, 2025. The loss was recorded within *research and development* in our consolidated statements of operations.

Fair Value of Financial Instruments

The carrying amounts of *cash and cash equivalents, accounts receivable,* and *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 above within the fair value hierarchy. See Note 4–*Investments*.

6. Accounts Payable and Accrued Expenses

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

	As of December 31,	
	2025	2024
Accounts payable	$ 7.1	$ 6.0
Accrued expenses:		
Sales-related (royalties, rebates, and fees)	299.0	181.5
Payroll-related	105.1	94.2
Research and development-related	23.0	31.5
Other	53.8	31.3
Total accrued expenses	$ 480.9	$ 338.5
Total accounts payable and accrued expenses	**$ 488.0**	**$ 344.5**

7. Debt

2025 Credit Agreement

In April 2025, we entered into a credit agreement (the **2025 Credit Agreement**) with Wells Fargo Bank, National Association (**Wells Fargo**) as administrative agent and a swingline lender, and various other lender parties, which provides for an unsecured revolving credit facility of up to $2.5 billion (which facility may, at our request, be increased by up to $750 million in the aggregate subject to obtaining commitments from existing or new lenders for such increase and other conditions). The facility will mature on April 25, 2030, 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 2025 Credit Agreement, up to a maximum of two such extensions.

At our option, amounts borrowed under the 2025 Credit Agreement bear interest at either an adjusted Term Secured Overnight Finance Rate (**Term SOFR**) 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 2025 Credit Agreement). To date, we have elected to calculate interest on the outstanding balance at an adjusted Term SOFR plus an applicable margin.

On April 25, 2025, we borrowed $200.0 million under the 2025 Credit Agreement, and used the funds to repay outstanding indebtedness under the 2022 Credit Agreement, as discussed below under the *2022 Credit Agreement*.

During the second quarter of 2025, we paid down the entire $200.0 million balance under the 2025 Credit Agreement, which brought our aggregate outstanding balance to zero as of June 30, 2025. Our aggregate outstanding balance under the 2025 Credit Agreement remained zero as of December 31, 2025.

The 2025 Credit Agreement contains customary events of default and customary affirmative and negative covenants. As of December 31, 2025, we were in compliance with these covenants.

The interest expense reported in our consolidated statements of operations for each of the years ended December 31, 2025, 2024, and 2023, relates to our borrowings under the 2025 Credit Agreement and 2022 Credit Agreement.

2022 Credit Agreement

In March 2022, we entered into a credit agreement (the **2022 Credit Agreement**) with Wells Fargo, as administrative agent and a swingline lender, and various other lender parties, which provided for: (1) an unsecured revolving credit facility of up to $1.2 billion; and (2) a second unsecured revolving credit facility of up to $800.0 million.

As of December 31, 2024, our outstanding aggregate principal balance under the 2022 Credit Agreement was $300.0 million. During the first quarter of 2025, we paid down $100.0 million of our balance under the 2022 Credit Agreement, which brought our aggregate outstanding balance down to $200.0 million as of March 31, 2025.

On April 25, 2025, we terminated the 2022 Credit Agreement and entered into the 2025 Credit Agreement. We repaid in full all our obligations under the 2022 Credit Agreement in connection with the termination of the 2022 Credit Agreement and our entry into the 2025 Credit Agreement. There were no penalties associated with the early termination of the 2022 Credit Agreement.

8. Share-Based Compensation

As of December 31, 2025, we have one shareholder-approved equity incentive plan: the United Therapeutics Corporation Amended and Restated 2015 Stock Incentive Plan (as amended to date, the **2015 Plan**). The 2015 Plan provides for the issuance of up to 14,770,000 shares of our common stock pursuant to awards granted under the 2015 Plan, which includes 950,000 shares that were added pursuant to an amendment and restatement of the 2015 Plan approved by our shareholders in June 2025. We also have one equity incentive plan, the United Therapeutics Corporation 2019 Inducement Stock Incentive Plan (the **2019 Inducement Plan**), that has not been approved by our shareholders, as permitted by the Nasdaq Stock Market rules. The 2019 Inducement Plan was approved by our Board of Directors in February 2019 and provides for the issuance of up to 99,000 shares of our common stock under awards granted to newly-hired employees. Currently, we grant equity-based awards to employees and members of our Board of Directors in the form of stock options and restricted stock units (**RSUs**) under the 2015 Plan, and we may grant RSUs to newly-hired employees under the 2019 Inducement Plan. See the sections entitled *Stock Options* and *RSUs* below for additional information regarding these equity-based awards.

During the years ended December 31, 2025, 2024, and 2023, we issued stock options and RSUs to certain executives with vesting conditions tied to the achievement of specified performance criteria through the end of 2027, 2026, and 2025, respectively. Additionally, during the year ended December 31, 2025, we issued RSUs to certain other employees with vesting conditions tied to the achievement of specified performance criteria through the end of 2026 and 2028. Throughout the performance period, we reassess the estimated performance and update the number of performance-based awards that we believe will ultimately vest. Estimating future performance requires the use of judgment. Upon the conclusion of the performance period, the performance level achieved and the ultimate number of stock options and RSUs that may vest are 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.

We previously issued awards under the STAP. We discontinued the issuance of STAP awards in June 2015 and all remaining outstanding STAP awards were exercised during the first quarter of 2025. See the section entitled *STAP Awards* below for additional information regarding STAP awards.

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. See the section entitled *ESPP* below for additional information regarding the ESPP.

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

	Year Ended December 31,		
	2025	2024	2023
Stock options	$ 42.3	$ 29.8	$ 15.4
RSUs	103.1	79.7	52.4
STAP awards	(0.8)	32.3	(30.7)
ESPP	3.1	2.2	2.0
Total share-based compensation expense before tax	$ 147.7	$144.0	$ 39.1
Share-based compensation capitalized as part of inventory	$ 1.6	$ 1.4	$ 1.3

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.

During the years ended December 31, 2025, 2024, and 2023, in addition to time-based stock options, we granted 0.3 million, 0.5 million, and 0.4 million performance-based stock options with a total grant date fair value of $38.0 million, $50.2 million, and $35.6 million, respectively, in each case calculated based on the assumed achievement of maximum performance of the relevant financial performance condition. During the years ended December 31, 2025, 2024, and 2023, we recorded $38.8 million, $26.3 million, and $8.3 million of share-based compensation expense, respectively, related to performance-based stock options, calculated based on the assumed levels of performance achievement.

A description of the key inputs, requiring estimates, used in determining the fair value of 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, 2025, 2024, and 2023, 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, see the *STAP Awards* 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 that 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, 2025, 2024, and 2023:

	Year Ended December 31,		
	2025	2024	2023
Expected term of awards (in years)	5.1	6.5	6.4
Expected volatility	32.1 %	31.6 %	31.4 %
Risk-free interest rate	4.1 %	4.3 %	3.6 %
Expected dividend yield	– %	– %	– %

A summary of the activity and status of stock options under our equity incentive plans during the year ended December 31, 2025 is presented below:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value (in millions)
Outstanding as of January 1, 2025	5,571,545	$ 148.62		
Granted	377,716	307.19		
Exercised	(1,312,781)	132.48		
Forfeited	(150)	217.50		
Outstanding as of December 31, 2025	**4,636,330**	**$ 166.11**	**3.3**	**$ 1,488.9**
Exercisable as of December 31, 2025	**3,312,354**	**$ 132.42**	**1.7**	**$ 1,175.3**
Unvested as of December 31, 2025	**1,323,976**	**$ 250.38**	**7.4**	**$ 313.6**

The weighted average fair value of a stock option granted during each of the years in the three-year period ended December 31, 2025, was $110.21, $98.06, and $85.39, respectively. The total fair value of stock options that vested for each of the years in the three-year period ended December 31, 2025, was $3.4 million, $3.5 million, and $54.9 million, respectively.

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

	Year Ended December 31,		
	2025	2024	2023
Cost of sales	$ –	$ 0.1	$ 0.1
Research and development	0.4	0.4	0.2
Selling, general, and administrative	41.9	29.3	15.1
Share-based compensation expense before taxes	42.3	29.8	15.4
Related income tax benefit	(0.9)	(0.9)	(0.8)
Share-based compensation expense, net of taxes	**$ 41.4**	**$ 28.9**	**$ 14.6**

As of December 31, 2025, unrecognized compensation cost relating to stock options was $53.3 million. Unvested outstanding stock options as of December 31, 2025 had a weighted average remaining vesting period of 1.7 years.

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

	Year Ended December 31,		
	2025	2024	2023
Number of options exercised	1,312,781	1,193,975	850,162
Cash received from options exercised	$ 173.9	$ 152.5	$ 98.0
Total intrinsic value of options exercised	$ 375.4	$ 194.9	$ 105.7
Tax benefits realized from options exercised[1]	$ 53.7	$ 39.8	$ 24.3

(1) We recognize these tax benefits in our consolidated statements of operations within *income tax expense*.

