UNITED THERAPEUTICS CORP

FORM 10-Q
(Quarterly Report)

Filed 04/30/25 for the Period Ending 03/31/25

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Telephone	3016089292
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SIC Code	2834 - Pharmaceutical Preparations
Industry	Pharmaceuticals
Sector	Healthcare
Fiscal Year	12/31

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 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)

(Former Name, Former Address and Former Fiscal Year, If Changed Since Last Report)
Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of exchange on which registered
Common Stock, par value $0.01 per share	UTHR	Nasdaq Global Select Market

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The number of shares outstanding of the issuer's common stock, par value $.01 per share, as of April 23, 2025 was 45,106,623.

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PART I. FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements

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

	March 31, 2025	December 31, 2024
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 1,899.9	$ 1,697.2
Marketable investments	1,421.4	1,569.8
Accounts receivable, no allowance for 2025 and 2024	322.0	279.3
Inventories, net	165.4	157.9
Other current assets	131.1	169.7
Total current assets	3,939.8	3,873.9
Marketable investments	1,710.7	1,475.3
Goodwill and other intangible assets, net	111.7	111.9
Property, plant, and equipment, net	1,302.7	1,222.4
Deferred tax assets, net	456.6	458.4
Other non-current assets	222.4	222.1
Total assets	$ 7,743.9	$ 7,364.0
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 367.0	$ 344.5
Line of credit	200.0	300.0
Other current liabilities	154.5	93.6
Total current liabilities	721.5	738.1
Other non-current liabilities	215.2	181.9
Total liabilities	936.7	920.0
Commitments and contingencies		
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, 75,241,141 and 74,997,896 shares issued, and 45,074,551 and 44,831,306 shares outstanding as of March 31, 2025 and December 31, 2024, respectively	0.8	0.8
Additional paid-in capital	2,737.7	2,698.9
Accumulated other comprehensive loss	(1.2)	(3.4)
Treasury stock, 30,166,590 shares as of March 31, 2025 and December 31, 2024, respectively	(3,474.5)	(3,474.5)
Retained earnings	7,544.4	7,222.2
Total stockholders' equity	6,807.2	6,444.0
Total liabilities and stockholders' equity	$ 7,743.9	$ 7,364.0

See accompanying notes to consolidated financial statements.

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

	Three Months Ended March 31,	
	2025	2024
	(Unaudited)	
Total revenues	$ 794.4	$ 677.7
Operating expenses:		
Cost of sales	92.5	72.9
Research and development	149.0	104.1
Selling, general, and administrative	170.1	144.4
Total operating expenses	411.6	321.4
Operating income	382.8	356.3
Interest income	51.1	53.8
Interest expense	(6.1)	(13.3)
Other (expense) income, net	(4.3)	1.8
Total other income, net	40.7	42.3
Income before income taxes	423.5	398.6
Income tax expense	(101.3)	(92.0)
Net income	$ 322.2	$ 306.6
Net income per common share:		
Basic	$ 7.18	$ 6.52
Diluted	$ 6.63	$ 6.17
Weighted average number of common shares outstanding:		
Basic	44.9	47.0
Diluted	48.6	49.7

See accompanying notes to consolidated financial statements.

Consolidated Statements of Comprehensive Income
(In millions)

	Three Months Ended March 31,	
	2025	2024
	(Unaudited)	
Net income	$ 322.2	$ 306.6
Other comprehensive income (loss):		
Foreign currency translation loss included in net income	—	2.4
Defined benefit pension plan:		
Actuarial loss arising during period, net of tax	(2.8)	(0.5)
Actuarial gain and prior service cost included in net periodic pension cost, net of tax	(0.4)	(1.2)
Total defined benefit pension plan, net of tax	(3.2)	(1.7)
Available-for-sale debt securities:		
Unrealized gain (loss) arising during period, net of tax	5.4	(4.6)
Realized loss included in net income, net of tax	—	1.1
Total gain (loss) on available-for-sale debt securities, net of tax	5.4	(3.5)
Other comprehensive income (loss), net of tax	2.2	(2.8)
Comprehensive income	$ 324.4	$ 303.8

During the three months ended March 31, 2025 and 2024, the tax (benefit) expense in other comprehensive income was zero and $(0.1) million, respectively, for the defined benefit pension plan and $1.7 million and $(1.2) million, respectively, for the available-for-sale debt securities.

See accompanying notes to consolidated financial statements.

Consolidated Statements of Stockholders' Equity
(In millions)

	Three Months Ended March 31, 2025 (Unaudited)						
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Treasury Stock	Retained Earnings	Stockholders' Equity
	Shares	Amount					
Balance, January 1, 2025	75.0	$ 0.8	$ 2,698.9	$ (3.4)	$ (3,474.5)	$ 7,222.2	$ 6,444.0
Net income	—	—	—	—	—	322.2	322.2
Other comprehensive income, net of tax	—	—	—	2.2	—	—	2.2
Shares issued under employee stock purchase plan (**ESPP**)	—	—	4.9	—	—	—	4.9
Restricted stock units (**RSUs**) withheld for taxes	—	—	(15.3)	—	—	—	(15.3)
Common stock issued for RSUs vested	0.1	—	—	—	—	—	—
Exercise of stock options	0.1	—	16.6	—	—	—	16.6
Share-based compensation	—	—	32.6	—	—	—	32.6
Balance, March 31, 2025	75.2	$ 0.8	$ 2,737.7	$ (1.2)	$ (3,474.5)	$ 7,544.4	$ 6,807.2

	Three Months Ended March 31, 2024 (Unaudited)						
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Treasury Stock	Retained Earnings	Stockholders' Equity
	Shares	Amount					
Balance, January 1, 2024	73.7	$ 0.7	$ 2,549.0	$ (12.8)	$ (2,579.2)	$ 6,027.1	$ 5,984.8
Net income	—	—	—	—	—	306.6	306.6
Other comprehensive loss, net of tax	—	—	—	(2.8)	—	—	(2.8)
Shares issued under ESPP	—	—	3.9	—	—	—	3.9
RSUs withheld for taxes	—	—	(11.4)	—	—	—	(11.4)
Share repurchase	—	—	(200.0)	—	(800.0)	—	(1,000.0)
Excise tax on net share repurchase	—	—	—	—	(6.9)	—	(6.9)
Common stock issued for RSUs vested	0.1	—	—	—	—	—	—
Exercise of stock options	0.3	—	42.2	—	—	—	42.2
Share-based compensation	—	—	21.7	—	—	—	21.7
Balance, March 31, 2024	74.1	$ 0.7	$ 2,405.4	$ (15.6)	$ (3,386.1)	$ 6,333.7	$ 5,338.1

See accompanying notes to consolidated financial statements.

Consolidated Statements of Cash Flows
(In millions)

	Three Months Ended March 31,	
	2025	2024
	(Unaudited)	
Cash flows from operating activities:		
Net income	$ 322.2	$ 306.6
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	19.8	15.0
Share-based compensation expense	31.8	25.6
Other	9.4	(10.5)
Changes in operating assets and liabilities:		
Accounts receivable	(42.7)	(28.3)
Inventories	(11.2)	(9.3)
Accounts payable and accrued expenses	(2.6)	1.9
Other assets and liabilities	134.5	75.5
Net cash provided by operating activities	461.2	376.5
Cash flows from investing activities:		
Purchases of property, plant, and equipment	(74.9)	(38.2)
Deposits	(9.2)	(4.3)
Purchases of available-for-sale debt securities	(692.3)	(529.3)
Maturities of available-for-sale debt securities	611.7	475.3
Sales of available-for-sale debt securities	—	831.8
Net cash (used in) provided by investing activities	(164.7)	735.3
Cash flows from financing activities:		
Payments to repurchase common stock	—	(1,000.0)
Repayment of line of credit	(100.0)	(100.0)
Payments of debt issuance costs	—	(2.7)
Proceeds from the exercise of stock options	16.6	42.2
Proceeds from the issuance of stock under ESPP	4.9	3.9
RSUs withheld for taxes	(15.3)	(11.4)
Net cash used in financing activities	(93.8)	(1,068.0)
Net increase in cash and cash equivalents	$ 202.7	$ 43.8
Cash and cash equivalents, beginning of period	1,697.2	1,207.7
Cash and cash equivalents, end of period	$ 1,899.9	$ 1,251.5
Supplemental cash flow information:		
Cash paid for interest	$ 5.4	$ 12.6
Cash paid for income taxes	$ 0.5	$ 4.7
Non-cash investing and financing activities:		
Non-cash additions to property, plant, and equipment	$ 47.2	$ 23.6
Measurement period adjustment to purchase price	$ —	$ 1.4
Excise tax on net share repurchase	$ —	$ 6.9

See accompanying notes to consolidated financial statements.

