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 September 30, 2026

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 registrant's common stock, par value $0.01 per share, as of October 28, 2026, was 42,588,726.

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PART I. FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements

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

	September 30, 2026	December 31, 2025
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 1,188.9	$ 1,557.1
Marketable investments	879.0	1,363.2
Accounts receivable, no allowance for 2026 and 2025	348.6	350.2
Inventories, net	201.9	183.1
Other current assets	261.8	248.9
Total current assets	2,880.2	3,702.5
Marketable investments	1,467.8	1,776.7
Goodwill and other intangible assets, net	114.6	116.5
Property, plant, and equipment, net	2,041.9	1,729.7
Deferred tax assets, net	270.2	357.7
Other non-current assets	259.4	196.9
Total assets	**$ 7,034.1**	**$ 7,880.0**
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 520.2	$ 488.0
Other current liabilities	104.1	72.6
Total current liabilities	624.3	560.6
Other non-current liabilities	133.8	223.2
Total liabilities	758.1	783.8
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, par value $0.01, 10,000,000 shares authorized, no shares issued	–	–
Common stock, par value $0.01, 245,000,000 shares authorized, 78,715,003 and 76,452,253 shares issued, and 42,382,126 and 43,643,165 shares outstanding as of September 30, 2026 and December 31, 2025, respectively	0.8	0.8
Additional paid-in capital	3,021.0	2,798.0
Accumulated other comprehensive (loss) income	(30.3)	0.9
Treasury stock, 36,332,877 and 32,809,088 shares as of September 30, 2026 and December 31, 2025, respectively	(6,138.9)	(4,260.4)
Retained earnings	9,423.4	8,556.9
Total stockholders' equity	6,276.0	7,096.2
Total liabilities and stockholders' equity	**$ 7,034.1**	**$ 7,880.0**

See accompanying notes to consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	(Unaudited)		(Unaudited)	
Total revenues	$ 832.5	$ 799.5	$ 2,397.3	$ 2,392.5
Operating expenses:				
Cost of sales	99.1	100.9	332.0	281.0
Research and development	279.2	127.5	563.7	410.5
Selling, general, and administrative	146.4	182.6	537.2	565.2
Total operating expenses	524.7	411.0	1,432.9	1,256.7
Operating income	307.8	388.5	964.4	1,135.8
Interest income	33.7	46.4	107.0	148.8
Interest expense	(2.9)	(3.0)	(8.8)	(16.4)
Other income, net	34.2	6.1	1.2	1.7
Total other income, net	65.0	49.5	99.4	134.1
Income before income taxes	372.8	438.0	1,063.8	1,269.9
Income tax expense	(114.2)	(99.3)	(197.3)	(299.5)
Net income	**$ 258.6**	**$ 338.7**	**$ 866.5**	**$ 970.4**
Net income per common share:				
Basic	**$ 6.06**	**$ 7.73**	**$ 20.20**	**$ 21.76**
Diluted	**$ 5.71**	**$ 7.16**	**$ 18.80**	**$ 20.17**
Weighted average number of common shares outstanding:				
Basic	**42.7**	**43.8**	**42.9**	**44.6**
Diluted	**45.3**	**47.3**	**46.1**	**48.1**

See accompanying notes to consolidated financial statements.

Consolidated Statements of Comprehensive Income (In millions)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	(Unaudited)		(Unaudited)	
Net income	$ 258.6	$ 338.7	$ 866.5	$ 970.4
Other comprehensive (loss) income:				
Defined benefit pension plan:				
Actuarial gain (loss) arising during period, net of tax	–	(1.0)	0.1	(3.8)
Actuarial gain and prior service cost included in net periodic pension cost, net of tax	(0.2)	(0.6)	(0.5)	(1.4)
Total defined benefit pension plan, net of tax	(0.2)	(1.6)	(0.4)	(5.2)
Available-for-sale debt securities:				
Unrealized (loss) gain arising during period, net of tax	(13.9)	1.9	(29.0)	9.5
Realized gain included in net income, net of tax	–	(0.2)	(1.8)	(0.8)
Total (loss) gain on available-for-sale debt securities, net of tax	(13.9)	1.7	(30.8)	8.7
Other comprehensive (loss) income, net of tax	(14.1)	0.1	(31.2)	3.5
Comprehensive income	**$ 244.5**	**$ 338.8**	**$ 835.3**	**$ 973.9**

During the three and nine months ended September 30, 2026, the tax (benefit) expense in other comprehensive income was zero for the defined benefit pension plan and $(4.4) million and $(9.9) million, respectively, for the available-for-sale debt securities.

During the three and nine months ended September 30, 2025, the tax (benefit) expense in other comprehensive income was $(0.2) million and $(0.3) million, respectively, for the defined benefit pension plan and $0.7 million and $2.9 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 September 30, 2026 (Unaudited)						
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	Treasury Stock	Retained Earnings	Stockholders' Equity
	Shares	Amount					
Balance, July 1, 2026	78.0	$ 0.8	$ 2,895.8	$ (16.2)	$(5,644.9)	$9,164.8	$ 6,400.3
Net income	–	–	–	–	–	258.6	258.6
Other comprehensive loss, net of tax	–	–	–	(14.1)	–	–	(14.1)
Shares issued under employee stock purchase plan (**ESPP**)	–	–	5.0	–	–	–	5.0
Restricted stock units (**RSUs**) withheld for taxes	–	–	(0.8)	–	–	–	(0.8)
Share repurchases	–	–	(7.4)	–	(492.6)	–	(500.0)
Excise tax on net share repurchases	–	–	–	–	(1.4)	–	(1.4)
Exercise of stock options	0.7	–	87.4	–	–	–	87.4
Share-based compensation	–	–	41.0	–	–	–	41.0
Balance, September 30, 2026	**78.7**	**$ 0.8**	**$ 3,021.0**	**$ (30.3)**	**$(6,138.9)**	**$9,423.4**	**$ 6,276.0**

	Three Months Ended September 30, 2025 (Unaudited)						
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	Treasury Stock	Retained Earnings	Stockholders' Equity
	Shares	Amount					
Balance, July 1, 2025	75.4	$ 0.8	$ 2,793.4	$ –	$(3,474.5)	$7,853.9	$ 7,173.6
Net income	–	–	–	–	–	338.7	338.7
Other comprehensive income, net of tax	–	–	–	0.1	–	–	0.1
Shares issued under ESPP	–	–	4.3	–	–	–	4.3
RSUs withheld for taxes	–	–	(0.5)	–	–	–	(0.5)
Share repurchases	–	–	(217.8)	–	(782.2)	–	(1,000.0)
Excise tax on net share repurchases	–	–	–	–	(5.3)	–	(5.3)
Exercise of stock options	0.3	–	40.2	–	–	–	40.2
Share-based compensation	–	–	39.1	–	–	–	39.1
Balance, September 30, 2025	**75.7**	**$ 0.8**	**$ 2,658.7**	**$ 0.1**	**$(4,262.0)**	**$8,192.6**	**$ 6,590.2**

	Nine Months Ended September 30, 2026 (Unaudited)						
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	Treasury Stock	Retained Earnings	Stockholders' Equity
	Shares	Amount					
Balance, January 1, 2026	76.5	$ 0.8	$ 2,798.0	$ 0.9	$(4,260.4)	$8,556.9	$ 7,096.2
Net income	–	–	–	–	–	866.5	866.5
Other comprehensive loss, net of tax	–	–	–	(31.2)	–	–	(31.2)
Shares issued under ESPP	–	–	10.6	–	–	–	10.6
RSUs withheld for taxes	–	–	(59.6)	–	–	–	(59.6)
Share repurchases	–	–	(128.3)	–	(1,871.7)	–	(2,000.0)
Excise tax on net share repurchases	–	–	–	–	(6.8)	–	(6.8)
Common stock issued for RSUs vested	0.1	–	–	–	–	–	–
Exercise of stock options	2.1	–	282.0	–	–	–	282.0
Share-based compensation	–	–	118.3	–	–	–	118.3
Balance, September 30, 2026	**78.7**	**$ 0.8**	**$ 3,021.0**	**$ (30.3)**	**$(6,138.9)**	**$9,423.4**	**$ 6,276.0**

	Nine Months Ended September 30, 2025 (Unaudited)						
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive (Loss) Income	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	–	–	–	–	–	970.4	970.4
Other comprehensive income, net of tax	–	–	–	3.5	–	–	3.5
Shares issued under ESPP	–	–	9.2	–	–	–	9.2
RSUs withheld for taxes	–	–	(16.0)	–	–	–	(16.0)
Share repurchases	–	–	(217.8)	–	(782.2)	–	(1,000.0)
Excise tax on net share repurchases	–	–	–	–	(5.3)	–	(5.3)
Common stock issued for RSUs vested	0.1	–	–	–	–	–	–
Exercise of stock options	0.6	–	74.9	–	–	–	74.9
Share-based compensation	–	–	109.5	–	–	–	109.5
Balance, September 30, 2025	**75.7**	**$ 0.8**	**$ 2,658.7**	**$ 0.1**	**$(4,262.0)**	**$8,192.6**	**$ 6,590.2**

See accompanying notes to consolidated financial statements.

Consolidated Statements of Cash Flows (In millions)

	Nine Months Ended September 30,	
	2026	2025
	(Unaudited)	
Cash flows from operating activities:		
Net income	$ 866.5	$ 970.4
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	73.2	62.8
Share-based compensation expense	118.3	108.7
Impairment of property, plant, and equipment	–	21.7
Net unrealized losses on equity securities	29.0	3.5
Deferred income taxes	100.1	100.9
Other	45.7	10.5
Changes in operating assets and liabilities:		
Accounts receivable	1.6	(18.4)
Inventories	(83.4)	(36.1)
Accounts payable and accrued expenses	30.0	74.7
Other assets and liabilities	(97.6)	(83.7)
Net cash provided by operating activities	1,083.4	1,215.0
Cash flows from investing activities:		
Purchases of property, plant, and equipment	(389.5)	(347.6)
Deposits	(9.9)	(15.5)
Purchases of investments in privately held companies	(25.0)	(30.0)
Purchases of available-for-sale debt securities	(1,329.7)	(2,885.1)
Maturities of available-for-sale debt securities	747.4	1,098.4
Sales of available-for-sale debt securities	1,307.9	1,861.6
Other	19.4	(5.5)
Net cash provided by (used in) investing activities	320.6	(323.7)
Cash flows from financing activities:		
Payments to repurchase common stock	(2,000.0)	(1,000.0)
Excise tax paid on net share repurchases	(1.8)	(5.0)
Proceeds from line of credit	–	200.0
Repayment of line of credit	–	(500.0)
Payments of debt issuance costs	(3.4)	(11.5)
Proceeds from the exercise of stock options	282.0	74.9
Proceeds from the issuance of stock under ESPP	10.6	9.2
RSUs withheld for taxes	(59.6)	(16.0)
Net cash used in financing activities	(1,772.2)	(1,248.4)
Net decrease in cash and cash equivalents	**$ (368.2)**	**$ (357.1)**
Cash and cash equivalents, beginning of period	1,557.1	1,697.2
Cash and cash equivalents, end of period	**$ 1,188.9**	**$ 1,340.1**
Supplemental cash flow information:		
Cash paid for interest	**$ 5.7**	**$ 11.5**
Cash paid for income taxes	**$ 106.2**	**$ 262.3**
Non-cash investing and financing activities:		
Non-cash additions to property, plant, and equipment	**$ 78.9**	**$ 92.2**
Excise tax on net share repurchase	**$ 6.8**	**$ 5.3**

See accompanying notes to consolidated financial statements.

Notes to Consolidated Financial Statements September 30, 2026 (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, 2025, as filed with the SEC on February 25, 2026.

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 September 30, 2026 and December 31, 2025, our statements of operations, comprehensive income, and stockholders' equity for the three- and nine-month periods ended September 30, 2026 and 2025, and our statements of cash flows for the nine-month periods ended September 30, 2026 and 2025. Interim results are not necessarily indicative of results for an entire year. Certain prior period amounts in the consolidated statements of cash flows have been reclassified to conform to the current period presentation. Specifically, amounts previously included in *other* and *other assets and liabilities* within operating activities are now presented separately as *net unrealized losses on equity securities* and *deferred income taxes*, respectively.