RSUs

We issue RSUs to employees and non-employee directors. Each RSU entitles the recipient to one share of our common stock upon vesting. We measure the fair value of RSUs using the stock price on the date of grant. Share-based compensation expense for RSUs is recorded ratably over their vesting period.

During the years ended December 31, 2025, 2024, and 2023, in addition to time-based RSUs, we granted 0.1 million, 0.2 million, and 0.2 million performance-based RSUs to certain executives with a total grant date fair value of $38.0 million, $47.5 million, and $32.2 million, respectively, calculated based on the assumed achievement of maximum performance of the relevant financial and non-financial performance conditions. Additionally, during the year ended December 31, 2025, in addition to time-based RSUs, we granted 0.1 million performance-based RSUs to certain other employees with a total grant date fair value of $29.3 million, calculated based on the assumed achievement of maximum performance of the relevant financial and non-financial performance conditions. During the years ended December 31, 2025, 2024, and 2023, we recorded $39.4 million, $23.2 million, and $4.7 million of share-based compensation expense, respectively, related to performance-based RSUs, calculated based on the assumed levels of performance achievement.

A summary of the activity with respect to, and status of, RSUs during the year ended December 31, 2025 is presented below:

	Number of RSUs	Weighted Average Grant Date Fair Value
Unvested as of January 1, 2025	1,219,654	$ 225.40
Granted	382,436	327.23
Vested	(159,817)	220.98
Forfeited	(25,402)	254.72
Unvested as of December 31, 2025	**1,416,871**	**$ 252.86**

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

	Year Ended December 31,		
	2025	2024	2023
Cost of sales	$ 4.0	$ 4.2	$ 3.9
Research and development	30.7	23.4	18.1
Selling, general, and administrative	68.4	52.1	30.4
Share-based compensation expense before taxes	103.1	79.7	52.4
Related income tax benefit	(16.5)	(13.9)	(11.7)
Share-based compensation expense, net of taxes	**$ 86.6**	**$ 65.8**	**$ 40.7**

As of December 31, 2025, unrecognized compensation cost related to the grant of RSUs was $164.6 million. Unvested outstanding RSUs as of December 31, 2025 had a weighted average remaining vesting period of 2.0 years.

STAP Awards

STAP awards conveyed the right to receive in cash an amount equal to the appreciation of our common stock, which was measured as the increase in the closing price of our common stock between the dates of grant and exercise. STAP awards expired on the tenth anniversary of the grant date, and in most cases, they vested in equal increments on each anniversary of the grant date over a four-year period. We discontinued the issuance of STAP awards in June 2015 and all remaining outstanding STAP awards were exercised during the first quarter of 2025.

The aggregate liability balance associated with outstanding STAP awards was zero and $11.0 million as of December 31, 2025 and 2024, respectively.

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

	Year Ended December 31,		
	2025	2024	2023
Cost of sales	$ (0.1)	$ 1.2	$ (1.4)
Research and development	(0.2)	4.2	(3.8)
Selling, general, and administrative	(0.5)	26.9	(25.5)
Share-based compensation (benefit) expense before taxes	(0.8)	32.3	(30.7)
Related income tax expense (benefit)	0.2	(4.4)	5.3
Share-based compensation (benefit) expense, net of taxes	**$ (0.6)**	**$ 27.9**	**$ (25.4)**

Cash paid to settle STAP awards exercised during the years ended December 31, 2025, 2024, and 2023 was $10.2 million, $56.7 million, and $14.7 million, respectively.

ESPP

In June 2012, our shareholders approved the 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.

9. Stockholders' Equity

Earnings Per Common Share

Basic earnings per common 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, adjusted for the potential dilutive effect of our outstanding stock options, outstanding RSUs, and shares issuable under the ESPP, as if the RSUs were vested, the stock options were exercised, and the shares expected to be issued under the ESPP at the end of the then-current offering period were issued.

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

	Year Ended December 31,		
	2025	2024	2023
Numerator:			
Net income	$1,334.7	$1,195.1	$ 984.8
Denominator:			
Weighted average outstanding shares – basic	44.3	45.2	46.8
Effect of dilutive securities[1]:			
Stock options, RSUs, and ESPP[2]	3.6	3.3	2.9
Weighted average shares – diluted[2]	47.9	48.5	49.7
Net income per common share:			
Basic	$ 30.13	$ 26.44	$ 21.04
Diluted	$ 27.86	$ 24.64	$ 19.81
Stock options and RSUs excluded from calculation[2]	0.2	0.4	0.3

(1) Calculated using the treasury stock method.

(2) The common shares underlying certain stock options and RSUs have been excluded from the computation of diluted earnings per share because their impact would be anti-dilutive.

2025 Share Repurchase

In July 2025, our Board of Directors approved a share repurchase program authorizing up to $1.0 billion in aggregate repurchases of our common stock (plus the amount of any customary contingent settlement obligations that may arise upon the expiration or early termination of an accelerated share repurchase contract). Pursuant to this authorization, we entered into two accelerated share repurchase agreements (the **2025 ASR agreements**) with Citibank, N.A. (**Citi**) on August 1, 2025 to repurchase approximately $1.0 billion of our common stock in the aggregate.

Under the terms of the 2025 ASR agreements, comprised of a $500 million uncollared stock repurchase agreement (the **Uncollared ASR**) and a $500 million collared stock repurchase agreement (the **Collared ASR**), we made an aggregate upfront payment of $1.0 billion to Citi on August 4, 2025. Under the Uncollared ASR, we received an initial delivery of 1,274,296 shares of our common stock, representing approximately 75 percent of the total shares expected to be repurchased under the Uncollared ASR, measured based on the closing price of our common stock on August 1, 2025. Under the Collared ASR, we received an initial delivery of 849,531 shares of our common stock, representing approximately 50 percent of the total shares expected to be repurchased under the Collared ASR, measured based on the closing price of our common stock on August 1, 2025. Upon completion of an agreed-upon hedging period and the subsequent determination of the minimum and maximum share amounts to be repurchased under the Collared ASR, we received an additional 514,789 shares of our common stock on August 25, 2025. The final settlement of the Uncollared ASR occurred in November 2025, and we received an additional 3,882 shares of our common stock upon settlement. The final settlement of the Collared ASR occurred in January 2026, and we received no additional shares of our common stock upon settlement as a result of a collar provision that established the minimum and maximum number of shares to be repurchased, as well as other adjustments. In total, we repurchased 2,642,498 shares of our common stock under the 2025 ASR agreements that we currently hold as treasury stock in our consolidated balance sheets.

The final number of shares that we ultimately repurchased pursuant to the Uncollared ASR was based on the average of the daily volume-weighted average price per share of our common stock during the repurchase period, less a discount and subject to adjustments pursuant to the terms and conditions of the Uncollared ASR.

The initial repurchase of our common stock and final settlements under the 2025 ASR agreements, including the subsequent receipt of our common stock upon completion of the hedging period, were treated as a reduction of the outstanding shares used to calculate the weighted average common stock outstanding for basic and diluted earnings per common share. The initial repurchase of our common stock under the 2025 ASR agreements was accounted for as a reduction to stockholders' equity in our consolidated balance sheets. The hedging period under the Collared ASR was classified as part of the unsettled forward contract at inception and was equity classified upon settlement on August 25, 2025. The final settlements of the 2025 ASR agreements were accounted for as unsettled forward contracts indexed to our common stock until the final settlement occurred. The forward contracts related to the 2025 ASR agreements were equity classified, in accordance with ASC 815, *Derivatives and Hedging*, through final settlement. As of December 31, 2025, we recorded a liability of $1.8 million for an excise tax imposed under the IRA as a result of our repurchase of shares under the 2025 ASR agreements.

2024 Share Repurchase

In March 2024, our Board of Directors approved a share repurchase program authorizing up to $1.0 billion in aggregate repurchases of our common stock. Pursuant to this authorization, we entered into an accelerated share repurchase agreement (the **2024 ASR agreement**) with Citi on March 25, 2024, to repurchase approximately $1.0 billion of our common stock. Under the 2024 ASR agreement, we made an aggregate upfront payment of $1.0 billion to Citi and received an aggregate initial delivery of 3,275,199 shares of our common stock on March 27, 2024, which represented approximately 80 percent of the total shares that would be repurchased under the 2024 ASR agreement, measured based on the closing price of our common stock on March 25, 2024.

The share repurchase under the 2024 ASR agreement was divided into two tranches, resulting in upfront payments of $300 million and $700 million, respectively. The final settlement of the $300 million tranche occurred in June 2024, and we received an additional 181,772 shares of our common stock upon settlement. The final settlement of the $700 million tranche occurred in September 2024, and we received an additional 90,403 shares of our common stock upon settlement. In total, we repurchased 3,547,374 shares of our common stock under the 2024 ASR agreement that we currently hold as treasury stock in our consolidated balance sheets.

The final number of shares that we ultimately repurchased pursuant to the 2024 ASR agreement was based on the average of the daily volume-weighted average price per share of our common stock during the repurchase period, less a discount and subject to adjustments pursuant to the terms and conditions of the 2024 ASR agreement.