Notes to Consolidated Financial Statements
March 31, 2025 (Unaudited)

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. Basis of Presentation

The accompanying unaudited consolidated financial statements have been prepared in accordance with the rules and regulations of the U.S. Securities and Exchange Commission (**SEC**) for interim financial information. Accordingly, they do not include all of the information required by U.S. generally accepted accounting principles for complete financial statements. These consolidated financial statements should be read in conjunction with our audited consolidated financial statements and the accompanying notes to our consolidated financial statements contained in our Annual Report on Form 10-K for the year ended December 31, 2024, as filed with the SEC on February 26, 2025.

In our management's opinion, the accompanying consolidated financial statements contain all adjustments, including normal, recurring adjustments, necessary to fairly present our financial position as of March 31, 2025 and December 31, 2024, and our statements of operations, comprehensive income, stockholders' equity, and cash flows for the three-month periods ended March 31, 2025 and 2024. Interim results are not necessarily indicative of results for an entire year. Certain prior year amounts have been reclassified to conform to the current year presentation. In the consolidated balance sheets, we reclassified the prior year amount within *share tracking awards plan* to *other current liabilities* to conform with the current period presentation.

Recently Issued Accounting Standards

Accounting Standards Adopted During the Period

None.

Accounting Standards Not Yet 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 the Company's Annual Report on Form 10-K for the year ended December 31, 2025. The adoption of ASU 2023-09 will expand our income tax disclosures, but will have no impact on reported income tax expense or related tax assets or liabilities.

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.

3. 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 loss* in stockholders' equity, until realized. Available-for-sale debt securities consisted of the following (in millions):

As of March 31, 2025	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. government and agency securities	$ 2,681.0	$ 6.8	$ (1.1)	$ 2,686.7
Corporate debt securities	586.8	2.5	(0.1)	589.2
Total	$ 3,267.8	$ 9.3	$ (1.2)	$ 3,275.9

Reported under the following captions in our consolidated balance sheets:

Cash and cash equivalents	$ 162.4
Current marketable investments	1,402.8
Non-current marketable investments	1,710.7
Total	$ 3,275.9

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 March 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 March 31, 2025	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
U.S. government and agency securities	$ 708.6	$ (1.0)	$ 146.5	$ (0.1)	$ 855.1	$ (1.1)
Corporate debt securities	48.9	(0.1)	22.0	—	70.9	(0.1)
Total	$ 757.5	$ (1.1)	$ 168.5	$ (0.1)	$ 926.0	$ (1.2)

	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 March 31, 2025 and December 31, 2024, we held 181 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 March 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 three months ended March 31, 2025 and 2024.

During the first quarter of 2024, we sold certain available-for-sale debt securities prior to maturity to fund the repurchase of our common stock. See Note 9—*Stockholders' Equity—Share Repurchase* for further information. As a result of the sale, we received $831.8 million in proceeds and recognized gross realized gains of $0.4 million and gross realized losses of $1.8 million. The net realized loss of $1.4 million is included in *other (expense) income, net* in our consolidated statements of operations.

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 March 31, 2025	
	Amortized Cost	Fair Value
Due within one year	$ 1,564.5	$ 1,565.2
Due in one to three years	1,703.3	1,710.7
Total	$ 3,267.8	$ 3,275.9

Investments in Equity Securities with Readily Determinable Fair Values

We held investments in equity securities with readily determinable fair values, in the aggregate, of $18.6 million and $23.9 million as of March 31, 2025 and December 31, 2024, respectively, which are included in *current marketable investments* in our consolidated balance sheets. Changes in the fair value of publicly-traded equity securities are recorded in our consolidated statements of operations within *other (expense) income, net*. See Note 4—*Fair Value Measurements*.

Investments in Privately-Held Companies

As of March 31, 2025 and December 31, 2024, we maintained non-controlling equity investments in privately-held companies of $59.0 million in the aggregate. We measure these investments using the measurement alternative because the fair values of these investments are not readily determinable. Under this alternative, the investments are measured at cost, less any impairment, and adjusted for any observable price changes. 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 ASC 820, *Fair Value Measurements*.

4. Fair Value Measurements

We account for certain assets and liabilities at fair value and classify these assets and liabilities within the fair value hierarchy (Level 1, Level 2, or Level 3). 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 March 31, 2025			
	Level 1	Level 2	Level 3	Balance
Assets				
Money market funds[1]	$ 836.5	$ —	$ —	$ 836.5
Time deposits[1]	196.9	—	—	196.9
U.S. government and agency securities[2]	—	2,686.7	—	2,686.7
Corporate debt securities[2]	—	589.2	—	589.2
Equity securities[3]	18.6	—	—	18.6
Total assets	$ 1,052.0	$ 3,275.9	$ —	$ 4,327.9
Liabilities				
Contingent consideration[4]	—	—	28.8	28.8
Total liabilities	$ —	$ —	$ 28.8	$ 28.8

	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 3—*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 three months ended March 31, 2025, and March 31, 2024 we recognized $5.3 million of net unrealized losses and $5.6 million of net unrealized gains, respectively, on these securities. We recorded these gains and losses in our consolidated statements of operations within *other (expense) income, net*. See Note 3—*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 $4.1 million during the period from December 31, 2024 to March 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 3—*Investments*. The carrying value of our debt is a reasonable estimate of the fair value of the outstanding debt based on the variable interest rate of the debt.

5. 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):

	March 31, 2025	December 31, 2024
Raw materials	$ 34.1	$ 28.6
Work-in-progress	34.3	34.3
Finished goods	97.0	95.0
Total inventories	$ 165.4	$ 157.9

6. Property, Plant, and Equipment

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

	March 31, 2025	December 31, 2024
Land and land improvements	$ 192.5	$ 181.9
Buildings, building improvements, and leasehold improvements	869.3	863.8
Buildings under construction	276.8	218.2
Furniture, equipment, and vehicles	474.8	449.7
Subtotal	1,813.4	1,713.6
Less—accumulated depreciation	(510.7)	(491.2)
Property, plant, and equipment, net	$ 1,302.7	$ 1,222.4

Depreciation expense for the three months ended March 31, 2025 and 2024 was $19.6 million and $14.8 million, respectively.

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*.

The aggregate balance of $200.0 million under our 2025 Credit Agreement remained outstanding as of April 30, 2025.

The 2025 Credit Agreement contains customary events of default and customary affirmative and negative covenants. As of April 30, 2025, we were in compliance with these covenants.

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, providing 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 three months ended March 31, 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. We classified all

$200.0 million of the outstanding balance as a current liability in our consolidated balance sheet as of March 31, 2025, as we intended to repay this amount within one year.

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.

The 2022 Credit Agreement contained customary events of default and customary affirmative and negative covenants. As of March 31, 2025, we were in compliance with these covenants.

The interest expense reported in our consolidated statements of operations for the three months ended March 31, 2025 and 2024 relates to our borrowings under the 2022 Credit Agreement.

8. Share-Based Compensation

As of March 31, 2025, we have one shareholder-approved equity incentive plan: the United Therapeutics Corporation Amended and Restated 2015 Stock Incentive Plan (the **2015 Plan**). The 2015 Plan provides for the issuance of up to 13,820,000 shares of our common stock pursuant to awards granted under the 2015 Plan. 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 three months ended March 31, 2025 and 2024, 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 and 2026, respectively. Additionally, during the three months ended March 31, 2025 we issued RSUs to certain 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 United Therapeutics Corporation 2011 Share Tracking Awards Plan (the **STAP**). We discontinued the issuance of STAP awards in June 2015 and all remaining outstanding STAP awards were exercised during the three months ended March 31, 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):

	Three Months Ended March 31,	
	2025	**2024**
Stock options	$ 8.5	$ 5.7
RSUs	23.4	15.5
STAP awards	(0.8)	3.9
ESPP	0.7	0.5
Total share-based compensation expense before tax	$ 31.8	$ 25.6

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 three months ended March 31, 2025 and 2024, in addition to time-based stock options, we granted 0.3 million and 0.5 million performance-based stock options with a total grant date fair value of $38.0 million and $50.2 million, respectively, in each case calculated based on the assumed achievement of maximum performance of the relevant financial performance condition. During the three months ended March 31, 2025 and 2024 we recorded $7.7 million and $4.8 million, respectively, of share-based compensation expense, respectively, related to performance-based stock options, calculated based on the assumed levels of performance achievement.