Recently Issued Accounting Standards

Accounting Standards Adopted During the Period

None.

Accounting Standards Not Yet Adopted

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

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

As of September 30, 2026	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. government and agency securities	$ 1,837.7	$ 0.2	$ (21.6)	$ 1,816.3
Corporate debt securities	440.0	–	(5.4)	434.6
Total	$ 2,277.7	$ 0.2	$ (27.0)	$ 2,250.9
Reported under the following captions in our consolidated balance sheets:				
Cash and cash equivalents				$ 2.0
Current marketable investments				781.1
Non-current marketable investments				1,467.8
Total				$ 2,250.9

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

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 September 30, 2026 and December 31, 2025, 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 September 30, 2026	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
U.S. government and agency securities	$ 1,718.7	$ (21.6)	$ –	$ –	$ 1,718.7	$ (21.6)
Corporate debt securities	394.0	(5.4)	–	–	394.0	(5.4)
Total	$ 2,112.7	$ (27.0)	$ –	$ –	$ 2,112.7	$ (27.0)

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

As of September 30, 2026 and December 31, 2025, we held 331 and 87 available-for-sale debt securities, respectively, that were in an unrealized loss position. In assessing whether the decline in fair value as of September 30, 2026 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 and nine months ended September 30, 2026 and 2025.

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 September 30, 2026	
	Amortized Cost	Fair Value
Due within one year	$ 784.5	$ 783.1
Due in one to three years	1,493.2	1,467.8
Total	**$ 2,277.7**	**$ 2,250.9**

Investments in Equity Securities with Readily Determinable Fair Values

We held investments in equity securities with readily determinable fair values, in the aggregate, of $97.9 million and $126.9 million as of September 30, 2026 and December 31, 2025, 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 income, net*. See Note 4—*Fair Value Measurements*.

Investments in Privately Held Companies

As of September 30, 2026 and December 31, 2025, we maintained non-controlling equity investments in privately held companies of $90.1 million and $53.8 million, respectively. We invested zero and $25.0 million in privately held companies during the three and nine months ended September 30, 2026, respectively, as compared to $30.0 million during the three and nine months ended September 30, 2025. 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.

When an observable price transaction occurs that is identified as similar or identical to our investment, we perform a valuation analysis to assess the fair value of our investment using various inputs, such as the discount rate, time to a liquidation event, and price volatility of peer company stocks. We adjust the fair value of our investment based on the valuation analysis and recognize the gain or loss in the period in which the observable price change occurred. During the first quarter of 2026, one of the privately held companies in which we invested raised additional capital by issuing equity securities similar to ours at an increased valuation compared to prior financing rounds, which resulted in an increase of $12.8 million in the value of our investment. This gain was recorded within *other income, net* in our consolidated statements of operations.

During the third quarter of 2026, a privately held company in which we held an investment was acquired. We received $15.5 million in cash as a result of the acquisition and realized a gain of $14.0 million. The gain was recorded within *other income, net* in our consolidated statements of operations.

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*.

For non-controlling equity investments in privately held companies in which we held an investment as of September 30, 2026, cumulative impairments and downward fair value adjustments were $5.3 million and cumulative upward fair value adjustments were $14.8 million.

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 September 30, 2026			
	Level 1	Level 2	Level 3	Balance
Assets				
Money market funds[1]	$ 218.0	$ –	$ –	$ 218.0
Time deposits[1]	211.4	–	–	211.4
U.S. government and agency securities[2]	–	1,816.3	–	1,816.3
Corporate debt securities[2]	–	434.6	–	434.6
Equity securities[3]	97.9	–	–	97.9
Total assets	**$ 527.3**	**$ 2,250.9**	**$ –**	**$ 2,778.2**
Liabilities				
Contingent consideration[4]	–	–	34.6	34.6
Total liabilities	**$ –**	**$ –**	**$ 34.6**	**$ 34.6**

	As of December 31, 2025			
	Level 1	Level 2	Level 3	Balance
Assets				
Money market funds[1]	$ 753.1	$ –	$ –	$ 753.1
Time deposits[1]	–	–	–	–
U.S. government and agency securities[2]	–	2,443.2	–	2,443.2
Corporate debt securities[2]	–	606.8	–	606.8
Equity securities[3]	126.9	–	–	126.9
Total assets	**$ 880.0**	**$ 3,050.0**	**$ –**	**$ 3,930.0**
Liabilities				
Contingent consideration[4]	–	–	32.5	32.5
Total liabilities	**$ –**	**$ –**	**$ 32.5**	**$ 32.5**

(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 and nine months ended September 30, 2026, we recognized $19.2 million of net unrealized gains and $29.0 million of net unrealized losses, respectively, on these securities. During the three and nine months ended September 30, 2025, we recognized $5.8 million of net unrealized gains and $3.5 million of net unrealized losses, respectively, on these securities. These net unrealized gains and losses are recorded within *other income, net* in our consolidated statements of operations. 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 $2.1 million during the period from December 31, 2025 to September 30, 2026. 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*.

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):

	September 30, 2026	December 31, 2025
Raw materials	$ 35.6	$ 30.6
Work-in-progress	37.4	35.3
Finished goods	128.9	117.2
Total inventories	**$ 201.9**	**$ 183.1**

6. Property, Plant, and Equipment

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

	September 30, 2026	December 31, 2025
Land and land improvements	$ 320.5	$ 266.5
Buildings, building improvements, and leasehold improvements	1,053.8	944.7
Buildings under construction	766.6	592.7
Furniture, equipment, and vehicles	537.3	493.6
Subtotal	2,678.2	2,297.5
Less—accumulated depreciation	(636.3)	(567.8)
Property, plant, and equipment, net	**$ 2,041.9**	**$ 1,729.7**

Depreciation expense for the nine months ended September 30, 2026 and 2025 was $69.1 million and $62.0 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). In accordance with the terms of the 2025 Credit Agreement, in May 2026, we extended the maturity date of the 2025 Credit Agreement by one year, to April 2031. The 2025 Credit Agreement provides the lenders with the ability to extend the maturity date by one additional year, to April 2032, if we request such an extension.

At our option, amounts borrowed under the 2025 Credit Agreement bear interest at either an adjusted Term Secured Overnight Financing Rate (**Term SOFR**) or a fluctuating base rate, in each case, plus an applicable margin determined on a quarterly basis based on our consolidated ratio of total indebtedness to EBITDA (as calculated in accordance with the 2025 Credit Agreement). To date, we have elected to calculate interest on the outstanding balance at an adjusted Term SOFR plus an applicable margin.

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

During the second quarter of 2025, we paid down the entire $200.0 million balance under the 2025 Credit Agreement, which brought our aggregate outstanding balance to zero as of June 30, 2025. Our aggregate outstanding balance under the 2025 Credit Agreement remained zero as of September 30, 2026.

The 2025 Credit Agreement contains customary events of default and customary affirmative and negative covenants. As of September 30, 2026, we were in compliance with these covenants.

The interest expense reported in our consolidated statements of operations for the nine months ended September 30, 2026 and 2025 relates to the 2025 Credit Agreement and 2022 Credit Agreement.

2022 Credit Agreement

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

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

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

8. Share-Based Compensation

As of September 30, 2026, we have one shareholder-approved equity incentive plan: the United Therapeutics Corporation 2026 Stock Incentive Plan (the **2026 Plan**), which was approved by our shareholders on June 26, 2026. The 2026 Plan replaced the United Therapeutics Corporation Amended and Restated 2015 Stock Incentive Plan (the **Prior Plan**). As of June 26, 2026, 3,913,730 shares were initially available for future grants, consisting of 2,413,730 shares that remained available for future grants under the Prior Plan and 1,500,000 newly authorized shares. In addition, as of September 30, 2026, 10,802 shares subject to outstanding Prior Plan awards had been canceled, expired, forfeited, withheld for taxes, or otherwise not issued or settled in cash and therefore became available for future grants under the 2026 Plan, and an additional 4,238,060 shares subject to outstanding awards under the Prior Plan may become available if those awards are canceled, expired, forfeited, or otherwise not issued or are settled in cash. No further awards may be granted under the Prior Plan, although awards previously granted under the Prior Plan remained outstanding in accordance with their terms. 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 (**Board**) 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 in the form of stock options and restricted stock units (**RSUs**) under the 2026 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 nine months ended September 30, 2026 and 2025, we issued stock options and RSUs to certain executives with vesting conditions tied to the achievement of specified performance criteria through the end of 2028 and 2027, respectively. Additionally, during the nine months ended September 30, 2026 and 2025, we issued RSUs to certain other employees with vesting conditions tied to the achievement of specified performance criteria during specified performance periods, with the latest performance period ending in 2028. Throughout each performance period, we reassess the probability of achieving the performance criteria 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 first quarter of 2025.

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 September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Stock options	$ 11.0	$ 11.3	$ 35.3	$ 30.9
RSUs	29.1	27.1	80.3	76.5
STAP awards	–	–	–	(0.8)
ESPP	0.9	0.7	2.7	2.1
Total share-based compensation expense before tax	**$ 41.0**	**$ 39.1**	**$ 118.3**	**$ 108.7**

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 nine months ended September 30, 2026 and 2025, in addition to time-based stock options, we granted 0.3 million performance-based stock options in each period with grant date fair values of $53.9 million and $38.0 million, respectively, calculated based on the assumed achievement of the relevant financial performance condition. During the three and nine months ended September 30, 2026, we recorded $9.5 million and $31.8 million of share-based compensation expense, respectively, related to performance-based stock options, calculated based on the assumed levels of performance achievement, as compared to $10.3 million and $28.3 million for the same periods in 2025.

The following weighted average assumptions were used in estimating the fair value of stock options granted to employees during the nine months ended September 30, 2026 and 2025:

	September 30, 2026	September 30, 2025
Expected term of awards (in years)	4.9	5.1
Expected volatility	32.5 %	32.1 %
Risk-free interest rate	3.9 %	4.1 %
Expected dividend yield	0.0 %	0.0 %

A summary of the activity and status of stock options under the Prior Plan and the 2026 Plan during the nine-month period ended September 30, 2026 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, 2026	4,636,330	$ 166.11		
Granted	305,346	535.66		
Exercised	(2,054,008)	137.31		
Forfeited	(565)	267.47		
Outstanding as of September 30, 2026	**2,887,103**	**$ 225.66**	**4.5**	**$ 913.0**
Exercisable as of September 30, 2026	**1,708,761**	**$ 150.43**	**2.9**	**$ 668.9**
Unvested as of September 30, 2026	**1,178,342**	**$ 334.75**	**6.6**	**$ 244.1**

The weighted average fair value of a stock option granted during each of the nine-month periods ended September 30, 2026 and September 30, 2025 was $189.28 and $110.21, respectively. These stock options have an aggregate grant date fair value of $57.8 million and $41.6 million, respectively. The total grant date fair value of stock options that vested during the nine-month periods ended September 30, 2026 and September 30, 2025 was $39.3 million and $3.4 million, respectively.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Cost of sales	$ –	$ –	$ –	$ –
Research and development	0.4	0.1	0.6	0.3
Selling, general, and administrative	10.6	11.2	34.7	30.6
Share-based compensation expense before taxes	11.0	11.3	35.3	30.9
Related income tax benefit	(0.3)	(0.2)	(0.8)	(0.6)
Share-based compensation expense, net of taxes	**$ 10.7**	**$ 11.1**	**$ 34.5**	**$ 30.3**

As of September 30, 2026, unrecognized compensation cost related to stock options was $68.7 million. Unvested outstanding stock options as of September 30, 2026 had a weighted average remaining vesting period of 1.9 years.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Number of options exercised	663,336	300,521	2,054,008	570,521
Cash received	$ 87.4	$ 40.2	$ 282.0	$ 74.9
Total intrinsic value of options exercised	$ 255.4	$ 77.4	$ 816.8	$ 130.2

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 nine months ended September 30, 2026 and 2025, in addition to time-based RSUs, we granted 0.2 million performance-based RSUs in each period with total grant date fair values of $90.2 million and $67.3 million, respectively, calculated based on the assumed achievement of the relevant financial and non-financial performance conditions. During the three and nine months ended September 30, 2026, we recorded $9.3 million and $24.7 million of share-based compensation expense, respectively, related to performance-based RSUs, calculated based on the assumed levels of performance achievement, as compared to $11.2 million and $29.3 million for the same periods in 2025.