The initial repurchase of our common stock and final settlement of each tranche was treated as a reduction of the outstanding shares used to calculate the weighted average common stock outstanding for basic and diluted earnings per common share. The initial repurchase of our common stock under each tranche was accounted for as a reduction to stockholders' equity in our consolidated balance sheets. The final settlement of the transactions under the 2024 ASR agreement was accounted for as an unsettled forward contract indexed to our common stock until the final settlement occurred. The forward contract related to the first and second tranche was equity classified, in accordance with ASC 815, *Derivatives and Hedging*, through final settlement. During the second quarter of 2025, we paid $5.0 million for an excise tax imposed under the Inflation Reduction Act as a result of our repurchase of shares under the 2024 ASR agreement.

Accumulated Other Comprehensive Income (Loss)

The following table includes changes in accumulated other comprehensive income (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, 2025	$ 11.0	$ (15.5)	$ 1.1	$ (3.4)
Other comprehensive income before reclassifications	(3.7)	–	10.5	6.8
Amounts reclassified from accumulated other comprehensive income (loss)	(1.7)	–	(0.8)	(2.5)
Net current-period other comprehensive income	(5.4)	–	9.7	4.3
Balance, December 31, 2025	**$ 5.6**	**$ (15.5)**	**$ 10.8**	**$ 0.9**

	Defined Benefit Pension Plan[1]	Foreign Currency Translation Losses	Unrealized Gains and (Losses) on Available-for-Sale Securities	Total
Balance, January 1, 2024	$ 15.9	$ (17.9)	$ (10.8)	$ (12.8)
Other comprehensive income before reclassifications	(0.3)	–	10.8	10.5
Amounts reclassified from accumulated other comprehensive income (loss)	(4.6)	2.4	1.1	(1.1)
Net current-period other comprehensive income	(4.9)	2.4	11.9	9.4
Balance, December 31, 2024	**$ 11.0**	**$ (15.5)**	**$ 1.1**	**$ (3.4)**

(1) See Note 11–*Employee Benefit Plans–Supplemental Executive Retirement Plan*, which identifies the captions within our consolidated statements of operations where reclassification adjustments were recognized and their associated tax impact.

10. Income Taxes

Components of income from continuing operations before income taxes include (in millions):

	Year Ended December 31,		
	2025	2024	2023
United States	$ 1,708.4	$ 1,540.5	$ 1,270.4
Foreign	5.5	(1.5)	3.9
Income before income taxes	**$ 1,713.9**	**$ 1,539.0**	**$ 1,274.3**

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

	Year Ended December 31,		
	2025	2024	2023
Current:			
Federal	$ 208.8	$ 326.4	$ 287.2
State	71.5	80.8	66.6
Foreign	1.2	0.8	0.1
Total current	281.5	408.0	353.9
Deferred			
Federal	85.7	(56.7)	(43.8)
State	12.5	(7.4)	(20.1)
Foreign	(0.5)	–	(0.5)
Total deferred	97.7	(64.1)	(64.4)
Total income tax expense	**$ 379.2**	**$ 343.9**	**$ 289.5**

Presented below is a reconciliation of income tax expense computed at the statutory federal tax rate of 21 percent in 2025, 2024, and 2023 to income tax expense as reported (in millions):

	Year Ended December 31,					
	2025		2024		2023	
	Amount	Percent	Amount	Percent	Amount	Percent
U.S. Federal statutory tax rate	$ 359.9	21.0 %	$ 323.2	21.0 %	$ 267.6	21.0 %
State and local income taxes, net of federal income tax effect[1]	58.7	3.4 %	47.6	3.1 %	37.4	2.9 %
Excess tax benefits from share-based compensation	(41.6)	(2.4)%	(27.1)	(1.8)%	(17.7)	(1.4)%
Tax credits:						
Research and development tax credits	(26.6)	(1.6)%	(27.2)	(1.8)%	(19.0)	(1.5)%
Other tax credits	–	– %	(0.5)	– %	(1.6)	(0.1)%
Nontaxable or nondeductible items:						
Nondeductible compensation	19.4	1.1 %	17.0	1.1 %	3.9	0.3 %
Other nontaxable or nondeductible items	6.3	0.4 %	4.1	0.3 %	14.0	1.1 %
Changes in unrecognized tax benefits	6.6	0.4 %	12.0	0.8 %	9.0	0.7 %
Effect of cross-border tax laws	(2.3)	(0.1)%	(6.6)	(0.4)%	(5.2)	(0.4)%
Foreign tax effects	(0.5)	– %	1.0	0.1 %	(1.3)	(0.1)%
Changes in valuation allowances	(0.1)	– %	0.5	– %	2.4	0.2 %
Other	(0.6)	(0.1)%	(0.1)	(0.1)%	–	– %
Income tax expense and effective tax rate	**$ 379.2**	**22.1 %**	**$ 343.9**	**22.3 %**	**$ 289.5**	**22.7 %**

(1) State taxes in Illinois and Tennessee for 2025 and Illinois for 2023 and 2024 made up the majority (greater than 50 percent) of the tax effect in this category.

Components of income taxes paid, net of refunds, consist of the following (in millions):

	Year Ended December 31,		
	2025	2024	2023
United States Federal	$ 230.5	$ 339.6	$ 267.5
U.S. States:			
Illinois	35.1	30.3	41.7
Tennessee[1]	33.5	–	–
Other U.S. States	13.7	30.6	23.2
Foreign	0.5	0.1	0.1
Total Income Taxes Paid	**$ 313.3**	**$ 400.6**	**$ 332.5**

(1) The amount of income taxes paid during the years ended December 31, 2024 and 2023 does not meet the 5 percent disaggregation threshold.

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

	As of December 31,	
	2025	2024
Deferred tax assets:		
Capitalized research and development	$ 176.9	$ 266.1
Intangible assets	142.2	144.0
Share-based compensation	45.0	46.6
Reserves and accrued liabilities	64.2	45.3
Net operating loss carryforwards	22.2	19.8
Basis differences in investments	–	9.6
SERP	7.7	8.9
Other	24.2	22.6
Total deferred tax assets	482.4	562.9
Less: Valuation allowance	(35.6)	(30.1)
Total net deferred tax assets	446.8	532.8
Deferred tax liabilities:		
Property, plant, and equipment	(74.9)	(64.1)
Right-of-use assets	(7.2)	(7.3)
Other	(7.0)	(3.0)
Total deferred tax liabilities	(89.1)	(74.4)
Total deferred tax assets, net	**$ 357.7**	**$ 458.4**

As of December 31, 2025, we had gross federal, foreign, and state net operating loss carryforwards of $38.9 million, $7.5 million, and $205.8 million, respectively, which either expire at various dates beginning in 2026 or have no expiration date. As of December 31, 2025, we had federal and state research credit carryforwards, of $5.3 million and $5.4 million, respectively, which expire at various dates beginning in 2028. We expect that certain of these carryforwards will expire unused, so we have established valuation allowances for that portion of the related deferred tax assets.

The One Big Beautiful Bill Act of 2025 reinstated the option to deduct research and development expenditures in the period incurred beginning in 2025, to deduct unamortized domestic costs from 2024 and prior, and to expense 100 percent of certain qualifying assets in the year placed in service. These changes decreased our cash paid for income taxes for 2025 and our deferred tax assets as of December 31, 2025.

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 2022.

As of December 31, 2025 and 2024, we had $22.8 million and $16.7 million of unrecognized tax benefits, excluding interest and penalties, that would impact our effective tax rate if recognized. The following table represents a reconciliation of the total unrecognized tax benefit liability, excluding interest and penalties, for the years ended December 31, 2025, 2024, and 2023 (in millions):

	Year Ended December 31,		
	2025	2024	2023
Unrecognized tax benefits, beginning of the period	$ 19.6	$ 24.1	$ 15.2
Gross decreases related to prior period tax positions	–	–	–
Gross increases related to prior period tax positions	–	8.8	9.3
Gross increases related to current period tax positions	9.2	8.7	1.5
Gross decreases as a result of settlements during the current period	–	(21.1)	–
Reductions due to lapse of applicable statute of limitations	(1.8)	(0.9)	(1.9)
Unrecognized tax benefits, end of the period	**$ 27.0**	**$ 19.6**	**$ 24.1**

We record interest and penalties related to uncertain tax positions as a component of income tax expense. As of December 31, 2025 and 2024, our liability for unrecognized tax benefits included approximately $1.7 million and $1.0 million, respectively, for the accrual of interest and penalties. For the years ended December 31, 2025, 2024, and 2023, we recorded an approximately $0.7 million expense, $0.6 million benefit, and $0.9 million expense, respectively, for the accrual of interest and penalties in our consolidated statements of operations.

11. Employee Benefit Plans

Supplemental Executive Retirement Plan

We maintain the 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 lives. 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, 2025 and 2024, 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,	
	2025	2024
Projected benefit obligation at the beginning of the year	$ 52.1	$ 48.8
Service cost	2.0	1.6
Interest cost	2.0	1.6
Benefits paid	(5.0)	(0.2)
Actuarial loss	3.7	0.3
Projected benefit obligation at the end of the year	**$ 54.8**	**$ 52.1**
Amount included in other current liabilities[1]	**$ 26.0**	**$ 30.8**
Amount included in other non-current liabilities	**$ 28.8**	**$ 21.3**

(1) 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.