The following weighted average assumptions were used in estimating the fair value of stock options granted to employees during the three months ended March 31, 2025 and 2024:

	March 31, 2025	March 31, 2024
Expected term of awards (in years)	5.0	6.5
Expected volatility	32.2 %	31.6 %
Risk-free interest rate	4.1 %	4.3 %
Expected dividend yield	0.0 %	0.0 %

A summary of the activity and status of stock options under our equity incentive plans during the three-month period ended March 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	353,966	307.24		
Exercised	(131,474)	126.91		
Forfeited	—	—		
Outstanding as of March 31, 2025	5,794,037	$ 158.80	3.6	$ 866.5
Exercisable as of March 31, 2025	4,476,271	$ 131.81	2.2	$ 789.9
Unvested as of March 31, 2025	1,317,766	$ 250.48	8.1	$ 76.6

The weighted average fair value of a stock option granted during each of the three-month periods ended March 31, 2025 and March 31, 2024 was $110.11 and $97.18, respectively. These stock options have an aggregate grant date fair value of $39.0 million and $51.9 million, respectively. The total grant date fair value of stock options that vested during the three-month periods ended March 31, 2025 and March 31, 2024 was $1.2 million and $0.9 million, respectively.

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

	Three Months Ended March 31,	
	2025	2024
Cost of sales	$ —	$ —
Research and development	0.1	0.1
Selling, general, and administrative	8.4	5.6
Share-based compensation expense before taxes	8.5	5.7
Related income tax benefit	(0.2)	(0.2)
Share-based compensation expense, net of taxes	$ 8.3	$ 5.5

As of March 31, 2025, unrecognized compensation cost related to stock options was $84.4 million. Unvested outstanding stock options as of March 31, 2025 had a weighted average remaining vesting period of 2.3 years.

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

	Three Months Ended March 31,	
	2025	2024
Number of options exercised	131,474	327,267
Cash received	$ 16.6	$ 42.2
Total intrinsic value of options exercised	$ 29.1	$ 35.7

RSUs

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 three-months periods ended March 31, 2025 and 2024, in addition to time-based RSUs, we granted 0.1 million and 0.2 million performance-based RSUs to certain executives with a total grant date fair value of $38.0 million and $47.5 million, respectively, calculated based on the assumed achievement of maximum performance of the relevant financial and non-financial performance conditions. Additionally, during the three months ended March 31, 2025, in addition to time-based RSUs, we granted 0.1 million performance-based RSUs to certain 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 three months ended March 31, 2025 and 2024, we recorded $8.3 million and $2.1 million, respectively, of share-based compensation expense 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 three-month period ended March 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	364,948	325.72
Vested	(143,012)	212.66
Forfeited	(4,113)	263.17
Unvested as of March 31, 2025	1,437,477	$ 252.03

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

	Three Months Ended March 31,	
	2025	2024
Cost of sales	$ 1.0	$ 0.9
Research and development	6.7	5.6
Selling, general, and administrative	15.7	9.0
Share-based compensation expense before taxes	23.4	15.5
Related income tax benefit	(3.8)	(3.3)
Share-based compensation expense, net of taxes	$ 19.6	$ 12.2

As of March 31, 2025, unrecognized compensation cost related to the grant of RSUs was $236.1 million. Unvested outstanding RSUs as of March 31, 2025 had a weighted average remaining vesting period of 2.6 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 three months ended March 31, 2025.

The aggregate liability balance associated with outstanding STAP awards was zero and $11.0 million as of March 31, 2025 and December 31, 2024, respectively, all of which was classified as a current liability in our consolidated balance sheets.

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

	Three Months Ended March 31,	
	2025	2024
Cost of sales	$ (0.1)	$ 0.2
Research and development	(0.2)	0.5
Selling, general, and administrative	(0.5)	3.2
Share-based compensation (benefit) expense before taxes	(0.8)	3.9
Related income tax expense (benefit)	0.2	(0.8)
Share-based compensation (benefit) expense, net of taxes	$ (0.6)	$ 3.1

Cash paid to settle STAP awards exercised during the three-month periods ended March 31, 2025 and March 31, 2024 was $10.2 million and $10.1 million, respectively.

ESPP

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. 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 expires in June 2032 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 current offering period were issued.

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

	Three Months Ended March 31,	
	2025	2024
Numerator:		
Net income	$ 322.2	$ 306.6
Denominator:		
Weighted average outstanding shares — basic	44.9	47.0
Effect of dilutive securities[1]:		
Stock options, RSUs, and ESPP[2]	3.7	2.7
Weighted average shares — diluted[2]	48.6	49.7
Net income per common share:		
Basic	$ 7.18	$ 6.52
Diluted	$ 6.63	$ 6.17
Stock options and RSUs excluded from calculation[2]	0.1	0.7

(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.

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 **ASR agreement**) with Citibank, N.A. (**Citi**) on March 25, 2024, to repurchase approximately $1.0 billion of our common stock. Under the 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 ASR agreement, measured based on the closing price of our common stock on March 25, 2024.

The share repurchase under the 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 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 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 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 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. As of March 31, 2025, a liability of $5.0 million was recorded for an excise tax imposed under the Inflation Reduction Act as a result of our repurchase of shares under the ASR agreement.

10. Income Taxes

Our effective income tax rate (**ETR**) for the three months ended March 31, 2025 and 2024 was 24 percent and 23 percent, respectively. Our ETR for the three months ended March 31, 2025 increased compared to our ETR for the three months ended March 31, 2024 primarily due to decreased excess tax benefits from share-based compensation.

We record interest and penalties related to uncertain tax positions as a component of income tax expense. As of March 31, 2025 and December 31, 2024, our unrecognized tax benefits, including related interest, were approximately $23.2 million and $20.6 million, respectively. The total amount of unrecognized tax benefits relating to our tax positions as of March 31, 2025 is subject to change based on future events and it is reasonably possible that the balance could change significantly over the next 12 months. Given the uncertainty of future events, we are unable to reasonably estimate the range of possible adjustments to our unrecognized tax benefits.

11. 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* to our consolidated financial statements contained in our Annual Report on Form 10-K for the year ended December 31, 2024, as filed with the SEC on February 26, 2025.

Our CODM is regularly provided with revenue and expense forecasts, including product development plans, to manage the operations of our operating segment. Our CODM compares 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's 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 were as follows (in millions):

	Three Months Ended March 31,							
2025	**Tyvaso DPI[1]**	**Nebulized Tyvaso[1]**	**Remodulin[2]**	**Orenitram**	**Unituxin**	**Adcirca**	**Other**	**Total**
Total revenues	$ 302.5	$ 163.8	$ 138.2	$ 120.7	$ 58.2	$ 6.0	$ 5.0	$ 794.4
Cost of sales	48.1	8.5	13.8	8.3	5.2	2.6	6.0	92.5
Gross profit (loss)	$ 254.4	$ 155.3	$ 124.4	$ 112.4	$ 53.0	$ 3.4	$ (1.0)	$ 701.9
2024								
Total revenues	$ 227.5	$ 145.0	$ 128.0	$ 106.2	$ 58.4	$ 6.4	$ 6.2	$ 677.7
Cost of sales	33.3	8.9	7.9	9.2	3.6	2.6	7.4	72.9
Gross profit (loss)	$ 194.2	$ 136.1	$ 120.1	$ 97.0	$ 54.8	$ 3.8	$ (1.2)	$ 604.8

(1) Total revenues and cost of sales include both the drug product and the respective inhalation device.

(2) Total revenues and cost of sales include sales of infusion devices, including the Remunity Pump.

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):

	Three Months Ended March 31,					
	2025			**2024**		
	U.S.	**ROW**	**Total**	**U.S.**	**ROW**	**Total**
Net product sales:						
Tyvaso DPI[1]	$ 302.5	$ —	$ 302.5	$ 227.5	$ —	$ 227.5
Nebulized Tyvaso[1]	138.6	25.2	163.8	133.7	11.3	145.0
Total Tyvaso	441.1	25.2	466.3	361.2	11.3	372.5
Remodulin[2]	120.2	18.0	138.2	108.3	19.7	128.0
Orenitram	120.7	—	120.7	106.2	—	106.2
Unituxin	56.9	1.3	58.2	53.4	5.0	58.4
Adcirca	6.0	—	6.0	6.4	—	6.4
Other	4.7	0.3	5.0	6.0	0.2	6.2
Total revenues	$ 749.6	$ 44.8	$ 794.4	$ 641.5	$ 36.2	$ 677.7

(1) Net product sales include both the drug product and the respective inhalation device.