A summary of the activity with respect to, and status of, RSUs during the nine-month period ended September 30, 2026 is presented below:

	Number of RSUs	Weighted Average Grant Date Fair Value
Unvested as of January 1, 2026	1,416,871	$ 252.86
Granted	322,521	520.30
Vested	(291,460)	238.19
Forfeited	(28,829)	312.25
Unvested as of September 30, 2026	**1,419,103**	**$ 315.45**

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Cost of sales	$ 1.0	$ 0.9	$ 3.1	$ 3.0
Research and development	10.4	8.0	25.6	22.3
Selling, general, and administrative	17.7	18.2	51.6	51.2
Share-based compensation expense before taxes	29.1	27.1	80.3	76.5
Related income tax benefit	(5.3)	(4.2)	(13.6)	(12.3)
Share-based compensation expense, net of taxes	**$ 23.8**	**$ 22.9**	**$ 66.7**	**$ 64.2**

As of September 30, 2026, unrecognized compensation cost related to the grant of RSUs was $210.4 million. Unvested outstanding RSUs as of September 30, 2026 had a weighted average remaining vesting period of 2.1 years.

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.

Basic and diluted earnings per common share are computed independently for each quarter and the year-to-date period presented. The sum of the earnings per common share for each quarter in a year-to-date period may not equal the earnings per common share for such year-to-date period due to rounding.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Numerator:				
Net income	**$ 258.6**	**$ 338.7**	**$ 866.5**	**$ 970.4**
Denominator:				
Weighted average outstanding shares – basic	42.7	43.8	42.9	44.6
Effect of dilutive securities[1]:				
Stock options, RSUs, and ESPP[2]	2.6	3.5	3.2	3.5
Weighted average shares – diluted[2]	**45.3**	**47.3**	**46.1**	**48.1**
Net income per common share:				
Basic	**$ 6.06**	**$ 7.73**	**$ 20.20**	**$ 21.76**
Diluted	**$ 5.71**	**$ 7.16**	**$ 18.80**	**$ 20.17**
Stock options and RSUs excluded from calculation[2]	**0.3**	**0.4**	**0.2**	**0.3**

(1) Calculated using the treasury stock method.

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

Share Repurchases

In July 2025, our Board approved a share repurchase program authorizing up to $1.0 billion in aggregate repurchases of our common stock. Subsequently, in March 2026, our Board approved a share repurchase program authorizing up to $2.0 billion in aggregate repurchases of our common stock. Under these share repurchase program authorizations, we executed a combination of accelerated share repurchases (**ASRs**) and Rule 10b5-1 trading plan repurchases.

The following table summarizes the terms of the share repurchase agreements that have been executed under the share repurchase authorizations (dollars in millions):

			Initial Delivery		Hedging Period		Final Settlement		
Agreement	Execution Date[1]	Amount	Shares Received	Value of Shares as % of Contract Value	Hedging Period Settlement Date	Shares Received	Settlement Date	Shares Received	Total Shares Received
August 2025 Uncollared ASR	August 1, 2025	$ 500.0	1,274,296	75 %	N/A	N/A	November 25, 2025	3,882	1,278,178
August 2025 Collared ASR	August 1, 2025	$ 500.0	849,531	50 %	August 25, 2025	514,789	January 26, 2026	–	1,364,320
March 2026 Uncollared ASR	March 9, 2026	$ 750.0	992,120	70 %	N/A	N/A	June 23, 2026	378,936	1,371,056
March 2026 Collared ASR	March 9, 2026	$ 750.0	708,657	50 %	March 30, 2026	463,682	August 4, 2026	215,948	1,388,287
Rule 10b5-1 trading plan	August - September 2026	$ 22.4	N/A	N/A	N/A	N/A	N/A	N/A	45,070
September 2026 ASR	September 8, 2026	$ 477.6	719,376	75 %	N/A	N/A	Fourth quarter of 2026	N/A	719,376

(1) With respect to the Rule 10b5-1 trading plan, this column indicates the period during which repurchases were made.

Under the terms of each ASR, we made an aggregate upfront payment to Citibank, N.A. (**Citi**) and received an initial delivery of shares of our common stock based on a percentage of the upfront payment and the closing price of our common stock on the date the ASR was executed. In collared ASRs, a collar provision established the minimum and maximum numbers of shares to be repurchased based on the results of an agreed-upon hedging period, and we received additional shares equal to the minimum number of shares to be repurchased (less the amount delivered in the initial delivery) upon completion of that hedging period. The number of additional shares received upon final settlement of each ASR is based on the difference between (1) the upfront payment divided by the average of the daily volume-weighted average price per share of our common stock during the applicable repurchase period, less a discount and subject to adjustments pursuant to the terms and conditions of the applicable agreement; and (2) the number of shares received in the initial delivery of shares, including any shares received at the completion of the hedging period under collared ASRs.

The upfront payment for the ASRs is initially accounted for in two components, including an upfront treasury stock repurchase transaction, reflecting the cost of the initial delivery of shares, and an unsettled forward contract indexed to our common stock. The unsettled forward contract component under all completed ASRs was equity classified at inception and remained equity classified through their respective final settlement. The initial repurchase of our common stock under the ASRs was accounted for as a reduction to stockholders' equity in our consolidated balance sheets. Shares of our common stock received under the ASRs reduced the outstanding shares used to calculate the weighted average common stock outstanding for basic and diluted earnings per common share.

As of September 30, 2026, the final settlement of the September 2026 ASR had not occurred and the related forward contract remained unsettled and equity classified. At the final settlement of the September 2026 ASR, we may be entitled to receive additional shares of our common stock, or, under certain limited circumstances, be required to make an additional cash payment to Citi or, if we so elect, deliver shares of our common stock to Citi. The final settlement of the September 2026 ASR is expected to occur in the fourth quarter of 2026, which is subject to acceleration at the option of Citi or extensions due to market disruption events or additional valuation periods required to calculate our obligation if necessary.

As of September 30, 2026, no amount remained available under the share repurchase programs authorized by our Board in July 2025 and March 2026. As of September 30, 2026 and December 31, 2025, we recorded an excise tax liability associated with these share repurchases of $6.8 million and $1.8 million, respectively.

On October 21, 2026, our Board approved a share repurchase program authorizing up to $2.0 billion in aggregate repurchases of our common stock (plus the amount of any customary contingent settlement obligations that may arise upon the expiration or early termination of an accelerated share repurchase contract), through October 21, 2027.

10. Income Taxes

Our effective income tax rate (**ETR**) for the nine months ended September 30, 2026 and 2025 was 19 percent and 24 percent, respectively. Our ETR for the nine months ended September 30, 2026 decreased compared to the same period in 2025 primarily due to increased excess tax benefits from share-based compensation, partially offset by nondeductible in-process research and development (**IPR&D**) expense related to the acquisition of Thymmune Therapeutics, Inc. (**Thymmune**). See Note 13–*Asset Acquisition*.

On July 4, 2025, the One Big Beautiful Bill Act (**OBBBA**) was enacted in the United States. The OBBBA includes provisions that allow both the immediate deduction of domestic research and experimental expenditures and the full expensing of the cost of certain qualifying assets in the year placed in service. The impacts of the OBBBA were reflected in our consolidated financial statements beginning in the period of enactment and continue to be reflected in the period ended September 30, 2026, resulting in decreases to both our deferred tax assets and cash tax liabilities. The OBBBA provisions did not have a material impact on our ETR for the nine-month period ended September 30, 2026.

We record interest and penalties related to uncertain tax positions as a component of income tax expense. As of September 30, 2026 and December 31, 2025, our unrecognized tax benefits, including related interest, were approximately $37.6 million and $28.7 million, respectively.

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, 2025, as filed with the SEC on February 25, 2026.

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

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

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

	Three Months Ended September 30,							
2026	**Tyvaso DPI**	**Nebulized Tyvaso**	**Remodulin[2]**	**Orenitram**	**Unituxin**	**Adcirca**	**Other**	**Total**
Total revenues	$ 378.5	$ 125.3	$ 122.0	$ 145.0	$ 52.3	$ 4.5	$ 4.9	$ 832.5
Cost of sales[1]	49.9	6.5	16.0	8.5	5.1	2.1	11.0	99.1
Gross profit (loss)	**$ 328.6**	**$ 118.8**	**$ 106.0**	**$ 136.5**	**$ 47.2**	**$ 2.4**	**$ (6.1)**	**$ 733.4**
2025								
Total revenues	$ 336.2	$ 141.8	$ 125.9	$ 131.1	$ 47.9	$ 9.7	$ 6.9	$ 799.5
Cost of sales[1]	55.3	6.7	13.1	6.8	3.6	4.4	11.0	100.9
Gross profit (loss)	**$ 280.9**	**$ 135.1**	**$ 112.8**	**$ 124.3**	**$ 44.3**	**$ 5.3**	**$ (4.1)**	**$ 698.6**

	Nine Months Ended September 30,							
2026	**Tyvaso DPI**	**Nebulized Tyvaso**	**Remodulin[2]**	**Orenitram**	**Unituxin**	**Adcirca**	**Other**	**Total**
Total revenues	$ 1,035.4	$ 378.5	$ 374.9	$ 406.3	$ 171.1	$ 14.1	$ 17.0	$ 2,397.3
Cost of sales[1]	184.2	24.0	49.5	22.0	12.1	6.1	34.1	332.0
Gross profit (loss)	**$ 851.2**	**$ 354.5**	**$ 325.4**	**$ 384.3**	**$ 159.0**	**$ 8.0**	**$ (17.1)**	**$ 2,065.3**
2025								
Total revenues	$ 953.9	$ 460.0	$ 398.8	$ 375.7	$ 164.5	$ 22.2	$ 17.4	$ 2,392.5
Cost of sales[1]	151.9	20.8	41.2	21.8	11.6	9.7	24.0	281.0
Gross profit (loss)	**$ 802.0**	**$ 439.2**	**$ 357.6**	**$ 353.9**	**$ 152.9**	**$ 12.5**	**$ (6.6)**	**$ 2,111.5**

(1) During the three and nine months ended September 30, 2026, we recorded $11.4 million and $75.5 million of inventory reserve expense, respectively, as compared to $11.6 million and $27.1 million for the same periods in 2025. Tyvaso DPI inventory reserve expense accounts for $0.4 million and $47.5 million of the total inventory reserve expense recorded during the three and nine months ended September 30, 2026, respectively, as compared to $9.6 million and $20.4 million for the same periods in 2025. The Tyvaso DPI inventory reserve expense increased in the nine months ended September 30, 2026 primarily because we recorded estimated losses of $34.4 million related to a commercial supply agreement. This agreement is intended to provide us with sufficient inventory to meet the needs of our patients.