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

	Year Ended December 31,	
	2025	2024
Discount rate	4.42 %	5.22 %
Salary increases	4.00 %	4.00 %
Lump-sum interest rate	5.25 %	5.25 %

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

	Year Ended December 31,		
	2025	2024	2023
Service cost	$ 2.0	$ 1.6	$ 2.1
Interest cost	2.0	1.6	2.1
Amortization of prior service cost	–	0.2	0.4
Amortization of net actuarial gain	(1.3)	(5.2)	(4.2)
Settlement	(0.6)	–	(1.8)
Total	**$ 2.1**	**$ (1.8)**	**$ (1.4)**

The service cost component is reported within *operating expenses* and the other components are reported in *other income (expense), net* in our consolidated statements of operations.

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

	Year Ended December 31,		
	2025	2024	2023
Net actuarial loss	$ (5.0)	$ (5.5)	$ (2.0)
Prior service cost	–	0.2	0.4
Settlement	(0.6)	–	(1.8)
Total recognized in other comprehensive income	(5.6)	(5.3)	(3.4)
Tax benefit	0.2	0.4	0.5
Total, net of tax	**$ (5.4)**	**$ (4.9)**	**$ (2.9)**

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

	Year Ended December 31,		
	2025	2024	2023
Net actuarial gain	$ (6.8)	$ (12.4)	$ (17.9)
Prior service cost	–	–	0.2
Total included in accumulated other comprehensive income (loss)	(6.8)	(12.4)	(17.7)
Tax expense	1.2	1.4	1.8
Total, net of tax	**$ (5.6)**	**$ (11.0)**	**$ (15.9)**

The accumulated benefit obligation, a measure that does not consider future increases in participants' salaries, was $47.6 million and $47.2 million as of December 31, 2025 and 2024, 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,	
2026	$ 26.0
2027	–
2028	13.0
2029	–
2030	–
Thereafter	24.4
Total	**$ 63.4**

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.

12. Commitments and Contingencies

Leases

We lease facilities and equipment under operating lease arrangements that have terms expiring at various dates through 2043. 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, 2025, are as follows (in millions):

Year Ending December 31,	
2026	$ 7.3
2027	7.2
2028	6.9
2029	6.1
2030	4.6
Thereafter	5.5
Total	**$ 37.6**

Total operating lease expense was $8.9 million, $7.6 million, and $5.7 million for the years ended December 31, 2025, 2024, and 2023, respectively. The amounts recorded in operating lease expense include short-term leases, which are immaterial.

In August 2021, we entered into a commercial supply agreement (**Supply Agreement**) with MannKind Corporation (**MannKind**), which was later amended. Pursuant to the Supply Agreement, MannKind is responsible for manufacturing and supplying Tyvaso DPI to us. Unless earlier terminated, the initial term of the Supply Agreement continues until December 31, 2031 and will thereafter be renewed automatically for additional, successive two-year terms unless either party provides notice of non-renewal. We determined that the Supply Agreement contains certain lease components and have elected the expedient to combine lease and non-lease components as a single lease component. All payment obligations under the Supply Agreement are variable in nature and we incurred costs of $216.4 million, $179.8 million, and $130.4 million during the years ended December 31, 2025, 2024, and 2023, respectively. In January 2026, we entered into an amendment to our Supply Agreement with MannKind related to production services that includes committed annual purchase amounts through December 31, 2031.

In September 2022, we entered into an agreement (**Lease Agreement**) to lease the entirety of a building. The Lease Agreement modified and replaced several of our pre-existing leases of portions of the same building, and has an initial term expiring in July 2027, with five renewal options of five years each, exercisable in our sole discretion. As a result, we remeasured the lease liability at our incremental borrowing rate, using a lease term that assumed we exercise one renewal option, due to our financing of significant leasehold improvements necessary for the research and development activities being performed at this location. Upon remeasurement, we determined that the lease remains an operating lease. As of December 31, 2025, our consolidated balance sheets included a right-of-use asset of $8.8 million, leasehold improvements, net of $28.8 million, and lease liability for the building of $9.5 million.

Milestone Payments and Royalty Obligations

We are party to certain license 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. In addition, we sometimes acquire companies under terms that include the potential payment of earn-out consideration in connection with future activities. The following table outlines our financial obligations under certain of these agreements:

Counterparty	Relevant Product	Our Financial Obligation
Arena Pharmaceuticals, Inc. (now owned by Pfizer)	Ralinepag	Low double-digit, tiered royalty 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-U.S. jurisdictions of an oral version of ralinepag to treat any indication
DEKA Research & Development Corp. (**DEKA**)	Remunity Pump RemunityPRO Pump	Product fees and single-digit royalty on net product sales of the Remunity and RemunityPRO Pumps and Remodulin for use with these pumps; reimbursement of DEKA's development and manufacturing costs
IVIVA Medical, Inc. (**IVIVA**) former securityholders	IVIVA kidney products	Two percent royalty on net product sales
Eli Lilly & Co.	Adcirca	Ten percent royalty on net product sales of Adcirca, plus milestone payments of $325,000 for each $1,000,000 in net product sales
MannKind Corporation	Tyvaso DPI	Ten percent royalty on net product sales of Tyvaso DPI
Revivicor, Inc. former securityholders	UHeart, UKidney, and UThymoKidney	Up to $25.0 million in milestone payments (of which $2.5 million has been paid), and a five percent royalty on net product sales
Supernus Pharmaceuticals, Inc.	Orenitram	Single-digit royalty on net product sales of Orenitram, through the fourth quarter of 2026
The Scripps Research Institute	Unituxin	One percent royalty on net product sales of Unituxin

13. Segment Information

Our Chief Executive Officer, as our Chief Operating Decision Maker (**CODM**), manages our company as a single operating and reporting segment at the consolidated level. Our operating segment focuses on the development and commercialization of products to address the unmet needs of patients with chronic and life-threatening conditions. The accounting policies of our one operating segment are the same as those described in Note 2–*Summary of Significant Accounting Policies*.

Our CODM is regularly provided with revenue and expense forecasts, including product development plans, to manage the operations of our operating segment. Our CODM monitors forecasted to actual results for net income when assessing performance and allocating resources across the operating segment. Significant segment expenses are presented as *operating expenses* in our consolidated statements of operations.

The measure of the operating segment assets is reported in our consolidated balance sheets as *total assets*.

Total revenues, cost of sales, and gross profit (loss) for each of our commercial products and other sources of revenues were as follows (in millions):

Year Ended December 31, 2025	Tyvaso DPI	Nebulized Tyvaso	Remodulin[1]	Orenitram	Unituxin	Adcirca	Other	Total
Total revenues	$ 1,292.5	$ 585.7	$ 526.8	$ 496.9	$ 226.8	$ 30.0	$ 24.0	$ 3,182.7
Cost of sales	210.6	27.2	49.3	28.7	17.5	13.1	38.0	384.4
Gross profit (loss)	**$ 1,081.9**	**$ 558.5**	**$ 477.5**	**$ 468.2**	**$ 209.3**	**$ 16.9**	**$ (14.0)**	**$ 2,798.3**
Year Ended December 31, 2024								
Total revenues	$ 1,033.6	$ 586.8	$ 538.1	$ 434.3	$ 238.7	$ 23.8	$ 22.1	$ 2,877.4
Cost of sales	148.4	34.1	47.4	28.4	14.4	10.1	26.9	309.7
Gross profit (loss)	**$ 885.2**	**$ 552.7**	**$ 490.7**	**$ 405.9**	**$ 224.3**	**$ 13.7**	**$ (4.8)**	**$ 2,567.7**
Year Ended December 31, 2023								
Total revenues	$ 731.1	$ 502.6	$ 494.8	$ 359.4	$ 198.9	$ 28.9	$ 11.8	$ 2,327.5
Cost of sales	115.6	32.4	38.2	24.2	16.5	12.3	18.3	257.5
Gross profit	**$ 615.5**	**$ 470.2**	**$ 456.6**	**$ 335.2**	**$ 182.4**	**$ 16.6**	**$ (6.5)**	**$ 2,070.0**

(1) Total revenues and cost of sales include sales of infusion devices, including the Remunity and RemunityPRO Pumps.