(2) Net product sales include sales of infusion devices, including the Remunity Pump.

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:

	Three Months Ended March 31,	
	2025	**2024**
Distributor 1	52 %	51 %
Distributor 2	34 %	34 %

12. 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. RareGen has no claim for breach of contract and, as a result, has no remaining claims in the litigation. 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 April 29, 2024, and the court heard closing arguments on June 4, 2024. The trial was limited to determining the amount of damages under the breach of contract claim. The court issued an opinion on September 6, 2024, but did not determine the amount of damages with specificity. The court directed the parties to confer about the amount of damages based on the opinion and submit a proposed judgment with an amount of damages based on the factual findings in the opinion. On October 7, 2024, the parties submitted to the court their respective positions on damages. 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 have appealed the final judgment, including the court's March 30, 2022 summary judgment decision.

We accrued a liability of $71.1 million during 2024, and an additional $0.7 million through the first 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 March 31, 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 has tentative approval from the FDA to market Yutrepia to treat PAH and PH-ILD following expiration of FDA-conferred exclusivity on May 23, 2025.

We have one 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 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. This case is pending, and trial is set for June 2025.

In June 2021, we filed a motion in one of our 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 employee, 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 is pending. We commenced a separate, related

case against Liquidia and Dr. Roscigno in North Carolina state court on May 9, 2024, and filed a complaint in this case including a claim for breach of contract on May 29, 2024.

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 plan to continue to vigorously enforce our intellectual property rights related to Tyvaso DPI and nebulized Tyvaso. In addition, we intend to vigorously defend ourselves against the claims made by Liquidia in its patent infringement lawsuit against us, which we believe is without merit.

FDA Litigation Regarding Yutrepia

On February 20, 2024, we filed an action against the FDA in the U.S. District Court for the District of Columbia regarding the FDA's review of Liquidia's efforts to obtain a PH-ILD indication for its Yutrepia product. Liquidia had previously submitted an amendment to its pending Yutrepia NDA to pursue approval for a PH-ILD indication. Our suit alleged that FDA rules, precedents, and procedures require that such a new indication be pursued in a new NDA rather than as an amendment to a pending NDA. Thus, we asked the FDA to require Liquidia to submit a new NDA if it desires to further pursue approval for a PH-ILD indication.

On March 4, 2024, we filed a motion for preliminary injunction and temporary restraining order seeking to prevent the FDA from approving the PH-ILD indication for Yutrepia by amendment. The court denied that motion on March 29, 2024, following a hearing on the motion.

On August 16, 2024, the FDA (1) confirmed that it was permitting Liquidia to add the PH-ILD indication to its pending Yutrepia NDA by amendment rather than requiring a new NDA and provided an explanation for that decision; and (2) granted Liquidia tentative approval for its Yutrepia NDA, including the PAH and PH-ILD indications. The FDA granted tentative rather than final approval because it determined that we are entitled to a period of exclusivity based on a clinical trial that we conducted to obtain approval for the PH-ILD indication, and that this exclusivity bars final approval of Liquidia's product until expiration of exclusivity in May 2025. Following the FDA's decisions, we voluntarily dismissed our case against the FDA.

On August 21, 2024, Liquidia filed an action against the FDA in the U.S. District Court for the District of Columbia challenging the FDA's decisions to award us exclusivity and to withhold final approval for Yutrepia until that exclusivity has expired. We intervened, and the parties briefed and argued cross-motions for summary judgment and preliminary injunction. On February 27, 2025, the court issued a decision affirming the FDA's award of exclusivity.

We also asserted a cross-claim against the FDA for improperly permitting Liquidia to pursue a PH-ILD indication in an amendment rather than a new NDA. This cross-claim is substantively identical to the claim we asserted against FDA in the action described above that we dismissed. We filed a motion for summary judgment on that cross-claim on January 17, 2025.

On April 17, 2025, we filed a motion for preliminary injunction on our cross-claim related to the PH-ILD indication that the FDA allowed Liquidia to pursue in an NDA amendment.

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.

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

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion should be read in conjunction with our Annual Report on Form 10-K for the year ended December 31, 2024 (the **2024 Annual Report**), and our consolidated financial statements and accompanying notes included in *Part I, Item 1* of this Quarterly Report on Form 10-Q. All statements in this filing are made as of the date this Quarterly Report on Form 10-Q is filed with the U.S. Securities and Exchange Commission (**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 (the **Exchange Act**) 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 Quarterly Report on Form 10-Q 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 our newest product, Tyvaso DPI, and anticipated growth in the number of patients with pulmonary hypertension associated with interstitial lung disease (**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 Inflation Reduction Act of 2022 (**IRA**) on our business;
- The anticipated impact our rebate agreements with pharmacy benefit managers will have on our net revenues;
- 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, Inc. (**Sandoz**) and Liquidia PAH, LLC (formerly known as RareGen, LLC) (**RareGen**); our patent and trade secret litigation with Liquidia Technologies, Inc. (**Liquidia**) related to its new drug application (**NDA**) for Yutrepia; Liquidia's patent lawsuit against us related to Tyvaso DPI; our cross-claims against the FDA related to Liquidia's efforts to add an indication for PH-ILD to the NDA for Yutrepia; 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 therapies such as Merck's recently-approved Winrevair™ and Liquidia's Yutrepia, if it is approved by the FDA;
- 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;
- 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 II, Item 1A—Risk Factors* of this Quarterly Report on Form 10-Q 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 pulmonary arterial hypertension (**PAH**) and PH-ILD. We initiated commercial shipments of Tyvaso DPI to our U.S. distributors in June 2022.
- *Nebulized Tyvaso,* a liquid inhaled formulation of treprostinil, approved by the FDA and regulatory authorities in Argentina, Israel, and Japan to improve exercise ability in patients with PAH. Nebulized Tyvaso was also approved by the FDA in March 2021 and by regulators in Israel and Japan in December 2022 and September 2024, respectively, to improve exercise ability in patients with PH-ILD. In addition, marketing authorization applications for nebulized Tyvaso to treat PAH and/or PH-ILD have also been approved, and others are pending, in various other countries in Latin America, Asia, and the Middle East.
- *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 Research & Development Corp. (**DEKA**). 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 plan to launch this new system, called RemunityPRO™, later this year.
- *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.

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 Health Group, Inc. and its affiliates (**Accredo**) and Caremark, L.L.C. (**CVS Specialty**) to distribute Tyvaso DPI, nebulized Tyvaso, Remodulin, the Remunity Pump, and Orenitram in the United States, and we have entered into an exclusive distribution agreement with ASD Specialty Healthcare, Inc., an affiliate of Cencora, Inc. (formerly known as AmerisourceBergen Corporation), to distribute Unituxin in the United States. We also sell nebulized Tyvaso, Remodulin, and Unituxin to distributors internationally. We sell Adcirca through the pharmaceutical wholesale network of Eli Lilly and Company (**Lilly**). 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 11—*Segment Information* to our consolidated financial statements included in this Quarterly Report on Form 10-Q.

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.

Generic Competition and Challenges to our Intellectual Property Rights

Remodulin—Generic Competition

We settled litigation with 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 March 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 (now a subsidiary of Liquidia Corporation, the parent company of 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 Smiths Medical CADD MS-3 pump. In addition, Liquidia has announced it is developing a new subcutaneous infusion system for its generic treprostinil product. See Note 12—*Litigation*, to our consolidated financial statements included in this Quarterly Report on Form 10-Q.

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**) and Actavis Laboratories FL, Inc. (**Actavis**) related to their ANDAs seeking FDA approval to market generic versions of nebulized Tyvaso and Orenitram, respectively, before the expiration of certain of our U.S. patents. Under the settlement agreements, Watson and Actavis can market their generic versions of nebulized Tyvaso and Orenitram in the United States beginning in January 2026 and June 2027, respectively, although they may be permitted to enter the market earlier under certain circumstances. In May 2022, we settled litigation with ANI Pharmaceuticals, Inc. (**ANI**) regarding its ANDA seeking FDA approval to market a generic version of Orenitram. Under the settlement agreement, ANI can market its generic version of Orenitram in the United States beginning in December 2027, although it may be permitted to enter the market earlier under certain circumstances. Competition from these generic companies could reduce our net product sales and profits.