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

Geographic revenues are determined based on the country to which our products are shipped. 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 September 30,					
	2026			2025		
	U.S.	ROW	Total	U.S.	ROW	Total
Net product sales:						
Tyvaso DPI	$ 378.2	$ 0.3	$ 378.5	$ 336.2	$ –	$ 336.2
Nebulized Tyvaso	118.0	7.3	125.3	133.9	7.9	141.8
Total Tyvaso	496.2	7.6	503.8	470.1	7.9	478.0
Remodulin(1)	108.5	13.5	122.0	110.7	15.2	125.9
Orenitram	145.0	–	145.0	131.1	–	131.1
Unituxin	49.9	2.4	52.3	46.5	1.4	47.9
Adcirca	4.5	–	4.5	9.7	–	9.7
Other	4.4	0.5	4.9	6.7	0.2	6.9
Total revenues	$ 808.5	$ 24.0	$ 832.5	$ 774.8	$ 24.7	$ 799.5

	Nine Months Ended September 30,					
	2026			2025		
	U.S.	ROW	Total	U.S.	ROW	Total
Net product sales:						
Tyvaso DPI	$ 1,035.1	$ 0.3	$ 1,035.4	$ 953.5	$ 0.4	$ 953.9
Nebulized Tyvaso	340.3	38.2	378.5	413.0	47.0	460.0
Total Tyvaso	1,375.4	38.5	1,413.9	1,366.5	47.4	1,413.9
Remodulin(1)	316.7	58.2	374.9	344.6	54.2	398.8
Orenitram	406.3	–	406.3	375.7	–	375.7
Unituxin	157.9	13.2	171.1	158.8	5.7	164.5
Adcirca	14.1	–	14.1	22.2	–	22.2
Other	15.9	1.1	17.0	16.4	1.0	17.4
Total revenues	$ 2,286.3	$ 111.0	$ 2,397.3	$ 2,284.2	$ 108.3	$ 2,392.5

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Distributor 1	50 %	52 %	50 %	52 %
Distributor 2	40 %	37 %	37 %	36 %

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.

In March 2022, the court granted our motion for summary judgment with respect to all claims brought by the plaintiffs except the breach of contract claim. As a result, all antitrust claims, all claims under state competition laws, and the common law tortious interference claim were resolved in our favor. These were the only claims in the case that gave rise to any potential for trebling of damages, punitive damages, disgorgement, and/or the award of attorneys' fees. The court also denied the plaintiffs' request for injunctive relief.

The court granted Sandoz's motion for summary judgment with respect to Sandoz's breach of contract claim. The issue of what, if any, damages Sandoz is entitled to based on the court's decision on the contract claim went to trial. On November 1, 2024, the court entered a final judgment in favor of Sandoz, ordering us to pay to Sandoz (1) approximately $61.6 million in damages; (2) prejudgment interest in the amount of approximately $9.0 million; and (3) post-judgment interest. All parties appealed the final judgment, including the court's March 30, 2022 summary judgment decision, to the U.S. Court of Appeals for the Third Circuit.

We accrued a liability of $71.1 million during 2024, an additional $3.0 million during 2025, and an additional $2.4 million during 2026 through the third quarter, reflecting, in the aggregate, the damages and prejudgment interest amounts awarded in the final judgment, as well as post-judgment interest accrued through September 30, 2026.

On October 7, 2026, the Third Circuit entered a decision (1) affirming the grant of summary judgment dismissing the antitrust and state unfair competition claims, citing our procompetitive conduct; (2) reversing the District Court's finding that we breached our contract with Sandoz and remanding these claims to the District Court; and (3) reversing the District Court's dismissal of the tortious interference claims, and remanding these claims to the District Court.

As more fully discussed below, on October 13, 2026, we entered into a settlement agreement with Liquidia Technologies, Inc. (**Liquidia**) (the **Settlement Agreement**) that provides for, among other terms, the settlement of all claims related to this matter in exchange for a $10.0 million payment by us to Liquidia. In exchange for this payment, Liquidia agreed to obtain any third-party approvals and consents, including from Sandoz, necessary to secure dismissal of the litigation. We made the $10.0 million payment to Liquidia on October 16, 2026. The case was dismissed by the District Court on October 28, 2026.

As a result of the Settlement Agreement, we recorded a $66.5 million reversal of the previously accrued liability, resulting in a remaining liability of $10.0 million as of September 30, 2026. We recorded the reversal within *selling, general, and administrative* in our consolidated statements of operations for the three and nine months ended September 30, 2026, and classified the remaining liability within *other current liabilities* in our consolidated balance sheet as of September 30, 2026.

Litigation with Liquidia Technologies, Inc.

Since March 2020, we have been engaged in litigation with Liquidia regarding its efforts to obtain FDA approval for Yutrepia®, a dry powder inhalation formulation of treprostinil. Liquidia received final approval from the FDA to market Yutrepia to treat pulmonary arterial hypertension (**PAH**) and pulmonary hypertension associated with interstitial lung disease (**PH-ILD**) in May 2025 and launched commercial sales in June 2025. The litigation included our patent infringement lawsuit against Liquidia, alleging infringement of U.S. Patent No. 11,826,327 (the **'327 patent**), which expires February 3, 2042, a lawsuit filed by Liquidia against us alleging that Tyvaso DPI infringes U.S. Patent No. 10,898,494 (the **'494 patent**), which expires May 5, 2037, and our lawsuit against Liquidia alleging that Yutrepia infringes U.S. Patent No. 11,357,782 (the **'782 patent**), which expires May 14, 2027.

In June 2021, we filed a motion in one of our earlier patent cases against Liquidia in the U.S. District Court for the District of Delaware to file an amended complaint adding trade secret misappropriation claims against Liquidia and a former Liquidia executive, Dr. Robert Roscigno. The court denied the motion based on a finding that adding the additional claims would impact the case schedule. Thus, we filed those claims as a separate case against Liquidia and Dr. Roscigno in North Carolina state court. Discovery is complete. On January 5, 2024, Dr. Roscigno filed a motion for summary judgment, which was denied on July 31, 2024. On July 3, 2024, Liquidia filed a motion for summary judgment, which was denied on July 23, 2025. The court scheduled trial to commence in January 2027.

We filed a new complaint on May 29, 2024, to commence a separate, related case against Liquidia and Dr. Roscigno in North Carolina state court. That case is in its early stages, and the parties are currently engaged in discovery.

On September 30, 2026, the U.S. District Court for the District of Delaware ruled that Yutrepia infringes two valid claims of the '327 patent. The claims of the '327 patent generally cover improving exercise capacity in patients suffering from PH-ILD by inhaling treprostinil at specific dosages.

On October 13, 2026, we entered into the Settlement Agreement, under which we and Liquidia agreed to seek dismissal with prejudice of all of the foregoing actions (except that we may continue to pursue our claims against Dr. Roscigno). The parties also agreed to releases that become effective upon: (1) our receipt of the $185.0 million payment from Liquidia described below and Liquidia's receipt of the $10.0 million payment from us described above; (2) our receipt of a Liquidia officer's declaration confirming cessation of marketing, promotion, distribution, sales, and offers for sale of Yutrepia bearing the PH-ILD indication following regulatory approval of the label amendment; and (3) dismissal of the covered proceedings. Key terms of the Settlement Agreement include the following:

- Liquidia agreed to pay us an aggregate of $330.4 million, consisting of: (1) $185.0 million, representing an estimate of damages for past sales of Yutrepia for PH-ILD, which we received on October 19, 2026; and (2) $145.4 million, representing an agreed estimate of damages for continuing sales of Yutrepia to PH-ILD patients after execution of the Settlement Agreement, payable in two equal installments of $72.7 million each on or before February 1, 2027 and April 30, 2027. We expect to recognize a gain of $330.4 million within *total other income, net* in our consolidated statements of operations in the fourth quarter of 2026.
- Liquidia agreed to immediately file with the FDA a supplement to its new drug application for Yutrepia to remove the PH-ILD indication and references to PH-ILD from the product's labeling, and to diligently and urgently pursue FDA approval of that amendment. Such a supplement had already been filed by Liquidia on October 1, 2026, as a result of the District Court decision in the '327 patent infringement case. Pending FDA approval of the label amendment, Liquidia may continue to sell Yutrepia under its current labeling subject to the Settlement Agreement, but Liquidia must immediately cease, desist, and terminate all activities related to the marketing, advertising, promotion, proactive medical education, and detailing of Yutrepia for the treatment of PH-ILD. Upon FDA approval of the label amendment, Liquidia must immediately cease all sales of Yutrepia bearing the PH-ILD indication.
- Going forward, Liquidia agreed that it will only market, detail, and promote Yutrepia to healthcare practitioners who, to Liquidia's knowledge, treat patients with PAH. Liquidia must send letters to healthcare practitioners advising that PH-ILD patients prescribed Yutrepia should be transitioned to an alternative therapy and to specified payers requesting immediate denial of prior authorization requests for Yutrepia for PH-ILD, and must instruct its sales force to no longer use marketing and detailing information containing any reference to PH-ILD or the *INCREASE* study. With immediate effect, Liquidia must include a mandatory certification with a checkbox that must be completed on any referral form, voucher application, prescription, or similar document for Yutrepia certifying that the patient has Group 1 PAH (or, in the future, any additional indication for which Yutrepia has received FDA approval), and require healthcare practitioners to certify the accuracy of the form. Liquidia must also send letters to all pharmacies carrying Yutrepia instructing them to include the mandatory Group 1 PAH certification on their own referral forms and to obtain verbal attestations from healthcare practitioners for pending referrals on old forms or forms lacking the certification. Liquidia must also terminate cohorts of its *ASCENT* clinical trial of Yutrepia that are studying PH-ILD as promptly as practicable, cease and desist from publishing any new data, and cease and desist disseminating already-published data, from cohorts of the *ASCENT* trial that are studying PH-ILD until after the expiration of the '327 patent.
- The parties have also agreed to certain covenants not to sue each other, and Liquidia agreed not to challenge certain of our patents subject to certain exceptions.

Unless earlier terminated, the Settlement Agreement expires on the later of (1) the expiration of our applicable patents containing a valid claim directed to PH-ILD; and (2) the expiration of the last valid claim of the applicable Liquidia patents. The applicable patents include our '327 and '782 patents and the '494 patent for Liquidia, together with the related patents and patent applications specified in the Settlement Agreement. The labeling, promotional, and patent-challenge obligations described above expire on the earlier of the end of the term and the expiration of our applicable patents containing a valid claim directed to PH-ILD.

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, and their deadlines for filing appeals have passed.

On April 24, 2024, Humana and United each filed lawsuits against us in the Circuit Court for Montgomery County, Maryland. These lawsuits include allegations similar to those in their lawsuits discussed above concerning charitable contributions. Humana and United allege that our donations to CVC give rise to common law causes of action, violations of state consumer protection statutes, and violations of insurance fraud statutes under the laws of various states. On July 22, 2024, we filed motions to dismiss both of these lawsuits. Oral argument on these motions to dismiss took place on October 24, 2024. On September 23, 2025, the court dismissed both lawsuits with prejudice. On October 20, 2025, Humana and United each appealed the court's decision to the Appellate Court of Maryland, and those appeals are currently pending. Oral argument is scheduled for November 9, 2026.

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

Litigation with Boehringer Ingelheim

Following the announcement of our successful *TETON-1* clinical study of Nebulized Tyvaso in patients with idiopathic pulmonary fibrosis (**IPF**), a number of pharmaceutical sales representatives left Boehringer Ingelheim Pharmaceuticals, Inc. (**Boehringer**) to join our sales force to promote Nebulized Tyvaso for the treatment of PH-ILD, and to prepare for the eventual launch of Nebulized Tyvaso for the treatment of IPF following the anticipated FDA approval of this indication.

On July 17, 2026, Boehringer filed a complaint against us with the Court of Chancery of the State of Delaware, alleging that our hiring of former Boehringer sales representatives was part of a campaign to "raid" Boehringer's interstitial lung disease sales force, and to procure and exploit Boehringer's trade secrets. Boehringer's complaint alleges misappropriation of trade secrets, aiding and abetting breaches of fiduciary duty of loyalty, and tortious interference with contracts. Boehringer seeks injunctive relief, monetary damages, and an award of attorneys' fees and costs.

We believe we have meritorious defenses to these claims, and we intend to vigorously defend ourselves against the claims made in this lawsuit. Boehringer is one of only two pharmaceutical companies marketing branded IPF drugs, and controls two of the three branded IPF drugs approved in the United States. In expanding our sales force to address the PH-ILD market (which includes patients with underlying IPF), it is natural that Boehringer sales representatives would be among those qualified for these new positions at our company. We did not engage in a campaign to "raid" Boehringer's sales force, and we have no interest in Boehringer's alleged trade secrets. To the contrary, we explicitly instructed the former Boehringer employees not to use, disclose, or retain any such information.