Geographic revenues are determined based on the country in which our customers (distributors) are located. Total revenues from external customers in the United States and rest-of-world (**ROW**) for each of our commercial products were as follows (in millions):

	Year Ended December 31,								
	2025			2024			2023		
	U.S.	ROW	Total	U.S.	ROW	Total	U.S.	ROW	Total
Net product sales:									
Tyvaso DPI	$1,291.8	$ 0.7	$1,292.5	$1,033.2	$ 0.4	$1,033.6	$ 731.1	$ –	$ 731.1
Nebulized Tyvaso	531.9	53.8	585.7	545.5	41.3	586.8	477.1	25.5	502.6
Total Tyvaso	1,823.7	54.5	1,878.2	1,578.7	41.7	1,620.4	1,208.2	25.5	1,233.7
Remodulin[(1)]	448.9	77.9	526.8	464.2	73.9	538.1	414.6	80.2	494.8
Orenitram	496.9	–	496.9	434.3	–	434.3	359.4	–	359.4
Unituxin	214.7	12.1	226.8	219.6	19.1	238.7	181.3	17.6	198.9
Adcirca	30.0	–	30.0	23.8	–	23.8	28.9	–	28.9
Other	22.8	1.2	24.0	19.1	3.0	22.1	9.8	2.0	11.8
Total revenues	$3,037.0	$ 145.7	$3,182.7	$2,739.7	$ 137.7	$2,877.4	$2,202.2	$ 125.3	$2,327.5

(1) Net product sales include sales of infusion devices, including the Remunity and RemunityPRO Pumps.

We recorded revenue from two distributors in the United States that exceeded ten percent of total revenues. Revenue from these two distributors as a percentage of total revenues is as follows:

Year Ended December 31,	2025	2024	2023
Distributor 1	51 %	51 %	51 %
Distributor 2	36 %	35 %	34 %

Long-lived assets, including PP&E and right-of-use assets, located by geographic area are as follows (in millions):

Year Ended December 31,	2025	2024	2023
United States	$ 1,743.5	$ 1,240.6	$ 1,057.8
Rest-of-World	15.8	11.7	12.0
Total	$ 1,759.3	$ 1,252.3	$ 1,069.8

14. Litigation

Sandoz Litigation

In April 2019, Sandoz Inc. (**Sandoz**) and its marketing partner RareGen, LLC (now known as Liquidia PAH, LLC, a subsidiary of Liquidia Corporation) (**RareGen**), filed a complaint in the U.S. District Court for the District of New Jersey against us and Smiths Medical ASD, Inc. (**Smiths Medical**), alleging that we and Smiths Medical engaged in anticompetitive conduct in connection with the plaintiffs' efforts to launch their generic version of Remodulin. In particular, the complaint alleged that we and Smiths Medical unlawfully impeded competition by entering into an agreement for Smiths Medical to produce cartridges used with the CADD-MS®3 (**MS-3**) infusion system specifically for the delivery of subcutaneous Remodulin for our patients, without making these cartridges available for the delivery of Sandoz's generic treprostinil injection. In March 2020, the plaintiffs filed an amended complaint to add a count alleging that we breached our earlier patent settlement agreement with Sandoz by refusing to grant Sandoz access to cartridges purchased for our patients.

Smiths Medical was dismissed from the case in November 2020, based on a settlement resolving the disputes between the plaintiffs and Smiths Medical. As part of this settlement, Smiths Medical paid the plaintiffs $4.25 million, disclosed and made available to the plaintiffs certain specifications and other information related to the MS-3 cartridges, and granted to the plaintiffs a non-exclusive, royalty-free license in the United States to Smiths Medical's patents and copyrights associated with the MS-3 cartridges and certain other information related to the MS-3 pumps and cartridges.

In March 2022, the court granted our motion for summary judgment with respect to all claims brought by the plaintiffs except the breach of contract claim. As a result, all antitrust claims, all claims under state competition laws, and the common law tortious interference claim were resolved in our favor. These were the only claims in the case that gave rise to any potential for

trebling of damages, punitive damages, disgorgement, and/or the award of attorneys' fees. The court also denied the plaintiffs' request for injunctive relief.

The court granted Sandoz's motion for summary judgment with respect to Sandoz's breach of contract claim. The issue of what, if any, damages Sandoz is entitled to based on the court's decision on the contract claim went to trial. On November 1, 2024, the court entered a final judgment in favor of Sandoz, ordering us to pay to Sandoz (a) approximately $61.6 million in damages; (b) prejudgment interest in the amount of approximately $9.0 million; and (c) post-judgment interest. All parties appealed the final judgment, including the court's March 30, 2022 summary judgment decision. The appeal is pending before the U.S. Court of Appeals for the Third Circuit, and oral argument was held in November 2025.

We accrued a liability of $71.1 million during 2024, and an additional $3.0 million through the fourth quarter of 2025, reflecting, in the aggregate, the damages and pre-judgment interest amounts awarded in the final judgment, as well as post-judgment interest accrued through the end of 2025. We currently do not expect that the amount of any loss in excess of these accruals would be material to our financial results; however, the amount ultimately payable, if any, could be higher or lower than this amount depending on the amount of post judgment interest, and the outcome of appeals. We recorded this liability within *other non-current liabilities* in our consolidated balance sheets.

We intend to continue to vigorously defend ourselves against the claims made in this litigation. Among other things, we believe our settlement agreement with Sandoz did not provide Sandoz any rights with respect to delivery systems such as the MS-3. We also believe that the plaintiffs, who were on notice that Smiths Medical would discontinue the MS-3 system, failed to fulfill their duty to properly mitigate their exposure as a result of such discontinuation, and any damages they incurred are the result of market conditions and their own failure to properly plan their own product launch. However, due to the uncertainty inherent in any litigation, we cannot guarantee that appeals will not result in an outcome adverse to us. This litigation has involved, and will likely continue to involve, substantial cost to defend, and an adverse appellate outcome could result in substantial monetary damages in excess of the liability we have accrued to-date.

Litigation with Liquidia Technologies, Inc.

Since March 2020, we have been engaged in litigation with Liquidia Technologies, Inc. (**Liquidia**) regarding its efforts to obtain FDA approval for Yutrepia®, a dry powder inhalation formulation of treprostinil. That litigation has included two petitions for *inter partes* review (**IPR**) filed by Liquidia with the Patent Trial and Appeal Board (**PTAB**) of the U.S. Patent and Trademark Office (**USPTO**), as well as multiple lawsuits we have brought alleging infringement by Liquidia of several of our patents. Most of these cases have now been finally resolved, and Liquidia received final approval from the FDA to market Yutrepia to treat PAH and PH-ILD in May 2025, and launched commercial sales in June 2025.

We have an ongoing patent infringement lawsuit against Liquidia, which was originally filed on September 5, 2023 in the U.S. District Court for the District of Delaware, alleging infringement of U.S. Patent No. 10,716,793 (the **'793 patent**), a patent related to Tyvaso with an expiration date in May 2027 that was later invalidated as a result of an IPR proceeding, and therefore is no longer at issue in this litigation. On November 30, 2023, we filed an amended complaint to assert a new patent: U.S. Patent No. 11,826,327 (the **'327 patent**), which expires February 3, 2042, and is now the only patent remaining at issue in the case. The claims of the '327 patent generally cover improving exercise capacity in patients suffering from PH-ILD by inhaling treprostinil at specific dosages. Trial took place in June 2025, and the parties are awaiting the court's decision. If we prevail in this lawsuit, we believe that we will be entitled to a court order requiring Liquidia to remove the PH-ILD indication from Yutrepia's product labeling, and that we may also be entitled to damages.

In June 2021, we filed a motion in one of our earlier patent cases against Liquidia in the U.S. District Court for the District of Delaware to file an amended complaint adding trade secret misappropriation claims against Liquidia and a former Liquidia executive, Dr. Robert Roscigno. The court denied the motion based on a finding that adding the additional claims would impact the case schedule. Thus, we filed those claims as a separate case against Liquidia and Dr. Roscigno in North Carolina state court. Discovery is complete. On January 5, 2024, Dr. Roscigno filed a motion for summary judgment, which was denied on July 31, 2024. On July 3, 2024, Liquidia filed a motion for summary judgment, which was denied on July 23, 2025. We filed a new complaint on May 29, 2024, to commence a separate, related case against Liquidia and Dr. Roscigno in North Carolina state court. That case is in its early stages, and the parties are developing a case schedule.

On April 21, 2025, Liquidia filed a lawsuit against us in the U.S. District Court for the Middle District of North Carolina, alleging that Tyvaso DPI infringes U.S. Patent No. 10,898,494. This patent's claims are directed to the treatment of pulmonary hypertension by administering specified amounts of treprostinil via a dry powder inhaler in a specified number of breaths. The patent expires May 5, 2037. Liquidia seeks damages and attorneys' fees. We filed a motion to dismiss or, alternatively, a motion to stay the case based on the argument that we co-own the asserted patent based on Liquidia's and Dr. Roscigno's alleged trade secret misappropriation subject to the pending North Carolina state court litigation. The court granted our motion to stay and denied the motion to dismiss. On May 9, 2025, we filed a lawsuit against Liquidia in the U.S. District Court for the Middle District of North Carolina, alleging that Yutrepia infringes U.S. Patent No. 11,357,782. This patent claims a method of treating pulmonary hypertension using inhaled treprostinil delivered using a specified dosage regimen. The patent expires May 14, 2027. We moved for a preliminary injunction, but the court denied that motion. Liquidia moved to dismiss or, alternatively, transfer the case to the U.S. District Court for the District of Delaware. The court denied Liquidia's motion.