Liquidia—Yutrepia

Liquidia has been granted tentative approval by the FDA to market Yutrepia, a dry powder formulation of treprostinil for inhalation, to treat PAH and PH-ILD, following the expiration of our regulatory exclusivity on May 23, 2025. The Yutrepia NDA was submitted under the 505(b)(2) regulatory pathway with nebulized Tyvaso as the reference listed drug. In March 2025, Liquidia announced resubmission and FDA acceptance of the Yutrepia NDA, with a Prescription Drug User Fee Act goal date of May 24, 2025. If and when Liquidia launches commercial sales of Yutrepia, it would compete directly with Tyvaso DPI, nebulized Tyvaso, and our other treprostinil-based products.

We are engaged in litigation with Liquidia concerning a patent covering the treatment of PH-ILD to improve exercise capacity in patients suffering from PH-ILD by inhaling treprostinil at specific dosages (the **PH-ILD patent**). In addition, Liquidia sued the FDA, challenging the grant of regulatory exclusivity to us through May 23, 2025. We intervened in this lawsuit and contend that the FDA acted improperly by allowing Liquidia to add PH-ILD to its pending NDA for Yutrepia instead of requiring that Liquidia submit an entirely new NDA. The court resolved the exclusivity question in our favor, affirming the FDA's award of regulatory exclusivity to us, and the court's decision on the PH-ILD amendment is pending.

For further details regarding these litigation matters, please see Note 12—*Litigation*, to our consolidated financial statements included in this Quarterly Report on Form 10-Q.

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 profit*s, contained in *Part II*, *Item 1A—Risk Factors* included in this Quarterly Report on Form 10-Q.

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 products and post-marketing research commitments. These costs also include share-based compensation and salary-related expenses for research and development functions, professional fees for preclinical and clinical studies, costs associated with clinical manufacturing, facilities-related expenses, regulatory costs, and costs associated with 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

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 three months ended March 31, 2025. Currently, we grant stock options and restricted stock units under the United Therapeutics Corporation Amended and Restated 2015 Stock Incentive Plan (the **2015 Plan**), and restricted stock units under our 2019 Inducement Stock Incentive Plan (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.

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.

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, bio-artificial organ alternatives, three-dimensional (**3D**) bioprinting of organ alternatives, 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

We are conducting two phase 3 studies of nebulized Tyvaso, called *TETON 1* and *TETON 2*, in patients with idiopathic pulmonary fibrosis (**IPF**). *TETON 1* is being conducted in the United States and Canada, and *TETON 2* is being conducted outside the United States and Canada. Enrollment in the *TETON 2* study was completed in July 2024 after enrolling a total of 597 patients, and *TETON 1* completed enrollment in January 2025 with 598 patients. 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 each *TETON* study is the change in absolute forced vital capacity (**FVC**) from baseline to week 52.

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, open-label extension (**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, 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.

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. Due to the similarities in the mechanism of fibrosis between IPF and PPF, we anticipate that anti-fibrotic therapies will impact disease progression similarly in patients with these conditions. Therefore, based on the FVC improvements in subjects with IPF observed in the *INCREASE* study, we are conducting a single pivotal study, *TETON PPF*, to evaluate the safety and efficacy of nebulized Tyvaso for the treatment of PPF. We are targeting enrollment of 698 patients in this study. We believe there are at least 60,000 PPF patients in the United States, but the number could be significantly greater as some estimates indicate the U.S. patient population could exceed 180,000.

Both the FDA and the European Medicines Agency (**EMA**) have granted orphan designation for treprostinil to treat IPF. The FDA denied our orphan designation application for PPF. If the *TETON* studies are successful, we plan to seek FDA approval to expand the nebulized Tyvaso label to include IPF and PPF. We also plan to seek FDA approval to expand the Tyvaso DPI label to include IPF and PPF, following completion of any FDA-required bridging studies. 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.

In February 2025, the data monitoring committee for the *TETON 1* and *TETON 2* studies completed a routine, unblinded safety review of data from over 1,100 patients enrolled in these studies, and unanimously recommended continuation of both trials without modification.

Ralinepag

Ralinepag is a next-generation, once-daily, oral, 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).

We are enrolling *ADVANCE OUTCOMES*, which is a phase 3, event-driven study 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. During the first quarter of 2023, we discontinued a separate phase 3 study of ralinepag called *ADVANCE CAPACITY*, due to slow enrollment and a redirection of our internal resources toward the *TETON PPF* study. In October 2023, the data monitoring committee for the *ADVANCE OUTCOMES* study completed a routine, unblinded safety review of data from nearly 510 patients enrolled in the study, and unanimously recommended continuation of the trial without modification. The study is targeting enrollment of approximately 700 patients. We plan to close enrollment in mid-2025 and accrue clinical worsening events through the end of 2025.

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 2024, Johnson & Johnson reported global sales of Uptravi of over $1.8 billion, including over $1.5 billion in U.S. sales, reflecting a growth rate of approximately 14 percent over 2023.

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, 3D bioprinting of organ alternatives, bio-artificial organ alternatives, 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 public benefit corporation (**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**) have performed preclinical testing of our porcine xenografts in animal models. In addition, we have worked with NYU and UAB to employ innovative preclinical human models to obtain insights into how xenografts function inside the human body.

In December 2024, we submitted an Investigational New Drug application (**IND**) to the FDA related to our UKidney product. In January 2025, the FDA cleared this IND, which enables us to commence a clinical trial. 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 Biologics License Application (**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.

Based on recent FDA interactions, we do not intend to conduct further preclinical animal studies of our UThymoKidney and UHeart products, and are preparing to submit INDs for these products with the goal of commencing human clinical studies in the near term.

In February 2024, we inaugurated a clinical-scale, designated pathogen-free (**DPF**) facility in Virginia and began populating the facility with animals during the first quarter of 2024. We expect this DPF 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. In 2024, we acquired land in Minnesota where we are constructing a second clinical-scale DPF facility for redundancy, and to support breeding of animals for future commercial use. In March 2025, we purchased land in Houston, Texas, where we plan to construct a third clinical-sale DPF facility. While we believe our clinical-scale DPF facilities will also be capable of producing organs for commercial use, we are 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.

Key accomplishments in our xenotransplantation program include the following:

- **First Successful Xenotransplants of Porcine Hearts.** University of Maryland School of Medicine (**UMSOM**) surgeons have successfully 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 successfully 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 successfully 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, the longest-ever human use of a xenotransplanted porcine organ.
- **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. Publications of the result of this experiment are expected in the near term.

Regenerative Medicine, Bio-Artificial Organ Alternatives, and 3D Bioprinting of Organ Alternatives

- **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 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 October 2024, Miromatrix initiated screening of patients for a phase 1 study of miroliver*ELAP* in patients with acute liver failure, which is the first human clinical trial of a manufactured organ alternative. 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 cells. In 2023, our Regenerative Medicine Laboratory in Research Triangle Park, North Carolina (**RTP**) produced 450 decellularized lung scaffolds, 220 recellularized lungs, and 1.7 trillion human cells for use in recellularization.
- **ULung™.** The ULung is a development-stage engineered lung alternative composed of a 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 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 has been accepted by the FDA and is under active review by the agency.

Over 500 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-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-powered helicopter at our test and development facility located in Quebec.

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 and new indications for existing products being developed in our pipeline, as described above under *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 as a result of additional payer rebates; (5) the competition we face within our industry, including competition from generic companies and the anticipated launch of new PAH and PH-ILD therapies; (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 II, Item 1A—Risk Factors*, included in this Quarterly Report on Form 10-Q.

We have budgeted approximately $750 million for capital expenditures during the second quarter of 2025 through the end of 2027 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 Tyvaso DPI manufacturing facility in RTP; construction of clinical-scale DPF facilities in Stewartville, Minnesota and Houston, Texas; and planned expenditures for future growth on our RTP campus. We plan to fund these capital expenditures using cash on hand.

We anticipate our commercial DPF facilities will provide an initial commercial supply of our xeno-organ products if and when they are approved by the FDA. Our additional DPF facilities will be very capital-intensive, but 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. In addition to the production capacity of our commercial DPF facilities, we anticipate that we will have additional commercial production capacity in at least three clinical-scale facilities: our existing DPF facility in Virginia, and DPF facilities we are building in Minnesota and Texas, as noted above.

We operate in a highly competitive market in which several large pharmaceutical companies control many of the available PAH therapies. These pharmaceutical companies are well established in the market and possess greater financial, technical, and marketing resources than we do. In addition, there are investigational products in late-stage development that, if approved, may erode the market share or net prices of our existing commercial therapies and make market acceptance more difficult to achieve for any therapies we attempt to market in the future. For example, Yutrepia has been tentatively approved by the FDA for the treatment of PAH and PH-ILD, with final approval potentially occurring in May 2025. If Yutrepia receives final approval and is commercially launched, our revenues from Tyvaso DPI could be materially adversely affected, and the impact may be greater if Yutrepia is ultimately approved for the treatment of PH-ILD.