We also believe that Boehringer has failed to adequately plead viable causes of action against us. On August 20, 2026, we filed a motion to dismiss the complaint and filed our opening brief in support of that motion on September 21, 2026. On September 11, 2026, we filed a motion to stay discovery that Boehringer had initiated on August 7, 2026. On September 25,

2026, before responding to our motion to dismiss, Boehringer filed its opposition to our motion to stay discovery, and simultaneously filed a motion to expedite discovery, more than two months after initiating the lawsuit and seven weeks after serving discovery. On October 5, 2026, the court denied both Boehringer's motion to expedite discovery and our motion to stay discovery and on October 22, 2026, Boehringer filed an amended complaint, and the parties are engaged in discovery.

13. Asset Acquisition

On July 1, 2026, we acquired all outstanding equity of Thymmune, a preclinical-stage company developing scalable, regenerative thymic cell therapies for the potential treatment of post-transplant organ tolerance, immunodeficiencies, and autoimmune diseases, for an upfront cash payment of approximately $140.0 million, subject to customary purchase price adjustments. The consideration for the acquisition also includes potential earnout consideration of up to $160.0 million, payable in cash to former Thymmune equityholders, upon the timely achievement of specified clinical and regulatory milestones for Thymmune's lead program, THY-100, consisting of (1) up to $60.0 million if the first patient is dosed in the initial human clinical trial on or before December 31, 2028; and (2) $100.0 million if the FDA accepts a Biologics License Application for review on or before December 31, 2031.

We accounted for this transaction as an asset acquisition, as substantially all of the fair value of the acquired assets was concentrated in a single IPR&D asset. We allocated $133.6 million of the purchase price to the IPR&D asset and, because the IPR&D asset had no alternative future use, expensed that amount immediately to *research and development* in our consolidated statements of operations for the three and nine months ended September 30, 2026. Because we accounted for this transaction as an asset acquisition, we will record the associated contingent consideration when the contingency is resolved and the consideration is paid or becomes payable. The amount allocated to the IPR&D asset is not deductible for tax purposes and was capitalized into the tax basis of the equity we acquired.

14. Subsequent Event

We entered into an Exclusive License Agreement, dated November 15, 2018 (the **License Agreement**), with Arena Pharmaceuticals, Inc., a subsidiary of Pfizer Inc. (**Arena**). The License Agreement granted to us perpetual, irrevocable, and exclusive rights to develop, manufacture, and commercialize ralinepag in exchange for (1) an upfront payment of $800.0 million paid on January 24, 2019; (2) a one-time milestone payment of $250.0 million for the first, if any, marketing approval we receive in the United States for an inhaled version of ralinepag to treat PAH; (3) a one-time milestone payment of $150.0 million for the first, if any, marketing approval we receive in any of Japan, France, Italy, the United Kingdom, Spain, or Germany for an oral version of ralinepag to treat any indication; and (4) low double-digit, tiered royalties on net sales of any pharmaceutical product containing ralinepag as an active ingredient, subject to certain adjustments for third-party license payments.

On November 3, 2026, we entered into an amendment to the License Agreement and made a lump-sum payment of $525.0 million to Arena in exchange for eliminating our obligation to pay royalties on future net sales of any pharmaceutical product containing ralinepag as an active ingredient (the **Royalty Substitution Payment**), including, if approved, ralinepag extended-release tablets and ralinepag DPI. We expect to recognize an expense of $525.0 million within *research and development* in our consolidated statements of operations in the fourth quarter of 2026 in connection with the Royalty Substitution Payment. Milestone payment obligations pursuant to the License Agreement remain in place.

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, 2025 (the **2025 Annual Report**), and our consolidated financial statements and accompanying notes included in *Part I, Item 1* of this Quarterly Report on Form 10-Q (this **Report**). 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, as amended (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 Report is filed with the SEC, include, among others, statements related to the following:

- Expectations of revenues, expenses, profitability, cash flows, and growth in the number of patients being treated with our products, including continued growth in sales of Tyvaso DPI, and anticipated growth in the number of patients with 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 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 and the Trump administration's most favored nation (**MFN**) pricing initiatives, as well as the timing and outcome of our efforts to secure Medicare coverage for Nebulized Tyvaso to treat idiopathic pulmonary fibrosis (**IPF**), following the anticipated approval by the U.S. Food and Drug Administration (**FDA**);
- The expected volume and timing of sales of our commercial products, as well as potential future commercial products, including the anticipated effect of various sales, marketing, 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, including our efforts to obtain FDA approval for Nebulized Tyvaso to treat IPF and ralinepag extended-release tablets to treat PAH and the potential impact of quality issues affecting our suppliers on such efforts;
- The outcome of pending and potential future legal and regulatory actions by the FDA and other regulatory and government enforcement agencies related to our products and potential competitive products;
- The parties' compliance with, and the implementation and impact of, our settlement agreement with Liquidia Technologies, Inc. (**Liquidia**), including the timing and receipt of remaining payments, the removal of PH-ILD from the Yutrepia label, and the potential impact on sales of Nebulized Tyvaso and Tyvaso DPI for PH-ILD;
- The timing and outcome of ongoing litigation, including our litigation with Humana Inc., United Healthcare Services, Inc., MSP Recovery Claims, Series LLC, and related entities; and the lawsuit filed against us by Boehringer Ingelheim Pharmaceuticals, Inc.;
- The impact of competing therapies on sales of our commercial products, including the impact of generic versions of Remodulin; established therapies such as Uptravi®; and newer therapies such as Merck's Winrevair® and Liquidia's Yutrepia;
- The expectation that we will be able to manufacture sufficient quantities and maintain adequate inventories of our commercial products, through both our in-house manufacturing capabilities and third-party manufacturing sites;
- Expectations regarding the amount and timing of capital expenditures to construct new facilities to support our product development and commercialization efforts, including our xenotransplantation-related facilities;
- Expectations regarding the timing and impact of our business development efforts;
- The adequacy of our intellectual property protection and the validity and expiration dates of the patents we own or license, as well as the regulatory exclusivity periods for our products;
- Any statements that include the words "believe," "seek," "expect," "anticipate," "forecast," "project," "intend," "estimate," "should," "could," "may," "will," "plan," or similar expressions; and
- Other statements contained or incorporated by reference in this Report that are not historical facts.

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

Overview of Marketed Products

We market and sell the following commercial products:

- *Tyvaso DPI,* a dry powder inhaled formulation of the prostacyclin analogue treprostinil, approved by the FDA in May 2022 to improve exercise ability in patients with pulmonary arterial hypertension (**PAH**) and PH-ILD.
- *Nebulized Tyvaso,* a nebulized liquid inhaled formulation of treprostinil, approved by the FDA to improve exercise ability in patients with PAH. Nebulized Tyvaso was also approved by the FDA in March 2021 to improve exercise ability in patients with PH-ILD. Nebulized Tyvaso has also been approved with respect to PAH and/or PH-ILD in various countries outside of the United States.
- *Remodulin*, a continuously infused formulation of treprostinil, approved by the FDA for subcutaneous and intravenous delivery to diminish symptoms associated with exercise in patients with PAH. Remodulin has also been approved in various countries outside of the United States. In February 2021, we launched U.S. sales of the Remunity Pump, a next-generation subcutaneous infusion system for Remodulin. In September 2025, we launched a new version of the Remunity Pump, called RemunityPRO, which is intended to improve the patient experience by making the pump easier to use.
- *Orenitram*, an oral extended-release tablet form of treprostinil, approved by the FDA to delay disease progression and improve exercise capacity in PAH patients.
- *Unituxin*, an infused monoclonal antibody approved in the United States and Canada for the treatment of high-risk neuroblastoma and approved in Japan for the treatment of neuroblastoma after high-dose chemotherapy.
- *Adcirca*, an oral immediate-release tablet form of the PDE-5 inhibitor tadalafil, approved by the FDA to improve exercise ability in PAH patients. We sell Adcirca under an in-license from Eli Lilly and Company (**Lilly**) that expires December 31, 2026. We have no plans to enter into an amendment to extend the term of the license, and our rights to commercialize Adcirca will terminate upon its expiration.

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 and RemunityPRO Pumps, and Orenitram in the United States, and we have entered into an exclusive distribution agreement with Cencora Global Procurement Ltd. to distribute Unituxin in the United States. We also sell Nebulized Tyvaso, Remodulin, and Unituxin to distributors internationally. We currently sell Adcirca through Lilly's pharmaceutical wholesale network. To the extent we have increased the price of any of our 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 Report.

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

Generic Competition and Challenges to our Intellectual Property Rights

Remodulin—Generic Competition

We settled litigation with Sandoz Inc. (**Sandoz**) related to its abbreviated new drug application (**ANDA**) seeking FDA approval to market a generic version of Remodulin and in March 2019, Sandoz announced the availability of its generic product in the United States. We have also entered into similar settlement agreements with other generic companies, some of which have also launched sales of generic versions of Remodulin. Through September 30, 2026, we have seen limited erosion of Remodulin sales as a result of generic treprostinil competition in the United States. We recently entered into an agreement with Liquidia to settle the litigation brought against us by Sandoz and its former marketing partner, RareGen, LLC (now known as Liquidia PAH, LLC, a subsidiary of Liquidia Corporation, the parent company of Liquidia) (**RareGen**), related to the infusion devices used to administer Remodulin subcutaneously, and the case was dismissed by the District Court on October 28, 2026. 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

October 2026, Liquidia announced that it has terminated its agreement with Sandoz related to the promotion of generic treprostinil. See Note 12—*Litigation*, to our consolidated financial statements included in this Report.

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

Nebulized Tyvaso and Orenitram—Potential Future Generic Competition

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

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

Liquidia—Yutrepia

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

We recently agreed to settle patent litigation with Liquidia concerning Yutrepia. Specifically, we alleged that Yutrepia infringes a patent we own covering the treatment of PH-ILD to improve exercise capacity in patients suffering from PH-ILD by inhaling treprostinil at specific dosages. On September 30, 2026, the District Court ruled that Liquidia's product infringes two valid claims of this patent. As a result of this decision, on October 1, 2026, Liquidia filed a supplement to its NDA to remove the PH-ILD indication from the Yutrepia labeling. Under our settlement agreement with Liquidia (**Settlement Agreement**), Liquidia is required to diligently seek approval of this updated label. In addition, our Settlement Agreement permits Liquidia to continue to sell Yutrepia under its current labeling, but must immediately cease, desist, and terminate all activities related to the marketing, advertising, promotion, proactive medical education, and detailing of Yutrepia for the treatment of PH-ILD. Upon FDA approval of the label amendment, Liquidia must immediately cease all sales of Yutrepia bearing the PH-ILD indication. We believe this outcome will result in an increase in the number of patients being prescribed Nebulized Tyvaso and Tyvaso DPI for PH-ILD, although the timing and extent of this impact is uncertain as it is unclear to what extent Yutrepia will continue to be used off-label to treat PH-ILD. Under our settlement agreement, Liquidia also agreed to pay us $330.4 million as an estimate of past and future damages resulting from infringing sales of its product.

For further details regarding these and other litigation matters involving Liquidia and Yutrepia, please see Note 12—*Litigation*, to our consolidated financial statements included in this Report.

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 have in the past been, and could in the future be, invalidated, found unenforceable, or found not to cover one or more generic forms of our products. If another 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 further adverse impact on our treprostinil-based product revenues, our profits, and our stock price. These potential effects are inherently difficult to predict, and could be significant. For additional discussion, see the risk factor entitled, *Limitations on our intellectual property rights may limit our ability to prevent third parties from competing with our products, and we may not prevail in litigation to enforce or defend those rights*, contained in *Part II*, *Item 1A—Risk Factors* included in this Report.

Operating Expenses

We devote substantial resources to our various clinical trials and other research and development efforts, which are conducted both internally and through third parties. From time to time, we also license or acquire additional technologies and compounds to be incorporated into our development pipeline. Our operating expenses include the costs described below.

Cost of Sales

Our cost of sales primarily includes costs to manufacture our products, royalty and sales-based milestone payments under license agreements granting us rights to sell related products, direct and indirect distribution costs incurred in the sale of our products, and the costs of inventory reserves for current and projected obsolescence. These costs also include share-based compensation and salary-related expenses for direct manufacturing and indirect support personnel, quality review and release for commercial distribution, direct materials and supplies, depreciation, facilities-related expenses, and other overhead costs.