We plan to continue to vigorously enforce our intellectual property rights related to Tyvaso DPI and Nebulized Tyvaso. In addition, we believe we have meritorious defenses and intend to vigorously defend ourselves against the claims made by Liquidia in its patent infringement lawsuit against us.

MSP Recovery Litigation

In July 2020, MSP Recovery Claims, Series LLC; MSPA Claims 1, LLC; and Series PMPI, a designated series of MAO-MSO Recovery II, LLC, filed a class action complaint against Caring Voices Coalition, Inc. (**CVC**) and us in the U.S. District Court for the District of Massachusetts. The complaint alleged that we violated the federal Racketeer Influenced and Corrupt Organizations (**RICO**) Act and various state laws by coordinating with CVC when making donations to a PAH fund so that those donations would go toward copayment obligations for Medicare patients taking drugs manufactured and marketed by us. The plaintiffs claim to have received assignments from various Medicare Advantage health plans and other insurance entities that allow them to bring this lawsuit on behalf of those entities to recover allegedly inflated amounts they paid for our drugs. In April 2021, the court granted our motion to transfer the case to the U.S. District Court for the Southern District of Florida.

In October 2021, the plaintiffs filed an amended complaint that includes state antitrust claims based on alleged facts similar to those raised by Sandoz and RareGen in the matter described above. The amended complaint added MSP Recovery Claims Series 44, LLC as a plaintiff and Smiths Medical and CVC as defendants. In December 2021, we filed a motion to dismiss all of the plaintiffs' claims in the amended complaint, including the new antitrust claims. Smiths Medical also filed a motion to dismiss the plaintiffs' claims against Smiths Medical. In September 2022, the court dismissed all of the plaintiffs' claims against us and Smiths Medical without prejudice.

In October 2022, the plaintiffs filed a second amended complaint, which added federal antitrust claims and consumer protection claims under other states' laws to the claims previously asserted. The second amended complaint also named Accredo Health Group, CVS Health Corporation, Express Scripts, Inc., and Express Scripts Holding Company (collectively, the **Specialty Pharmacies**), and the Adira Foundation as additional defendants. In March 2023, we filed our motion to dismiss the second amended complaint. The Specialty Pharmacies filed their own motion to dismiss, as did Smiths Medical. On March 22, 2024, the magistrate judge recommended dismissal of the plaintiffs' complaint against all defendants in its entirety with prejudice, and for administrative purposes, issued an order dismissing the complaint. On April 12, 2024, the plaintiffs filed an objection to the magistrate judge's recommendation. On May 10, 2024, we filed a response to the plaintiffs' objection, as did the other defendants. If the district court judge adopts the magistrate judge's recommendation and dismisses the case, the plaintiffs will have the right to appeal.

We intend to continue to vigorously defend ourselves against the claims made in this lawsuit.

Litigation with Humana and United Healthcare

Humana Inc. (**Humana**) and United Healthcare Services, Inc. (**United**) filed separate lawsuits against us in the U.S. District Court for the District of Maryland in December 2022 and November 2022, respectively. Each of these lawsuits includes allegations similar to those in the *MSP Recovery* matter discussed above concerning our charitable contributions to CVC. In particular, these lawsuits allege that our donations to CVC violated RICO and various state laws. We filed motions to dismiss both of these lawsuits in March 2023. On March 25, 2024, the court dismissed both the Humana and United complaints in their entirety. In both cases, the RICO claims were dismissed with prejudice. In the Humana case, the state law claims were dismissed without prejudice, and in the United case, some of the state law claims were dismissed with prejudice, while others were dismissed without prejudice. Neither Humana nor United filed an appeal to date, and their deadlines for filing appeals have passed.

On April 24, 2024, Humana and United each filed lawsuits against us in the Circuit Court for Montgomery County, Maryland. These lawsuits include allegations similar to those in their lawsuits discussed above concerning charitable contributions. Humana and United allege that our donations to CVC give rise to common law causes of action, violations of state consumer protection statutes, and violations of insurance fraud statutes under the laws of various states. On July 22, 2024, we filed motions to dismiss both of these lawsuits. Oral argument on these motions to dismiss took place on October 24, 2024. On September 23, 2025, the court dismissed both lawsuits with prejudice. On October 20, 2025, Humana and United each appealed the court's decision to the Appellate Court of Maryland, and those appeals are pending.

We intend to continue to vigorously defend ourselves against the claims made in these lawsuits.

15. Acquisitions

Asset Acquisition

In October 2023, we acquired all the outstanding equity of IVIVA, an early-stage company focused on developing manufactured kidney products, in exchange for an upfront cash payment of approximately $50.0 million. In addition to the

upfront payment, the transaction consideration includes potential earnout consideration, payable in cash, structured as a two percent royalty on net sales of IVIVA's kidney products, subject to certain reductions. The transaction was accounted for as an asset acquisition as substantially all of the fair value was concentrated in a single IPR&D asset we acquired. We allocated $46.0 million of the purchase price to the IPR&D and recorded the expense within *research and development* in our consolidated statements of operations for the year ended December 31, 2023. For tax purposes, the purchase price allocated to the IPR&D is not deductible and was capitalized into the tax basis of the equity we acquired. We also recorded an intangible asset of $1.3 million related to the asset acquisition and recorded the amount within *goodwill and other intangible assets, net* in our consolidated balance sheet as of December 31, 2023.

Business Combination

On October 29, 2023, we entered into an Agreement and Plan of Merger (the **Merger Agreement**) with Miromatrix Medical Inc. (**Miromatrix**), a publicly traded company developing bioengineered kidney and liver alternative products. On December 13, 2023, we completed the transactions contemplated by the Merger Agreement and Miromatrix became a wholly-owned subsidiary of United Therapeutics. Pursuant to the terms of the Merger Agreement, we paid former Miromatrix shareholders $3.25 per share in cash at closing, representing cash consideration paid to former Miromatrix shareholders of $89.1 million. Former Miromatrix shareholders also received one contractual contingent value right per share, representing the right to receive a contingent payment of $1.75 per share in cash (an aggregate of approximately $54.0 million) upon the first implantation of Miromatrix's development-stage, fully-implantable kidney alternative product known as mirokidney into a living human patient by the end of 2025 in a clinical trial meeting requirements set forth in the form of the Contingent Value Rights Agreement attached to the Merger Agreement (the **Milestone**). In addition to the cash consideration noted above, the aggregate purchase price included $2.5 million that we ascribed to the contingent value rights, of which $1.4 million was recorded as a measurement period adjustment during the first quarter of 2024. During the third quarter of 2024, we recorded a measurement period adjustment to decrease *goodwill and other intangible assets, net* and increase *deferred tax assets, net* by $2.8 million.

Purchase Price Allocation

The merger met the definition of a business combination in accordance with ASC 805, *Business Combinations*, and as such, 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 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 were based, in part, upon third-party valuations of certain assets, which included specifically-identified intangible assets.

The following table sets forth the final purchase price allocation, including measurement period adjustments, of the assets acquired and liabilities assumed as of the closing date. The purchase price allocation was considered complete as of September 30, 2024.

Purchase Price Allocation		Fair Value (in millions)
Cash	$	5.1
Other current assets		1.1
Intangible assets:		
IPR&D		63.0
Goodwill[(1)]		4.3
Deferred tax assets, net		18.3
Property, plant, and equipment, net		4.5
Other non-current assets		2.6
Total fair value of assets acquired	**$**	**98.9**
Accounts payable and accrued expenses		3.1
Other current liabilities		1.4
Other non-current liabilities		2.8
Total fair value of liabilities assumed	**$**	**7.3**
Total purchase price	**$**	**91.6**

(1) The goodwill is not deductible for income tax purposes.

We determined the fair value of the 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 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 $2.5 million to the contingent value rights as of the closing date based on a probability weighted discounted cash flow model, utilizing probability adjusted expectations of achieving the Milestone. The value of the contingent value rights was zero as of December 31, 2025 as the Milestone was not achieved.

Following the acquisition, the operating results of Miromatrix have been included in our consolidated financial statements. The acquisition did not have a material impact on our consolidated financial statements, and therefore, historical and pro forma disclosures have not been presented.

Costs incurred to complete the acquisition and integrate Miromatrix into our business were expensed as incurred and included within *selling, general, and administrative* in our consolidated statements of operations. During the year ended December 31, 2023, we recognized $3.5 million of acquisition-related costs. These costs represented transaction costs, legal fees, and professional third-party service fees.

Schedule II—Valuation and Qualifying Accounts
Years Ended December 31, 2025, 2024, and 2023
(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, 2025	$ 30.1	$ 5.5	$ –	$ –	$ 35.6
Year Ended December 31, 2024[1]	$ 30.8	$ 1.9	$ –	$ (2.6)	$ 30.1
Year Ended December 31, 2023[2]	$ 22.4	$ 4.4	$ 5.1	$ (1.1)	$ 30.8

(1) Deductions relate primarily to changes from finalization of acquisition accounting.