Results of Operations

Three Months Ended March 31, 2025 and March 31, 2024

Revenues

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

	Three Months Ended March 31,		Dollar Change	Percentage Change
	2025	2024		
Net product sales:				
Tyvaso DPI[1]	$ 302.5	$ 227.5	$ 75.0	33 %
Nebulized Tyvaso[1]	163.8	145.0	18.8	13 %
Total Tyvaso	466.3	372.5	93.8	25 %
Remodulin[2]	138.2	128.0	10.2	8 %
Orenitram	120.7	106.2	14.5	14 %
Unituxin	58.2	58.4	(0.2)	— %
Adcirca	6.0	6.4	(0.4)	(6)%
Other	5.0	6.2	(1.2)	(19)%
Total revenues	$ 794.4	$ 677.7	$ 116.7	17 %

(1) Net product sales include both the drug product and the respective inhalation device.

(2) Net product sales include sales of infusion devices, including the Remunity Pump.

Total Tyvaso net product sales grew 25% to $466.3 million for the three months ended March 31, 2025, as compared to $372.5 million for the same period in 2024. Tyvaso DPI net product sales increased for the three months ended March 31, 2025, as compared to the same period in 2024, due to an increase in quantities sold of $97.4 million and, to a lesser extent, a price increase, partially offset by higher gross-to-net deductions. The increase in Tyvaso DPI quantities sold was primarily due to continued growth in the number of patients following the product's launch (including growth in utilization by PH-ILD patients) and, to a lesser extent, increased commercial utilization following the implementation of the Medicare Part D benefit redesign under the Inflation Reduction Act. Nebulized Tyvaso net product sales increased for the three months ended March 31, 2025, as compared to the same period in 2024, primarily due to an increase in international nebulized Tyvaso net product sales, which was driven by the timing of orders by our international distributors and does not precisely reflect trends in underlying patient demand.

Remodulin net product sales increased for the three months ended March 31, 2025, as compared to the same period in 2024, primarily due to an increase in U.S. Remodulin net product sales, driven by an increase in quantities sold.

Orenitram net product sales increased for the three months ended March 31, 2025, as compared to the same period in 2024, primarily due to an increase in quantities sold and, to a lesser extent, a price increase, partially offset by higher gross-to-net deductions. 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 Inflation Reduction Act.

We have entered into contracts with all of the major pharmacy benefit managers for Medicare Part D and commercial insurance plans, which provide rebates on utilization of Tyvaso DPI and, in some cases, Orenitram and nebulized Tyvaso. We entered into these rebate agreements to encourage access to these therapies. Many of these rebates went into effect beginning in the second half of 2024, which impacted our net revenues by increasing gross-to-net deductions for the relevant products. These rebate contracts are effective at least through 2025.

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

	Three Months Ended March 31,					
	2025			2024		
	U.S.	ROW	Total	U.S.	ROW	Total
Net product sales:						
Tyvaso DPI[1]	$ 302.5	$ —	$ 302.5	$ 227.5	$ —	$ 227.5
Nebulized Tyvaso[1]	138.6	25.2	163.8	133.7	11.3	145.0
Total Tyvaso	441.1	25.2	466.3	361.2	11.3	372.5
Remodulin[2]	120.2	18.0	138.2	108.3	19.7	128.0
Orenitram	120.7	—	120.7	106.2	—	106.2
Unituxin	56.9	1.3	58.2	53.4	5.0	58.4
Adcirca	6.0	—	6.0	6.4	—	6.4
Other	4.7	0.3	5.0	6.0	0.2	6.2
Total revenues	$ 749.6	$ 44.8	$ 794.4	$ 641.5	$ 36.2	$ 677.7

(1) Net product sales include both the drug product and the respective inhalation device.

(2) Net product sales include sales of infusion devices, including the Remunity Pump.

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 accounts associated with these deductions (in millions):

	Three Months Ended March 31, 2025				
	Rebates and 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	124.8	18.4	0.2	10.5	153.9
Prior periods	8.4	0.1	(0.1)	(0.3)	8.1
Payments or credits attributed to sales in:					
Current period	(22.1)	(12.1)	—	(2.0)	(36.2)
Prior periods	(93.1)	(5.2)	(1.0)	(8.4)	(107.7)
Balance, March 31, 2025	$ 158.8	$ 6.3	$ 1.3	$ 11.4	$ 177.8

	Three Months Ended March 31, 2024				
	Rebates and 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	78.2	14.8	0.4	10.0	103.4
Prior periods	(1.8)	—	0.1	(0.8)	(2.5)
Payments or credits attributed to sales in:					
Current period	(8.7)	(9.3)	—	(3.3)	(21.3)
Prior periods	(61.7)	(5.3)	(0.1)	(7.4)	(74.5)
Balance, March 31, 2024	$ 114.4	$ 5.5	$ 2.3	$ 8.9	$ 131.1

Cost of Sales

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

	Three Months Ended March 31,			
	2025	2024	Dollar Change	Percentage Change
Category:				
Cost of sales	$ 91.6	$ 71.8	$ 19.8	28 %
Share-based compensation expense[1]	0.9	1.1	(0.2)	(18)%
Total cost of sales	$ 92.5	$ 72.9	$ 19.6	27 %

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

Cost of sales, excluding share-based compensation. Cost of sales for the three months ended March 31, 2025 increased as compared to the same period in 2024, primarily due to an increase in royalty expense and product costs, particularly for Tyvaso DPI driven by growth in Tyvaso DPI revenues.

Research and Development

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

	Three Months Ended March 31,			
	2025	2024	Dollar Change	Percentage Change
Category:				
External research and development[1]	$ 57.2	$ 52.7	$ 4.5	9 %
Internal research and development[2]	48.3	44.9	3.4	8 %
Share-based compensation expense[3]	6.9	6.4	0.5	8 %
Other[4]	36.6	0.1	36.5	NM[5]
Total research and development expense	$ 149.0	$ 104.1	$ 44.9	43 %

(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 FDA 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 FDA 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 and adjustments to the fair value of our contingent consideration obligations.

(5) Calculation is not meaningful.

Research and development, excluding share-based compensation. Research and development expense for the three months ended March 31, 2025 increased as compared to the same period in 2024, primarily due to: (1) an increase of $30.0 million related to milestone payments for drug delivery device technologies; (2) an increase of $6.6 million related to adjustments to the fair value of our contingent consideration obligations for manufactured organ and organ alternative projects; and (3) increased expenditures related to manufactured organ and organ alternative projects.

Selling, General, and Administrative

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

	Three Months Ended March 31,			
	2025	2024	Dollar Change	Percentage Change
Category:				
General and administrative	$ 119.5	$ 103.1	$ 16.4	16 %
Sales and marketing	26.6	23.2	3.4	15 %
Share-based compensation expense[1]	24.0	18.1	5.9	33 %
Total selling, general, and administrative expense	$ 170.1	$ 144.4	$ 25.7	18 %

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

General and administrative, excluding share-based compensation. General and administrative expense for the three months ended March 31, 2025 increased as compared to the same period in 2024, primarily due to an increase in personnel expense due to growth in headcount.

Share-Based Compensation

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

	Three Months Ended March 31,			
	2025	2024	Dollar Change	Percentage Change
Category:				
Stock options	$ 8.5	$ 5.7	$ 2.8	49 %
Restricted stock units	23.4	15.5	7.9	51 %
STAP awards	(0.8)	3.9	(4.7)	(121)%
Employee stock purchase plan	0.7	0.5	0.2	40 %
Total share-based compensation expense	$ 31.8	$ 25.6	$ 6.2	24 %

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

	Three Months Ended March 31,			
	2025	2024	Dollar Change	Percentage Change
Cost of sales	$ 0.9	$ 1.1	$ (0.2)	(18)%
Research and development	6.9	6.4	0.5	8 %
Selling, general, and administrative	24.0	18.1	5.9	33 %
Total share-based compensation expense	$ 31.8	$ 25.6	$ 6.2	24 %

Other (Expense) Income, Net

The change in *other (expense) income, net* for the three months ended March 31, 2025, as compared to the same period in 2024, was primarily due to net unrealized losses on equity securities. See Note 3—*Investments* and Note 4—*Fair Value Measurements* to our consolidated financial statements.