Research and Development

Our research and development expenses primarily include costs associated with the research and development of new products, new indications for existing products, and various post-marketing research activities. These costs also include share-based compensation and salary-related expenses for research and development functions, professional fees for preclinical and clinical studies, costs associated with clinical manufacturing, facilities-related expenses, regulatory costs, and costs associated with payments to third-party contract manufacturers before FDA approval of the relevant product. Expenses also include costs to acquire certain in-process research and development (**IPR&D**) assets, costs for third-party arrangements, including upfront fees and milestone payments required under license arrangements for therapies under development (including the $525.0 million payment we made to Arena Pharmaceuticals, Inc., a subsidiary of Pfizer Inc. (**Arena**) on November 3, 2026 in connection with an amendment to our licensing agreement with Arena (the **Arena Amendment**), discussed below, which we expect to record during the fourth quarter of 2026), and adjustments to the fair value of our contingent consideration obligations. We do not track fully burdened research and development expenses by individual product candidate.

Selling, General, and Administrative

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

Share-Based Compensation

Currently, we grant stock options and restricted stock units under the United Therapeutics Corporation 2026 Stock Incentive Plan (the **2026 Plan**), and we may grant restricted stock units to newly hired employees 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. Historically, we granted awards under our United Therapeutics Corporation Amended and Restated 2015 Stock Incentive Plan (the **Prior Plan**), including during the first and second quarters of 2026, and our Share Tracking Awards Plan (the **STAP**). The 2026 Plan replaced the Prior Plan and no further awards may be granted under the Prior Plan, although awards previously granted under the Prior Plan remain outstanding in accordance with their terms. Issuance of awards under the STAP was discontinued in 2015 and all remaining outstanding STAP awards were exercised during the first quarter of 2025.

Research and Development

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

Select Pipeline Programs

Product	Mode of Administration	Indication	Current Status	Our Territory
Nebulized Tyvaso (treprostinil)	Inhaled	IPF	Phase 3 *TETON-1* and *TETON-2* studies successful; sNDA under review by the FDA	Worldwide
Nebulized Tyvaso (treprostinil)	Inhaled	PPF	Phase 3 *TETON-PPF* study enrollment complete	Worldwide
Tyvaso DPI (treprostinil)	Inhaled	IPF, PPF	Preparing IND for phase 3 study in IPF	Worldwide
Ralinepag Extended-Release Tablets (IP receptor agonist)	Oral	PAH	Phase 3 *ADVANCE OUTCOMES* study successful; NDA under review by the FDA	Worldwide
Ralinepag DPI	Inhaled	PH-ILD, IPF, PPF	Pre-IND non-clinical testing	Worldwide
Treprostinil SMI	Inhaled	PAH, PH-ILD, IPF, PPF	Pivotal pharmacokinetic studies for PAH and PH-ILD ongoing	Worldwide
Treprostinil SMI	Inhaled	PH-COPD	IND cleared; preparing for phase 2 *SUMMIT* study	Worldwide
Treprostinil-Iloprost SMI	Inhaled PRN	PAH	IND cleared; preparing for phase 1 study	Worldwide

Nebulized Tyvaso – *TETON* Studies

In September 2025, we announced that the *TETON-2* phase 3 study of Nebulized Tyvaso in patients with IPF met its primary efficacy endpoint of demonstrating improvement in absolute forced vital capacity (**FVC**) relative to placebo. Nebulized Tyvaso demonstrated superiority over placebo for the change in absolute FVC by 95.6 mL (Hodges-Lehmann [**H-L**] estimate, p<0.0001) from baseline to week 52 in patients with IPF.

Statistically significant improvements relative to placebo were also observed in most secondary endpoints, including time to first clinical worsening event, as well as changes from baseline to week 52 in percent predicted FVC, King's Brief Interstitial Lung Disease quality of life questionnaire (**K-BILD**) score, and diffusion capacity of lungs for carbon monoxide (**DLCO**). While not statistically significant, both time to first acute exacerbation of IPF and overall survival at week 52 trended in favor of Nebulized Tyvaso. Data from the *TETON-2* study were published in *The New England Journal of Medicine* in March 2026.

In March 2026, we announced that the *TETON-1* study also met its primary endpoint, with an even stronger treatment effect than the *TETON-2* study. Specifically, the study demonstrated superiority of Nebulized Tyvaso over placebo for the change in absolute FVC by 130.1 mL (H-L estimate, p <0.0001) from baseline to week 52. Nebulized Tyvaso achieved statistical significance for reducing the risk of clinical worsening and showed numerical improvement in other important secondary endpoints relative to placebo, including time to first acute exacerbation of IPF and changes in percent predicted FVC, K-BILD score, and DLCO.

Integrated analyses of *TETON-1* and *TETON-2* showed statistically significant treatment effects compared to placebo from baseline to week 52 for the primary endpoint of change in absolute FVC by 111.8 mL (H-L estimate, p <0.0001) and most secondary endpoints, including time to first clinical worsening and first acute exacerbation of IPF and changes in percent predicted FVC, K-BILD score, and DLCO. Overall survival at week 52 trended in favor of Nebulized Tyvaso but did not meet statistical significance. Data from the *TETON-1* study, and combined analyses of data from the *TETON-1* and *TETON-2* studies, were published in *The New England Journal of Medicine* in May 2026.

The *TETON-2* study enrolled 597 patients and was conducted outside the United States and Canada. *TETON-1* enrolled 598 patients in the United States and Canada. Treatment with Nebulized Tyvaso in these studies was well-tolerated, and the safety profile was consistent with previous Tyvaso studies and known prostacyclin-related adverse events. Benefits of Nebulized Tyvaso were observed across all subgroups, such as use of background therapy (nintedanib, pirfenidone, or no background therapy), smoking status, and supplemental oxygen use. In June 2026, we submitted a supplemental NDA (**sNDA**) to the FDA to add IPF to the labeled indications for Nebulized Tyvaso. In September 2026, we were notified that the FDA had accepted our sNDA with a user fee goal date of April 26, 2027. We believe there are approximately 100,000 IPF patients in the United States.

We are also conducting a phase 3 study of Nebulized Tyvaso called *TETON-PPF* for the treatment of progressive pulmonary fibrosis (**PPF**); we enrolled the first patient in *TETON-PPF* in October 2023. The primary endpoint of the *TETON-PPF* study is the change in absolute FVC from baseline to week 52. The *TETON-PPF* study was also prompted by a post-hoc analysis of data from the *INCREASE* study. PPF is a group of ILD conditions that exhibit progressive, self-sustaining fibrosis, and a similar disease course to IPF. PPF includes idiopathic interstitial pneumonias, autoimmune ILDs, chronic fibrosing hypersensitivity pneumonitis, and fibrotic ILDs related to environmental/occupational exposure. We completed enrollment of the study in

August 2026, with 754 patients. We expect topline data from the *TETON-PPF* study will be available in the second half of 2027.

While estimates vary, we believe the size of the U.S. PPF population is approximately 200,000 patients.

We and our distributors will also consider seeking amendments to the marketing authorizations for Nebulized Tyvaso in other countries where it is approved, to include IPF and/or PPF indications, and we will also consider seeking approval of Nebulized Tyvaso for these indications in countries where it is not yet approved. Based on FDA pre-IND feedback, we are preparing an Investigational New Drug application (**IND**) to enable us to conduct a pivotal clinical trial of Tyvaso DPI to treat patients with IPF. We intend to conduct a similar study to treat patients with PPF pending the outcome of *TETON-PPF*. Both the FDA and the European Medicines Agency (**EMA**) have granted orphan designation for treprostinil to treat IPF. In October 2026, our distributor Grupo Ferrer announced that the EMA accepted for review its marketing authorization application for Nebulized Tyvaso to treat IPF.

Treprostinil SMI

We are developing a version of inhaled treprostinil that will be a drug-device combination consisting of treprostinil solution and a device known as a soft mist inhaler (**SMI**). SMI devices are propellant-free, hand-held mechanical devices with no compressor, tubing, or power source, which deliver an aerosol cloud of medication via a single breath. SMI devices would be more convenient for our patients than the current Tyvaso nebulizer, which requires several breaths using a much larger, electrically powered device. SMI devices are pocket-sized and disposable, require low upkeep, and include a pre-filled, multi-dose cartridge of drug product that is stored at room temperature and easily inserted into the device to begin use. Due to the multi-dose cartridge, which is intended to provide sufficient doses for up to 14 days of use, there is no need to fill the SMI device every day like a nebulizer. SMI devices may offer a more favorable tolerability profile than dry powder inhalers in patients prone to cough. We are targeting the same indications for which Nebulized Tyvaso is already approved (PAH and PH-ILD), as well as those for which we plan to seek FDA approval in the future (IPF and PPF), following completion of pivotal safety and efficacy trials. We are currently conducting pivotal pharmacokinetic studies to establish comparability between treprostinil SMI and Nebulized Tyvaso, to support a 505(b)(1) NDA for PAH and PH-ILD. In September 2026, we submitted an IND to the FDA to enable us to conduct a phase 2 study (known as *SUMMIT*) of treprostinil SMI to treat patients with pulmonary hypertension associated with chronic obstructive pulmonary disease (**PH-COPD**). In October 2026, this IND cleared, and we are preparing to commence the *SUMMIT* study.

We previously conducted a separate study, known as the *PERFECT* study, of Nebulized Tyvaso in patients with PH-COPD. While that study was not successful, we have designed the *SUMMIT* study with learnings from the *PERFECT* study, including the design of the trial and the patient inclusion criteria, and we also believe an SMI device may provide benefits not seen in the *PERFECT* study as the SMI device technology is already widely used by COPD patients to administer bronchodilator treatments.

While estimates vary, we believe the size of the U.S. PH-COPD population is approximately 400,000-800,000 patients.

Treprostinil-Iloprost SMI

We are developing a fixed-dose, drug-device combination product consisting of treprostinil and iloprost solution and an SMI. We are targeting this product for *pro re nata* (**PRN**), or "as-needed," use for PAH patients whose primary therapy is either an oral or inhaled prostacyclin-class therapy who may from time to time need a bridge between doses to provide episodic PAH symptom relief. Iloprost is a prostacyclin-class therapy that is approved by the FDA to treat PAH via nebulized inhalation solution. Based on a preclinical research study, we believe there may be beneficial synergies when treprostinil and iloprost are dosed together on a PRN basis. In October 2026, our IND with the FDA was cleared, enabling us to commence a phase 1 pharmacokinetics and safety study in healthy volunteers, and eventually, a pivotal efficacy study in PAH patients.

Ralinepag Extended-Release Tablets

Ralinepag is a next-generation, once-daily, oral, extended-release, titratable, selective, and potent prostacyclin (**IP**) receptor agonist that we are developing for the treatment of PAH. In March 2026, we announced the successful results of our pivotal *ADVANCE OUTCOMES* study, which was a phase 3, event-driven clinical trial of an extended-release formulation of ralinepag tablets in PAH patients with a primary endpoint of time to first clinical worsening event. The study met its primary endpoint, with ralinepag reducing the risk of a clinical worsening event by 55 percent compared with placebo in patients with PAH (hazard ratio 0.45, $p<0.0001$).

Ralinepag demonstrated durable efficacy in delaying disease progression during the study, in which 80 percent of patients were on dual background therapy and 70 percent of patients were considered World Health Organization (**WHO**)/New York Heart Association (**NYHA**) Functional Class (**FC**) II at baseline. Statistically significant improvements relative to placebo were also observed in important secondary endpoints, including six-minute walk distance (**6MWD**) and change in N-terminal pro-B-type natriuretic peptide (**NT-proBNP**), with ralinepag increasing the odds of achieving clinical improvement by 47 percent from baseline to week 28 ($p=0.015$).

Benefits were consistent across all patient subgroups, including time since diagnosis, disease etiology, baseline 6MWD, and use of background therapies, reinforcing the robustness of the treatment effect and the potential broad therapeutic relevance of ralinepag. Treatment with ralinepag was well-tolerated and the safety profile was consistent with known prostacyclin-related adverse events.