(2) Other additions relate to valuation allowances on certain tax attributes obtained through acquisitions. Deductions relate to state net operating losses.

	Inventory Reserves			
	Balance at Beginning of Year	Additions Charged to Expense	Deductions	Balance at End of Year
Year Ended December 31, 2025	$ 28.6	$ 40.5	$ (16.7)	$ 52.4
Year Ended December 31, 2024	$ 26.5	$ 14.9	$ (12.8)	$ 28.6
Year Ended December 31, 2023	$ 21.6	$ 17.3	$ (12.4)	$ 26.5

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 Chairperson 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, 2025. Based on that evaluation, our Chairperson and Chief Executive Officer and Chief Financial Officer and Treasurer concluded that our disclosure controls and procedures were effective as of December 31, 2025.

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, 2025, based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission 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, 2025, our internal control over financial reporting was effective.

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

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, 2025 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

Item 9B. Other Information

(c) Trading Plans

On October 31, 2025, James Edgemond, Chief Financial Officer and Treasurer, adopted a trading plan intended to satisfy Rule 10b5-1(c) to exercise up to 268,750 stock options and sell the shares of common stock received, subject to certain conditions.

On November 4, 2025, Judy Olian, a member of our Board of Directors, adopted a trading plan intended to satisfy Rule 10b5-1(c) to sell up to 800 shares of our common stock, subject to certain conditions.

On November 7, 2025, Dr. Martine Rothblatt, our Chairperson and Chief Executive Officer, adopted a trading plan intended to satisfy Rule 10b5-1(c) to exercise up to 1,734,410 stock options and sell the shares of our common stock received, subject to certain conditions. These transactions would commence no earlier than March 2, 2026, and end no later than December 31, 2026, ahead of the anticipated expiration date of these options, which is March 15, 2027. The 1,734,410 stock options covered by this trading plan include options that will be owned by a trust of which Dr. Rothblatt was settlor and in which she has a pecuniary interest.

On December 18, 2025, Christopher Patusky, a member of our Board of Directors, adopted a trading plan intended to satisfy Rule 10b5-1(c) to exercise up to 4,910 stock options and sell the shares of common stock received, subject to certain conditions.

During the three months ended December 31, 2025, no director or Section 16 officer terminated any Rule 10b5-1 plans or non-Rule 10b5-1 trading arrangements (in each case, as defined in Item 408(a) of Regulation S-K).

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

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 *Our Corporate Governance—Proposal 1: Election of Directors* in our definitive proxy statement for our 2026 annual meeting of shareholders currently scheduled for June 26, 2026 (the **2026 Proxy Statement**) is hereby incorporated herein by reference. Information regarding our executive officers appears in *Item 1* of this Report under the heading *Information about our Executive Officers*. Information regarding our Audit Committee and our Audit Committee's financial expert appearing under the heading *Our Corporate Governance—Board Structure and Operations—Board Committees—Audit Committee* in our 2026 Proxy Statement is hereby incorporated herein by reference.

Information appearing under the headings *Delinquent Section 16(a) Reports* and *Insider Trading Policies and Procedures* in our 2026 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.

Former Consultant and Healthcare Executive

Raymond Dwek, C.B.E., F.R.S.

Emeritus Director, Oxford Glycobiology Institute, Oxford University

Richard Giltner

Former Portfolio Manager at Lyxor Asset Management, an asset management group at Société Générale, S.A.

Ray Kurzweil

Chief AI Officer and Co-Founder, Beyond Imagination

Jan Malcolm

Former Commissioner of Health, State of Minnesota

Linda Maxwell, M.D., M.B.A.

Surgeon; Operating Partner, DCVC

Nilda Mesa, J.D.

Adjunct Professor, Columbia University; Former Director, NYC Mayor's Office of Sustainability

Judy D. Olian, Ph.D.

President Emerita, Quinnipiac University

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

Founding Principal, Patusky Associates, LLC

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

Chairperson and Chief Executive Officer of United Therapeutics

Louis Sullivan, M.D.

President Emeritus, Morehouse School of Medicine; Former Secretary, U.S. Department of Health and Human Services

Tommy Thompson, J.D.

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

Kevin J. Tracey, M.D.

President and Chief Executive Officer, The Feinstein Institutes for Medical Research

Item 11. Executive Compensation

Information concerning executive compensation required by Item 11 will appear under the heading *Executive Compensation* in our 2026 Proxy Statement and is incorporated herein by reference.

Information concerning the Compensation Committee required by Item 11 will appear under the heading *Executive Compensation—Compensation Committee Report* in our 2026 Proxy Statement and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information regarding beneficial ownership of our common stock required by Item 12 will appear under *Beneficial Ownership of Common Stock* in our 2026 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, 2025, regarding our securities authorized for issuance under equity compensation plans:

Plan category	Number of securities to be issued upon exercise of outstanding options and RSUs (a)[3]	Weighted average exercise price of outstanding options (b)[4]	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)[5]
Equity compensation plan approved by security holders[1]	6,019,453	$ 166.11	5,518,169
Equity compensation plan not approved by security holders[2]	33,748	–	2,619
Total	**6,053,201**	**$ 166.11**	**5,520,788**

(1) All outstanding stock options were issued under our equity incentive plan approved by security holders in 2015. Except for RSUs issued under the 2019 Inducement Plan discussed below, all outstanding 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 ESPP, which was approved by security holders in 2011. Information regarding these plans is contained in Note 8—*Share-Based Compensation* to our consolidated financial statements.

(2) We have one equity incentive plan, the 2019 Inducement Plan, that has not been approved by our shareholders, as permitted by the Nasdaq Stock Market rules. The 2019 Inducement Plan was approved by our Board of Directors in February 2019 and provides for the issuance of up to 99,000 shares of our common stock in the aggregate under awards granted to newly-hired employees. Information regarding this plan is contained in Note 8—*Share-Based Compensation* to our consolidated financial statements.

(3) Column (a) includes 4,636,330 shares of our common stock issuable upon the exercise of outstanding stock options issued under the 2015 Plan; 1,383,123 shares issuable upon the vesting of outstanding RSUs issued under the 2015 Plan; and 33,748 shares issuable upon the vesting of outstanding RSUs issued under the 2019 Inducement Plan. The number under column (a) represents the actual number of shares issuable under our outstanding awards without giving effect to the share counting formula described below in footnote 5.

(4) 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.

(5) Column (c) includes 3,086,374, 2,431,795, and 2,619 of shares available for future issuance under the 2015 Plan, the ESPP, and the 2019 Inducement Plan, respectively. Under the ESPP, employees may purchase shares based upon a six-month offering period at an amount 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. See Note 8—*Share-Based Compensation—ESPP* for more information. The 2015 Plan and 2019 Inducement Plan use a share counting formula for determining the number of shares available for issuance under the plans. In accordance with this formula, each RSU granted prior to March 17, 2020 under the 2015 Plan and each RSU granted under the 2019 Inducement Plan depletes the number of shares available for future issuance by 2.14 shares, while each RSU granted on or after March 17, 2020 under the 2015 Plan depletes the number of shares available for future issuance by 1.35 shares. Therefore, if any RSU does not vest, the number of shares available for future issuance will increase by 1.35 and 2.14 under the 2015 Plan and 2019 Inducement Plan, respectively, because of the share counting formula described above. Each stock option granted under the 2015 Plan depletes the number of shares available for future issuance by one share and does not use the share counting formula described 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, Our Corporate Governance–Board Composition and Refreshment–Director Nomination Process–Director Independence, and Our Corporate Governance–Board Structure and Operations–Board Committees* in our 2026 Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accountant 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 *Audit Matters* in our 2026 Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. Exhibits and 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 facts or disclose any other 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 our 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, 1000 Spring Street, Silver Spring, Maryland 20910.

Exhibit Index

Exhibit No.	Description
2.1*	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	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 October 1, 2021.
3.2	Eleventh Amended and Restated Bylaws of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed January 22, 2026.

Exhibit No.	Description
4.1	Reference is made to Exhibits 3.1 and 3.2.
4.2	Description of Securities Registered under Section 12 of the Exchange Act, incorporated by reference to Exhibit 4.2 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2023.
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 Current Report on Form 8-K filed October 1, 2021.
10.2**	Amended and Restated Executive Employment Agreement dated as of January 1, 2009, between the Registrant and Martine 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.
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 Supplemental Executive Retirement Plan, effective as of July 1, 2006, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on May 4, 2006.
10.16	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.
10.17	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.
10.18**	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.
10.19**	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 June 27, 2025.