Income Tax Expense

Income tax expense for the three months ended March 31, 2025 and 2024 was $101.3 million and $92.0 million, respectively. Our effective income tax rate (**ETR**) for the three months ended March 31, 2025 and 2024 was 24 percent and 23 percent, respectively. Our ETR for the three months ended March 31, 2025 increased compared to our ETR for the three months ended March 31, 2024, primarily due to decreased excess tax benefits from share-based compensation.

Share Repurchase

In March 2024, we entered into an accelerated share repurchase agreement (the **ASR agreement**) with Citibank, N.A. (**Citi**). Under the 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 ASR agreement, measured based on the closing price of our common stock on March 25, 2024.

The share repurchase under the 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 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 a credit agreement (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 $200.0 million as of April 30, 2025. See *Unsecured Revolving Credit Facilities* below for further details.

Cash and Cash Equivalents and Marketable Investments

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

	March 31, 2025	December 31, 2024	Dollar Change	Percentage Change
Cash and cash equivalents	$ 1,899.9	$ 1,697.2	$ 202.7	12 %
Marketable investments—current	1,421.4	1,569.8	(148.4)	(9)%
Marketable investments—non-current	1,710.7	1,475.3	235.4	16 %
Total cash and cash equivalents and marketable investments	$ 5,032.0	$ 4,742.3	$ 289.7	6 %

Cash Flows

Cash flows comprise the following (dollars in millions):

	Three Months Ended March 31,			
	2025	2024	Dollar Change	Percentage Change
Net cash provided by operating activities	$ 461.2	$ 376.5	$ 84.7	22 %
Net cash (used in) provided by investing activities	$ (164.7)	$ 735.3	$ (900.0)	(122)%
Net cash used in financing activities	$ (93.8)	$ (1,068.0)	$ 974.2	91 %

Operating Activities

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

The increase of $84.7 million in net cash provided by operating activities for the three months ended March 31, 2025, as compared to the three months ended March 31, 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 $900.0 million in net cash used in investing activities for the three months ended March 31, 2025, as compared to the three months ended March 31, 2024, was primarily due to: (1) an $858.4 million increase in cash used for total purchases, sales, and maturities of marketable investments; (2) a $36.7 million increase in cash paid to purchase property, plant, and equipment; and (3) a $4.9 million increase in deposits.

Financing Activities

The decrease of $974.2 million in net cash used in financing activities for the three months ended March 31, 2025, as compared to the three months ended March 31, 2024, was primarily due to a $1.0 billion payment in 2024 to repurchase our common stock; partially offset by a $25.6 million decrease in proceeds from the exercise of stock options.

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, providing 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 funds to repay all outstanding indebtedness under the 2022 Credit Agreement in connection with its termination. Refer to Note 7—*Debt—2025 Credit Agreement* to our consolidated financial statements.

Summary of Critical Accounting Policies and Estimates

The preparation of our consolidated financial statements in conformity with U.S. generally accepted accounting principles requires our management to make estimates and assumptions that affect the amounts reported in our consolidated financial statements and accompanying notes. We continually evaluate our estimates and judgments to determine whether they are reasonable, relevant, and appropriate. These assumptions are frequently developed from historical data or experience, currently available information, and anticipated developments. By their nature, our estimates are subject to an inherent degree of uncertainty; consequently, actual results may differ. We discuss critical accounting policies and estimates that involve a higher degree of judgment and complexity in *Part II, Item 7—Management's Discussion and Analysis of Financial Condition and Results of Operations* in our 2024 Annual Report. There have been no material changes to our critical accounting policies and estimates as disclosed in our 2024 Annual Report.

Recently Issued Accounting Standards

See Note 2—*Basis of Presentation*, to our consolidated financial statements for information on our anticipated adoption of recently issued accounting standards.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our exposure to market risk has not materially changed since December 31, 2024.

Item 4. Controls and Procedures

Based on their evaluation, as of March 31, 2025, our Chairperson and Chief Executive Officer and our Chief Financial Officer and Treasurer have concluded that our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) are effective to provide reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Securities Exchange Act of 1934, as amended, is recorded, summarized, processed, and reported within the time periods specified in the SEC's rules and forms and to provide reasonable assurance that such information is accumulated and communicated to our management, including our Chairperson and Chief Executive Officer and our Chief Financial Officer and Treasurer, as appropriate to allow timely decisions regarding required disclosure. There have been no changes in our internal control over financial reporting that occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, such internal control over financial reporting.

Part II. OTHER INFORMATION

Item 1. Legal Proceedings

Please see Note 12—*Litigation* to our consolidated financial statements contained elsewhere in this Quarterly Report on Form 10-Q, which is incorporated herein by reference.

Item 1A. Risk Factors

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 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, or to expand the product labeling 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 such as the COVID-19 pandemic, which initially caused us to suspend enrollment of most of our clinical studies; (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 good clinical practices (**GCP**) regulations and similar regulations outside the United States; (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 received approval for Winrevair (sotatercept-csrk) in March 2024, which competes with our treprostinil-based products. In addition, Liquidia is developing Yutrepia, which could receive final approval from the FDA for both PAH and PH-ILD in May 2025 and if successful would compete with our treprostinil-based products. Both products could potentially materially adversely affect our revenues. There are also two therapies approved for the treatment of IPF, and we are aware of a significant number of additional therapies being developed for the treatment of IPF, which would compete with Tyvaso DPI and nebulized Tyvaso if either of them is ultimately approved for that indication.

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 payers and third-party 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 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 new 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 the active ingredient in Unituxin, 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 current good manufacturing practices regulations 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 believe we and our third-party manufacturers 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. For example, MannKind Corporation (**MannKind**) recently expanded its capacity to manufacture Tyvaso DPI, at our expense. Longer-term, we are constructing our own facility to manufacture Tyvaso DPI. 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. If these plans are not successfully and timely implemented, we could be unable to meet the growing demand for Tyvaso DPI, which would negatively impact our Tyvaso DPI revenues.
- We may experience difficulty designing and implementing processes and procedures to ensure compliance 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. 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, earthquakes, flooding, terrorist attacks, and acts of war), disease outbreaks, and pandemics such as COVID-19 impacting our internal and third-party manufacturing sites could cause a supply disruption.
- The sterility and quality 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 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.
- Our supply chain for raw materials and consumables extends worldwide and is complex. Suppliers based in China and Taiwan play a role in our supply chain to support our second- and third-tier suppliers. Political unrest or trade disputes involving China, 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 the military conflicts in Ukraine and Israel. Although we do not directly source any raw materials or consumables from Ukraine, Russia, Belarus, Gaza, Lebanon, or Israel, our European- and Middle East-based suppliers and service providers 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 significantly as a result of inflation or tariffs, we could see higher than average year-over-year increases in cost of goods sold. Tariffs 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. Due to the nature of our products, alternative suppliers may not be readily available, causing us to rely solely on internal capabilities to meet future demand.
- In 2024, we began operating a clinical-scale, designated pathogen-free facility (**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 have begun construction of two additional clinical-scale 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 facilities. 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. 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 MS-3 pumps are fully exhausted. 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. In 2024, a manufacturer discontinued popular infusion tubing sets used with the Remunity Pumps (and expected to be used with RemunityPRO) and transferred this business to another manufacturer. This manufacturer has operations outside of the United States and is working to establish an additional U.S. distributor for their product. We are working to secure arrangements for alternative suppliers, but establishing these alternatives could take significant time and may not ultimately be successful. Specialty pharmacies have reportedly run low on these supplies, which threatens patients' ability to continue administering Remodulin.

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 — Minnetronix Inc. 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 currently rely entirely on MannKind to manufacture Tyvaso DPI finished drug product and inhalers for us. 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 Research Triangle Park 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 (which recently acquired Gilero LLC) 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. In addition, the success of certain products we are developing will depend on clinical trials sponsored by third parties. 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 xenotransplantation and regenerative medicine programs rely heavily on the use of animals to manufacture and test our products. Certain special interest groups categorically object to the use of animals for research purposes. Any negative attention, threats, or acts of vandalism directed against our animal research 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 transplantation programs, which include the development of xenotransplantation, regenerative medicine, 3D bioprinting of organ alternatives, and cell-based products. 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. If successful, citizen petitions can significantly delay, or even prevent, the approval of our products. For example, a third party submitted a citizen petition to the FDA requesting that the FDA refuse to approve Tyvaso DPI, and/or impose additional requirements in order to approve the product. While the petition was denied by the FDA, it delayed FDA approval of our NDA for Tyvaso DPI.

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, could result in slower response times and/or longer review periods, potentially affecting 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.

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.

In August 2022, President Biden signed the IRA into law. 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 (with resulting prices for the initial ten drugs first effective in 2026); 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). 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 redesign of certain Part D components, some of which went into effect in 2024, 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.