In June 2026, we submitted an NDA to the FDA seeking approval to market ralinepag extended-release tablets for PAH. In August 2026, we were notified that the FDA had accepted our NDA and established a user fee goal date of June 24, 2027.

We currently rely on a single contract manufacturer, ScinoPharm Taiwan, Ltd. (**ScinoPharm**), to produce ralinepag active pharmaceutical ingredient (**API**), including the API intended for our planned initial commercial supply of ralinepag tablets. In late September 2026, we were notified that the FDA had classified the outcome of a current Good Manufacturing Practices (**cGMP**) inspection of ScinoPharm's facility as "Official Action Indicated" (**OAI**), meaning that the facility is in an unacceptable state of compliance, and that the FDA may consider regulatory and/or administrative actions. The FDA has indicated that satisfactory resolution of the deficiencies identified in this inspection of the ScinoPharm facility, likely confirmed by the FDA after a cGMP reinspection and/or a preapproval inspection, will be required before the FDA can approve our NDA for ralinepag tablets.

We are in ongoing discussions with ScinoPharm about the potential impact of the FDA's findings on the FDA's review of our NDA and ScinoPharm's plan to restore compliance at their facility. As discussed in *Part II, Item 1A–Risk Factors*, our ability to control regulatory compliance by third-party manufacturers is limited. There can be no assurance that ScinoPharm's facility will be determined compliant, or that any required subsequent FDA inspections can be completed before the anticipated June 2027 action date for our ralinepag NDA. If the FDA does not determine that the facility is in compliance with cGMP requirements in the manufacture of ralinepag API, it may issue a complete response letter (**CRL**) with respect to our NDA, which could delay the approval and launch of the ralinepag extended-release tablets.

We are working to qualify our Silver Spring, Maryland facility to manufacture our primary commercial supply of ralinepag API, and also evaluating alternative third-party manufacturers. However, qualifying any new manufacturing source is a lengthy and uncertain process that likely will not be completed in advance of the anticipated June 2027 action date for our ralinepag NDA.

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

Triple Combination Therapy

We are developing an oral triple combination therapy consisting of multiple strengths of ralinepag, an endothelin receptor antagonist (**ERA**), and a PDE-5 inhibitor intended to provide convenient means of dosing patients with existing first-line oral therapies for PAH (an ERA and a PDE-5 inhibitor), along with once-daily ralinepag. We have completed formulation development and dosage design work and proposed to the FDA that we would conduct an initial study in healthy volunteers to demonstrate bioequivalence between the triple combo product and the three individual drugs. In October 2026, we received feedback from the FDA indicating that this study would not be sufficient to support approval, and that a full factorial pivotal clinical study would be needed to assess the safety and efficacy of the individual components of the product, which would include arms that would limit patients' available therapeutic options for the duration of the study. Due to the challenges in executing such a study, this program is paused while we consider alternative development pathways.

Ralinepag DPI

We are developing a dry powder inhalation (**DPI**) version of ralinepag. In August 2025, we exercised the option under our license and collaboration agreement with MannKind Corp. to develop ralinepag DPI utilizing the dry powder formulation technology used to manufacture Tyvaso DPI. We believe the half-life of ralinepag may support once-daily dosing of ralinepag DPI. We are currently in the process of conducting IND-enabling non-clinical studies. In parallel, we are planning a phase 1 study in healthy volunteers to characterize the pharmacokinetic profile of ralinepag inhalation powder, and evaluate systemic exposure relative to oral ralinepag extended-release tablets. This study will inform our subsequent clinical development plans. We initially intend to seek FDA approval of ralinepag DPI for PH-ILD. We also plan to seek approval for the treatment of IPF and PPF, which will require us to conduct additional clinical studies assessing safety and efficacy in patients with these conditions. Under the terms of our expanded agreement with MannKind, we will pay MannKind up to $35 million in development milestones and a 10 percent royalty on net sales of ralinepag DPI. In October 2026, we completed construction of a manufacturing facility in Research Triangle Park, North Carolina, which we plan to use to manufacture ralinepag DPI.

Manufactured Organs and Organ Alternatives

Each year, end-stage organ failure kills millions of people. A significant number of these patients could have benefited from an organ transplant. Unfortunately, the number of usable, donated organs available for transplantation has not grown significantly over the past half century, while the need has soared. Our long-term goals are aimed at addressing this shortage. With advances in technology, we believe that creating an unlimited supply of tolerable manufactured organs and organ alternatives is now principally an engineering challenge, and we are dedicated to finding engineering solutions. We are engaged in research and development of a variety of technologies designed to increase the supply of transplantable organs and tissues and to improve outcomes for transplant recipients through xenotransplantation, regenerative medicine, and *ex vivo* lung perfusion.

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

In January 2025, the FDA cleared our IND related to the *EXPAND* study of our UKidney product. This study is expected to enroll an initial cohort of six end-stage renal disease 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 and biologic approvals. The first transplant in this study occurred in the fourth quarter of 2025, and the study is ongoing.

In July 2025, we submitted an IND to the FDA related to our anticipated *EXTEND* clinical study of our UThymoKidney product. In August 2025, the FDA cleared this IND, enabling us to commence this study, which we expect will be similar in size and scope to the *EXPAND* study described above. In May 2026, the FDA granted clearance under our IND to proceed with a clinical study of our UHeart product. The study, which is known as the *EXPRESS* study, is expected to enroll an initial cohort of up to two adult patients with advanced heart failure. Following FDA review of available safety and efficacy data from the initial two transplants, the study may then be further expanded, with the intent to support a BLA with the FDA.

In February 2024, we completed a designated pathogen-free (**DPF**) facility in Virginia. We expect this DPF facility to supply xenografts compliant with FDA cGMP for human clinical trials, with a target capacity of up to 125 organs per year. In August and October 2026, we completed construction of two additional DPF facilities of similar size and capacity to the Virginia facility in Minnesota and Texas, respectively. While we believe these DPF facilities will be capable of producing organs for commercial use, we are also planning to build additional and potentially larger cGMP DPF facilities for commercial use. While these projects will be capital-intensive, the timing and volume of these expenditures will be staggered and paced in a manner intended to balance our need to address market demand as soon as possible following FDA approval with the need to defer the most significant capital expenditures until we achieve certain clinical trial milestones.

Regenerative Medicine

- **Miromatrix.** In December 2023, we acquired Miromatrix Medical Inc. (**Miromatrix**), a company based in Minnesota focused on the development of new technologies for generating manufactured kidney and liver alternatives composed of human primary cells. The development-stage Miromatrix external liver assist product, called miroliver*ELAP*®, uses a decellularized porcine liver matrix that has been seeded with human-derived cells and an extracorporeal blood circuit to maintain liver support in patients experiencing acute liver failure. Miromatrix first used its decellularization technology to successfully develop two acellular products, MiroMesh® and MiroDerm®, which received FDA 510(k) clearance for hernia repair and wound care applications, respectively, and which were later spun off by Miromatrix. In January 2026, we announced that Miromatrix completed a phase 1 study of miroliver*ELAP* in patients with acute liver failure. This study, which was the first human clinical trial of a manufactured organ alternative, met its primary endpoint. Miromatrix is planning to commence a phase 2 study, and the FDA has granted miroliver*ELAP* Regenerative Medicine Advanced Therapy designation. Miromatrix is also developing miroliver®, a fully implantable manufactured liver alternative product, and mirokidney®, a fully implantable manufactured kidney alternative product, both of which are based on decellularized porcine organ scaffolds that have been reseeded with human-derived cells. Initially the Miromatrix products are intended to be made with cells from a human donor other than the recipient (also called "allogeneic" cells), requiring the use of standard immunosuppression protocols. Future versions may be based on the patient's own cells (known as "autologous" cells), reducing or eliminating the need for immunosuppression drugs.
- **ULobe™.** The ULobe is a development-stage engineered lung lobe alternative made using a porcine lung scaffold that is decellularized and then re-cellularized with allogeneic human cells. In 2025, our Regenerative Medicine Laboratory in Research Triangle Park, North Carolina (**RTP**) produced 830 decellularized lung scaffolds, 345 recellularized lungs, and 1.65 trillion human cells for use in recellularization.
- **ULung™.** The ULung is a development-stage engineered lung alternative composed of a 3D printed lung scaffold cellularized with human lung cells, with the goal of using autologous cells and reducing or eliminating the need for immunosuppression. The lung scaffold used in the ULung is printed using 3D printers being developed in collaboration with 3D Systems, Inc. Our Organ Manufacturing Group, located in Manchester, New Hampshire, has achieved recognition for developing the world's most complex 3D printed object. Its lung scaffold designs consist of a record 44 trillion voxels that lay out 4,000 kilometers of pulmonary capillaries and 200 million alveoli, which demonstrate gas exchange in preclinical models. Under our agreement with 3D Systems, we also have the exclusive right to develop additional human solid organ alternatives using 3D Systems' printing technology.
- **IVIVA.** In October 2023, we completed the acquisition of IVIVA Medical, Inc. (**IVIVA**), a preclinical-stage company based in Massachusetts, focused on bio-artificial manufactured kidney alternative products. IVIVA's preclinical implantable kidney alternative product uses autologous cells to mimic important physiological functions of native kidneys in recipients to support their native kidney function without the need for immunosuppression. The product is designed to replace the need for external kidney dialysis.

Ex Vivo Lung Perfusion

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

Our wholly owned subsidiary, Lung Bioengineering Inc., provides commercial EVLP services on a fee-for-service basis to transplant centers through dedicated facilities located in Silver Spring, Maryland and Jacksonville, Florida, using the XPS System. In June 2026, Lung Bioengineering obtained FDA approval of a premarket approval application (**PMA**) for another centralized EVLP technology known as the LungFX™ system (formerly referred to as the Centralized Lung Evaluation System, or CLES). LungFX is the first device approved for centralized EVLP for donor organs not otherwise used for transplant. Lung Bioengineering expects to add LungFX to its commercially available services in 2027.

Over 800 patients have received lung transplants following use of our centralized EVLP services.

Sustainable Delivery of Organs and Organ Alternatives

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

Beginning in 2017, we entered into a series of agreements with BETA Technologies, Inc. to support the development of all-electric aircraft to help us meet our future distribution requirements for manufactured organs and organ alternatives. In October 2021, we successfully completed the first-ever drone delivery of a human lung for transplant at Toronto General

Hospital, demonstrating the feasibility of our goal of delivering our manufactured organs and organ alternatives with zero carbon footprint aircraft. In October 2024, we entered into a collaboration agreement with Robinson Helicopter Company to support our efforts to develop and certify zero-emission, hydrogen-electric powered helicopters based on Robinson's R44 and R66 helicopter models. In March 2025, we completed what we believe was the world's first successful test flight of a piloted hydrogen-electric powered helicopter at our test and development facility located in Quebec.

Thymic Immune Restoration

In July 2026, we acquired Thymmune Therapeutics, Inc. (**Thymmune**), a preclinical-stage company developing scalable, regenerative thymic cell therapies for the potential treatment of post-transplant organ tolerance, immunodeficiencies, and autoimmune diseases.

The thymus is a critical organ for the development and proper function of key parts of the immune system, including training T-cells, which are essential for fighting infections and other diseases. Thymmune has a proprietary process for converting human-induced pluripotent stem cells into thymic cells, which — once inside the body — are expected to mature into cell types that can restore healthy T-cell function.

Thymmune's lead candidate, THY-100, is in preclinical development for congenital athymia, an ultra-rare and life-threatening condition in which infants are born without a functional thymus. Animal studies have shown that treatment with THY-100 results in the *in vivo* formation of a neo-thymus that is capable of facilitating T-cell development. The clinical proof of concept and further development of THY-100 have the potential to broaden thymic regenerative medicine approaches for transplant tolerance, serious immune-mediated diseases, and enhanced longevity for older adults with diminished T-cell function.