Exhibit No.	Description
10.20**	Form of Grant Notice and Standard Terms and Conditions for Non-Qualified Stock Options Granted to Non-Employee Directors prior to 2025 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 June 29, 2015.
10.21**	Form of Grant Notice and Standard Terms and Conditions for Non Qualified Stock Options Granted to Non-Employee Directors in 2025 and thereafter under the United Therapeutics Corporation 2015 Stock Incentive Plan, incorporated by reference to Exhibit 10.28 of the Registrant's Annual Report on Form 10-K for the year ended December 31, 2024.
10.22**	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 June 29, 2015.
10.23**	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 June 29, 2015.
10.24**	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.
10.25**	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, 2016.
10.26**	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.
10.27**	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), incorporated by reference to Exhibit 10.45 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2018.
10.28**	Form of Grant Notice and Standard Terms and Conditions for Stock Options Granted to Employees (Performance Vesting) under the United Therapeutics Corporation Amended and Restated 2015 Stock Incentive Plan (applicable to performance-based stock options granted on or after March 15, 2023), incorporated by reference to Exhibit 10.37 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2022.
10.29**	Form of Grant Notice and Standard Terms and Conditions for Restricted Stock Units Granted to Employees (Performance Vesting) under the United Therapeutics Corporation Amended and Restated 2015 Stock Incentive Plan (applicable to performance-based restricted stock units granted on or after March 15, 2023), incorporated by reference to Exhibit 10.38 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2022.
10.30**	United Therapeutics Corporation 2019 Inducement Stock Incentive Plan, incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed March 1, 2019.
10.31**	Form of Restricted Stock Unit Grant Notice and Terms and Conditions under the 2019 Inducement Stock Incentive Plan, incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed March 1, 2019.
10.32*	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 Annual Report on Form 10-K for the year ended December 31, 2017.
10.33	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, incorporated by reference to Exhibit 10.47 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2018.
10.34	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, incorporated by reference to Exhibit 10.48 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2018.
10.35*	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, incorporated by reference to Exhibit 10.49 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2018.

Exhibit No.	Description
10.36+	Fourth Amendment to Wholesale Product Purchase Agreement, dated as of September 18, 2019, by and between Priority Healthcare Distribution, Inc., doing business as CuraScript SD Specialty Distribution, and the Registrant, incorporated by reference to Exhibit 10.52 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2019.
10.37+	Fifth Amendment to Wholesale Product Purchase Agreement, dated as of November 13, 2019, by and between Priority Healthcare Distribution, Inc., doing business as CuraScript SD Specialty Distribution, and the Registrant, incorporated by reference to Exhibit 10.59 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2019.
10.38+	Sixth Amendment to Wholesale Product Purchase Agreement, dated as of March 1, 2020, by and between Priority Healthcare Distribution, Inc., doing business as CuraScript SD Specialty Distribution, and the Registrant, incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended March 31, 2020.
10.39+	Seventh Amendment to Wholesale Product Purchase Agreement, dated as of May 12, 2020, by and between Priority Healthcare Distribution, Inc., doing business as CuraScript SD Specialty Distribution, and the Registrant, incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended June 30, 2020.
10.40	Eighth Amendment to Wholesale Product Purchase Agreement, dated as of May 13, 2020, by and between Priority Healthcare Distribution, Inc., doing business as CuraScript SD Specialty Distribution, and the Registrant, incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended June 30, 2020.
10.41	Ninth Amendment to Wholesale Product Purchase Agreement, dated as of October 6, 2021, by and between Priority Healthcare Distribution, Inc., doing business as CuraScript SD Specialty Distribution, and the Registrant, incorporated by reference to Exhibit 10.57 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2021.
10.42	Tenth Amendment to Wholesale Product Purchase Agreement, dated as of January 19, 2023, by and between Priority Healthcare Distribution, Inc., doing business as CuraScript SD Specialty Distribution, and the Registrant, incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended March 31, 2023.
10.43+	Eleventh Amendment to Wholesale Product Purchase Agreement, dated as of November 3, 2023, by and between Priority Healthcare Distribution, Inc., doing business as CuraScript SD Specialty Distribution, and the Registrant, incorporated by reference to Exhibit 10.52 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2023.
10.44	Twelfth Amendment to Wholesale Product Purchase Agreement, dated as of June 20, 2024, by and between Priority Healthcare Distribution, Inc., doing business as CuraScript SD Specialty Distribution, and the Registrant., incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2024.
10.45+†	Thirteenth Amendment to Wholesale Product Purchase Agreement, dated as of April 17, 2025, by and between Priority Healthcare Distribution, Inc., doing business as CuraScript SD Specialty Distribution, and the Registrant.
10.46+†	Fourteenth Amendment to Wholesale Product Purchase Agreement, dated as of October 31, 2025, by and between Priority Healthcare Distribution, Inc., doing business as CuraScript SD Specialty Distribution, and the Registrant.
10.47	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 Annual Report on Form 10-K for the year ended December 31, 2017.
10.48	First Amendment to Specialty Pharmacy Network Agreement, dated as of February 16, 2022, between the Registrant and Accredo Health Group, Inc., incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2022.
10.49	Second Amendment to Specialty Pharmacy Network Agreement, dated as of June 13, 2022, between the Registrant and Accredo Health Group, Inc., incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2022.
10.50	Third Amendment to Specialty Pharmacy Network Agreement, dated as of February 14, 2023, between the Registrant and Accredo Health Group, Inc., incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023.
10.51	Fourth Amendment to Specialty Pharmacy Network Agreement, dated as of May 15, 2023, between the Registrant and Accredo Health Group, Inc., incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2023.
10.52	Fifth Amendment to Specialty Pharmacy Network Agreement, dated as of August 2, 2023, between the Registrant and Accredo Health Group, Inc., incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023.

Exhibit No.	Description
10.53	Sixth Amendment to Specialty Pharmacy Network Agreement, dated as of November 7, 2023, between the Registrant and Accredo Health Group, Inc., incorporated by reference to Exhibit 10.59 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2023.
10.54	Seventh Amendment to Specialty Pharmacy Network Agreement, dated as of June 7, 2024, between the Registrant and Accredo Health Group, Inc., incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2024.
10.55	Eighth Amendment to Specialty Pharmacy Network Agreement, dated as of April 11, 2025, between the Registrant and Accredo Health Group, Inc., incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2025.
10.56+†	Ninth Amendment to Specialty Pharmacy Network Agreement, dated as of November 13, 2025, between the Registrant and Accredo Health Group, Inc.
10.57	Credit Agreement, dated as of April 25, 2025, among the Registrant, the lenders referred to therein, and Wells Fargo Bank, National Association, as administrative agent and as a swingline lender, incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on April 28, 2025.
10.58+	License and Collaboration Agreement, dated as of September 3, 2018, by and between the Registrant and MannKind Corporation, incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended June 30, 2022.
10.59+	First Amendment to License and Collaboration Agreement, dated August 24, 2025 between the Registrant and MannKind Corporation, incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended September 30, 2025.
19	Insider Trading Policy, incorporated by reference to Exhibit 19 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2024.
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.
97	United Therapeutics Corporation Clawback Policy, incorporated by reference to Exhibit 97 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2023.
101†	The following financial information from our Annual Report on Form 10-K for the year ended December 31, 2025, filed with the SEC on February 25, 2026, formatted in Inline Extensible Business Reporting Language (iXBRL): (1) our Consolidated Balance Sheets as of December 31, 2025 and 2024, (2) our Consolidated Statements of Operations for each of three years in the period ended December 31, 2025, (3) our Consolidated Statements of Comprehensive Income for each of the three years in the period ended December 31, 2025, (4) our Consolidated Statements of Stockholders' Equity for each of the three years in the period ended December 31, 2025, (5) our Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2025, and (6) the Notes to our Consolidated Financial Statements.
104†	Cover Page Interactive Data File (embedded within the iXBRL document)

\+ Certain identified information has been omitted from this exhibit because it is both (1) not material and (2) would be competitively harmful if publicly disclosed.

* Confidential treatment has been requested 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.

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 ROTHBLATT

Martine Rothblatt, Ph.D.
Chairperson and Chief Executive Officer

February 25, 2026

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 ROTHBLATT Martine Rothblatt	Chairperson, Chief Executive Officer, and Director (Principal Executive Officer)	February 25, 2026
/s/ JAMES C. EDGEMOND James C. Edgemond	Chief Financial Officer and Treasurer (Principal Financial Officer and Principal Accounting Officer)	February 25, 2026
/s/ CHRISTOPHER CAUSEY Christopher Causey	Director	February 25, 2026
/s/ RAYMOND DWEK Raymond Dwek	Director	February 25, 2026
/s/ RICHARD GILTNER Richard Giltner	Director	February 25, 2026
/s/ RAYMOND KURZWEIL Raymond Kurzweil	Director	February 25, 2026
/s/ JAN MALCOLM Jan Malcolm	Director	February 25, 2026
/s/ LINDA MAXWELL Linda Maxwell	Director	February 25, 2026
/s/ NILDA MESA Nilda Mesa	Director	February 25, 2026
/s/ JUDY D. OLIAN Judy D. Olian	Director	February 25, 2026
/s/ CHRISTOPHER PATUSKY Christopher Patusky	Director	February 25, 2026
/s/ LOUIS W. SULLIVAN Louis W. Sullivan	Director	February 25, 2026
/s/ TOMMY G. THOMPSON Tommy Thompson	Director	February 25, 2026