In addition, Congress enacted other statutes that could adversely affect our ability to successfully commercialize our products. The American Rescue Plan Act of 2021 eliminated the statutory cap on Medicaid Drug Rebate program rebates that manufacturers pay to state Medicaid programs, effective January 1, 2024. Previously, the rebate was capped at the drug’s average manufacturer price. Removal of the rebate cap could increase our Medicaid rebate liability.

Individual U.S. states continue to consider and have enacted legislation to limit the growth of healthcare costs, including the cost of prescription drugs. 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. These

state legislative measures could limit the price or payment for certain drugs, and 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.

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.

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.

It is difficult to predict the impact, if any, that future legislation or executive actions might have on the use of and reimbursement for our products in the United States, including the potential for the importation of generic versions 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 our pricing data, 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. 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 U.S. Centers for Medicare & Medicaid Services (**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 European Union (**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 Public Health Service's 340B drug pricing program (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, the U.S. Department of Health and Human Services (**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 the U.S. Health Resource Services Administration (**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. In December 2017, we entered into a civil Settlement Agreement with the U.S. Government to resolve a DOJ investigation of our support of non-profit patient assistance programs and paid $210.0 million, plus interest, to the U.S. Government upon settlement. We also entered into a Corporate Integrity Agreement (the **CIA**) with the OIG, which required us to maintain our corporate compliance program and to undertake a set of defined corporate integrity obligations for five years ending December 2022. As discussed in Note 12—*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 $71.8 million in connection with such suit, reflecting the final judgment and post-judgment interest accrued through the end of March 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 Unituxin. For further details, see *Part I, Item 2—*

Management's Discussion and Analysis of Financial Condition and Results of Operations—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. 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 the claims of this lawsuit are without merit, 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 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 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.

We may not be able to generate sufficient cash to service or repay our indebtedness, which may have a material adverse effect on our financial position, results of operations, and cash flows.

We may borrow up to $2.5 billion under our 2025 Credit Agreement, which matures in April 2030. Currently, our outstanding principal balance is $200.0 million. Our ability to repay or refinance our debt obligations under our 2025 Credit Agreement and any future debt that we may incur will depend on our financial condition and operating performance, which are subject to factors beyond our control. We may be unable to maintain a level of cash flows from operating activities sufficient to permit us to pay the principal and interest on our indebtedness. Our inability to generate sufficient cash flows to satisfy our debt obligations would materially and adversely affect our financial position and results of operations. If we cannot repay or refinance our debt as it becomes due, we may be forced to take disadvantageous actions, including reducing or delaying investments and capital expenditures, disposing of material assets or operations, seeking additional debt or equity capital, or restructuring or refinancing our indebtedness. We may not be able to implement any such alternative measures on commercially reasonable terms or at all and, even if successful, such actions may not enable us to meet any such debt service obligations. In addition, our ability to withstand competitive pressures and to react to changes in our industry could be impaired.

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.

During the fourth quarter of 2023, we acquired IVIVA and Miromatrix. We may continue to seek to expand 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 IPR&D 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 of generic versions of our products or other competitive products, such as Yutrepia, 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 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 2. Unregistered Sales of Equity Securities and Use of Proceeds

During the three months ended March 31, 2025, we did not (1) repurchase any of our outstanding equity securities; or (2) sell any of our equity securities in transactions that were not registered under the Securities Act of 1933, as amended.

Item 5. Other Information

(c) Trading Plans

During the three months ended March 31, 2025, no director or Section 16 officer adopted or 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 6. Exhibits

Exhibit No.	Description
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	Tenth 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 April 21, 2023
4.1	Reference is made to Exhibits 3.1 and 3.2
10.1	Credit Agreement, dated as of April 25, 2025, among the Registration, 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
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
32.1*	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101*	The following financial information from our Quarterly Report on Form 10-Q for the quarter ended March 31, 2025, filed with the SEC on April 30, 2025, formatted in Inline Extensible Business Reporting Language (iXBRL): (1) our Consolidated Balance Sheets as of March 31, 2025 and December 31, 2024; (2) our Consolidated Statements of Operations for the three-month periods ended March 31, 2025 and 2024; (3) our Consolidated Statements of Comprehensive Income for the three-month periods ended March 31, 2025 and 2024; (4) our Consolidated Statements of Stockholders' Equity for the three-month periods ended March 31, 2025 and 2024; (5) our Consolidated Statements of Cash Flows for the three-month periods ended March 31, 2025 and 2024; and (6) the Notes to our Consolidated Financial Statements.
104*	Cover Page Interactive Data File (embedded within the iXBRL document)

* 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.

Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

UNITED THERAPEUTICS CORPORATION

April 30, 2025

By: /s/ MARTINE ROTHBLATT
Martine Rothblatt, Ph.D.
Title: *Chairperson and Chief Executive Officer*
(Principal Executive Officer)

By: /s/ JAMES C. EDGEMOND
James C. Edgemond
Title: *Chief Financial Officer and Treasurer*
(Principal Financial and Accounting Officer)

EXHIBIT 31.1

CERTIFICATION PURSUANT TO RULE 13a-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934

I, Martine Rothblatt, certify that:

1. I have reviewed this quarterly report on Form 10-Q of United Therapeutics Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 30, 2025

/s/ MARTINE ROTHBLATT

By: Martine Rothblatt, Ph.D.
Title: *Chairperson and Chief Executive Officer*
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION PURSUANT TO RULE 13a-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934

I, James C. Edgemond, certify that:

1. I have reviewed this quarterly report on Form 10-Q of United Therapeutics Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: April 30, 2025

/s/ JAMES C. EDGEMOND

By: James C. Edgemond
Title: *Chief Financial Officer and Treasurer*
(Principal Financial and Accounting Officer)

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of United Therapeutics Corporation (the "Company") on Form 10-Q for the period ended March 31, 2025 as filed with the Securities and Exchange Commission (the "Report"), I, Martine Rothblatt, Chairperson and Chief Executive Officer of the Company, certify, to the best of my knowledge, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

April 30, 2025

/s/ MARTINE ROTHBLATT

Martine Rothblatt, Ph.D.
Chairperson and Chief Executive Officer
(Principal Executive Officer)
United Therapeutics Corporation

THE FOREGOING CERTIFICATION IS BEING FURNISHED SOLELY PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002 AND IS NOT BEING FILED AS PART OF THE FORM 10-Q OR AS A SEPARATE DISCLOSURE DOCUMENT.

A SIGNED ORIGINAL OF THIS WRITTEN STATEMENT REQUIRED BY SECTION 906, OR OTHER DOCUMENT AUTHENTICATING, ACKNOWLEDGING, OR OTHERWISE ADOPTING THE SIGNATURE THAT APPEARS IN TYPED FORM WITHIN THE ELECTRONIC VERSION OF THIS WRITTEN STATEMENT REQUIRED BY SECTION 906, HAS BEEN PROVIDED TO UNITED THERAPEUTICS CORPORATION AND WILL BE RETAINED BY UNITED THERAPEUTICS CORPORATION AND FURNISHED TO THE SECURITIES AND EXCHANGE COMMISSION OR ITS STAFF UPON REQUEST.

EXHIBIT 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the quarterly report of United Therapeutics Corporation (the "Company") on Form 10-Q for the period ended March 31, 2025 as filed with the Securities and Exchange Commission (the "Report"), I, James C. Edgemond, Chief Financial Officer and Treasurer of the Company, certify, to the best of my knowledge, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

April 30, 2025

/s/ JAMES C. EDGEMOND

James C. Edgemond
Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)
United Therapeutics Corporation

THE FOREGOING CERTIFICATION IS BEING FURNISHED SOLELY PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002 AND IS NOT BEING FILED AS PART OF THE FORM 10-Q OR AS A SEPARATE DISCLOSURE DOCUMENT.

A SIGNED ORIGINAL OF THIS WRITTEN STATEMENT REQUIRED BY SECTION 906, OR OTHER DOCUMENT AUTHENTICATING, ACKNOWLEDGING, OR OTHERWISE ADOPTING THE SIGNATURE THAT APPEARS IN TYPED FORM WITHIN THE ELECTRONIC VERSION OF THIS WRITTEN STATEMENT REQUIRED BY SECTION 906, HAS BEEN PROVIDED TO UNITED THERAPEUTICS CORPORATION AND WILL BE RETAINED BY UNITED THERAPEUTICS CORPORATION AND FURNISHED TO THE SECURITIES AND EXCHANGE COMMISSION OR ITS STAFF UPON REQUEST.