Under our agreement to acquire Thymmune, we will be obligated to pay former Thymmune equityholders up to $160.0 million in the aggregate upon the timely achievement of specified clinical and regulatory milestones for THY-100, consisting of (1) a potential payment of up to $60.0 million if the first patient is dosed in the initial human clinical trial of THY-100 on or before December 31, 2028; and (2) a potential payment of $100.0 million if the FDA accepts a Biologics License Application for THY-100 for review on or before December 31, 2031.

Future Prospects

We anticipate that revenue growth over the near-term will be driven primarily by: (1) continued growth in sales of Tyvaso DPI, including as a result of the expected removal of PH-ILD from the Yutrepia label; (2) growth in the number of PH-ILD patients prescribed Tyvaso DPI and Nebulized Tyvaso, which we believe will accelerate as a result of the anticipated removal of PH-ILD from the Yutrepia label; (3) the launch of ralinepag extended-release tablets for PAH, following FDA approval; (4) the launch of Nebulized Tyvaso for the treatment of IPF, following FDA approval; (5) FDA approval and launch of treprostinil SMI; (6) continued growth in the number of patients prescribed Orenitram; and (7) modest price increases for some of our products. We believe that additional revenue growth in the medium- and longer-term will be driven by the additional products and indications 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 new products and new indications for existing products; (2) the timing and degree of our success in commercially launching new products and new indications for existing products; (3) the demand for our products and the effects of our patient access programs on the timing and amount of revenues; (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, MFN, and other government initiatives focused on drug pricing, and as a result of additional payer rebates, and the timing and degree of success in obtaining reimbursement for new products and new indications for existing products; (5) competition within our industry, including competition from generic companies, competition from Winrevair and Yutrepia, which launched in the United States in 2024 and 2025, respectively, competition from Boehringer's Jascayd, which was approved for IPF and PPF in the fourth quarter of 2025; and the potential launch of new branded and generic therapies for PAH, PH-ILD, IPF, and/or PPF, such as Insmed Incorporated's treprostinil palmitil inhalation powder (**TPIP**) and Liquidia's L606; (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 Report.

We operate in a highly competitive market in which several large pharmaceutical companies control many of the available PAH therapies, including Merck, which received FDA approval for Winrevair (sotatercept-csrk) to treat PAH in March 2024. These pharmaceutical companies are well established in the market and possess greater financial, technical, and marketing resources than we do. In addition, Yutrepia was approved by the FDA in May 2025 for treatment of PAH and PH-ILD, and the product was launched commercially in June 2025. In October 2026, we entered into the Settlement Agreement with Liquidia which requires Liquidia to, among other actions, file with the FDA an amendment to its NDA for Yutrepia to remove the PH-ILD indication and references to PH-ILD from the product's labeling. Competition from these products has adversely affected our treprostinil-based product sales, and competition from these and any future approved products could materially adversely affect our revenues. We believe revenues from our existing product portfolio will grow, particularly given the

addressable U.S. market opportunity for Tyvaso DPI and Nebulized Tyvaso in patients with PH-ILD, and given that Yutrepia will no longer be indicated for the treatment of PH-ILD following FDA approval of Liquidia's label amendment. In addition, with the successful results of our *ADVANCE OUTCOMES*, *TETON-1*, and *TETON-2* studies, we anticipate FDA approval of ralinepag extended-release tablets for PAH and Nebulized Tyvaso for the treatment of IPF in the near-term, subject, in the case of ralinepag, to resolution of the API manufacturing issues described above, providing the opportunity for significant revenue through the end of the decade and beyond.

Results of Operations

Three and Nine Months Ended September 30, 2026 and September 30, 2025

Revenues

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

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2026	2025	Dollar Change	Percentage Change	2026	2025	Dollar Change	Percentage Change
Net product sales:								
Tyvaso DPI	$ 378.5	$ 336.2	$ 42.3	13 %	$ 1,035.4	$ 953.9	$ 81.5	9 %
Nebulized Tyvaso	125.3	141.8	(16.5)	(12)%	378.5	460.0	(81.5)	(18)%
Total Tyvaso	503.8	478.0	25.8	5 %	1,413.9	1,413.9	–	– %
Remodulin[(1)]	122.0	125.9	(3.9)	(3)%	374.9	398.8	(23.9)	(6)%
Orenitram	145.0	131.1	13.9	11 %	406.3	375.7	30.6	8 %
Unituxin	52.3	47.9	4.4	9 %	171.1	164.5	6.6	4 %
Adcirca	4.5	9.7	(5.2)	(54)%	14.1	22.2	(8.1)	(36)%
Other	4.9	6.9	(2.0)	(29)%	17.0	17.4	(0.4)	(2)%
Total revenues	**$ 832.5**	**$ 799.5**	**$ 33.0**	**4 %**	**$ 2,397.3**	**$ 2,392.5**	**$ 4.8**	**– %**

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

Total Tyvaso net product sales increased five percent to $503.8 million for the three months ended September 30, 2026, as compared to $478.0 million for the same period in 2025, driven by an increase in Tyvaso DPI net product sales, partially offset by a decrease in Nebulized Tyvaso net product sales. For the nine months ended September 30, 2026, total Tyvaso net product sales were unchanged as compared to the same period in 2025, as an increase in Tyvaso DPI net product sales was offset by a decrease in Nebulized Tyvaso net product sales.

Tyvaso DPI net product sales increased for the three and nine months ended September 30, 2026, as compared to the same periods in 2025, primarily due to an increase in quantities sold of $43.9 million and $66.8 million, respectively, and a price increase, partially offset by an increase in gross-to-net deductions.

Nebulized Tyvaso net product sales decreased for the three and nine months ended September 30, 2026, as compared to the same periods in 2025, primarily due to a decrease in U.S. quantities sold of $20.0 million and $90.9 million, respectively, partially offset by a price increase.

Remodulin net product sales decreased for the nine months ended September 30, 2026, as compared to the same period in 2025, primarily due to a decrease in U.S. quantities sold of $25.2 million, partially offset by an increase in international Remodulin net product sales.

We believe the availability of competitive therapies negatively impacted sales of Nebulized Tyvaso, Tyvaso DPI, and Remodulin for the three and nine months ended September 30, 2026.

Orenitram net product sales increased for the three and nine months ended September 30, 2026, as compared to the same periods in 2025, primarily due to an increase in quantities sold of $14.9 million and $27.1 million, respectively, and a price increase, partially offset by an increase in gross-to-net deductions.

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

	Three Months Ended September 30,					
	2026			2025		
	U.S.	ROW	Total	U.S.	ROW	Total
Net product sales:						
Tyvaso DPI	$ 378.2	$ 0.3	$ 378.5	$ 336.2	$ –	$ 336.2
Nebulized Tyvaso	118.0	7.3	125.3	133.9	7.9	141.8
Total Tyvaso	496.2	7.6	503.8	470.1	7.9	478.0
Remodulin(1)	108.5	13.5	122.0	110.7	15.2	125.9
Orenitram	145.0	–	145.0	131.1	–	131.1
Unituxin	49.9	2.4	52.3	46.5	1.4	47.9
Adcirca	4.5	–	4.5	9.7	–	9.7
Other	4.4	0.5	4.9	6.7	0.2	6.9
Total revenues	$ 808.5	$ 24.0	$ 832.5	$ 774.8	$ 24.7	$ 799.5

	Nine Months Ended September 30,					
	2026			2025		
	U.S.	ROW	Total	U.S.	ROW	Total
Net product sales:						
Tyvaso DPI	$ 1,035.1	$ 0.3	$ 1,035.4	$ 953.5	$ 0.4	$ 953.9
Nebulized Tyvaso	340.3	38.2	378.5	413.0	47.0	460.0
Total Tyvaso	1,375.4	38.5	1,413.9	1,366.5	47.4	1,413.9
Remodulin(1)	316.7	58.2	374.9	344.6	54.2	398.8
Orenitram	406.3	–	406.3	375.7	–	375.7
Unituxin	157.9	13.2	171.1	158.8	5.7	164.5
Adcirca	14.1	–	14.1	22.2	–	22.2
Other	15.9	1.1	17.0	16.4	1.0	17.4
Total revenues	$ 2,286.3	$ 111.0	$ 2,397.3	$ 2,284.2	$ 108.3	$ 2,392.5

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

Gross-to-Net Deductions

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

	Three Months Ended September 30, 2026				
	Rebates and Chargebacks	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, July 1, 2026	$ 251.3	$ 6.0	$ 1.0	$ 12.0	$ 270.3
Provisions attributed to sales in:					
Current period	153.0	19.8	0.1	11.6	184.5
Prior periods	(5.5)	0.1	(0.2)	(0.1)	(5.7)
Payments or credits attributed to sales in:					
Current period	(22.5)	(13.1)	–	(1.5)	(37.1)
Prior periods	(156.3)	(6.1)	(0.2)	(8.2)	(170.8)
Balance, September 30, 2026	**$ 220.0**	**$ 6.7**	**$ 0.7**	**$ 13.8**	**$ 241.2**

	Three Months Ended September 30, 2025				
	Rebates and Chargebacks	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, July 1, 2025	$ 173.8	$ 7.3	$ 1.6	$ 11.9	$ 194.6
Provisions attributed to sales in:					
Current period	126.4	18.6	0.3	10.2	155.5
Prior periods	(6.2)	–	(0.2)	(0.4)	(6.8)
Payments or credits attributed to sales in:					
Current period	(18.2)	(13.0)	–	(1.6)	(32.8)
Prior periods	(88.3)	(7.3)	(0.4)	(8.4)	(104.4)
Balance, September 30, 2025	**$ 187.5**	**$ 5.6**	**$ 1.3**	**$ 11.7**	**$ 206.1**

	Nine Months Ended September 30, 2026				
	Rebates and Chargebacks	Prompt Pay Discounts	Allowance for Sales Returns	Distributor Fees	Total
Balance, January 1, 2026	$ 238.9	$ 6.3	$ 1.4	$ 11.7	$ 258.3
Provisions attributed to sales in:					
Current period	427.1	56.2	0.5	32.1	515.9
Prior periods	(10.1)	(0.2)	1.3	(0.5)	(9.5)
Payments or credits attributed to sales in:					
Current period	(225.1)	(49.5)	(0.1)	(18.6)	(293.3)
Prior periods	(210.8)	(6.1)	(2.4)	(10.9)	(230.2)
Balance, September 30, 2026	**$ 220.0**	**$ 6.7**	**$ 0.7**	**$ 13.8**	**$ 241.2**

	Nine Months Ended September 30, 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	375.1	55.5	0.7	31.2	462.5
Prior periods	2.6	0.1	–	(0.5)	2.2
Payments or credits attributed to sales in:					
Current period	(202.3)	(49.9)	–	(19.6)	(271.8)
Prior periods	(128.7)	(5.2)	(1.6)	(11.0)	(146.5)
Balance, September 30, 2025	**$ 187.5**	**$ 5.6**	**$ 1.3**	**$ 11.7**	**$ 206.1**

Cost of Sales

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

	Three Months Ended September 30,		Dollar Change	Percentage Change	Nine Months Ended September 30,		Dollar Change	Percentage Change
	2026	2025			2026	2025		
Category:								
Cost of sales	$ 98.0	$ 100.0	$ (2.0)	(2)%	$ 328.9	$ 278.2	$ 50.7	18 %
Share-based compensation expense[1]	1.1	0.9	0.2	22 %	3.1	2.8	0.3	11 %
Total cost of sales	**$ 99.1**	**$ 100.9**	**$ (1.8)**	**(2)%**	**$ 332.0**	**$ 281.0**	**$ 51.0**	**18 %**

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

Cost of sales, excluding share-based compensation. The increase in cost of sales for the nine months ended September 30, 2026, as compared to the same period in 2025, was primarily due to an increase in inventory reserve expense. Of this increased amount for the nine-month period, $34.4 million related to estimated losses under a commercial supply agreement intended to provide sufficient Tyvaso DPI inventory to meet the needs of our patients.

Research and Development

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

	Three Months Ended September 30,		Dollar Change	Percentage Change	Nine Months Ended September 30,		Dollar Change	Percentage Change
	2026	2025			2026	2025		
Category:								
External research and development[1]	$ 77.1	$ 63.5	$ 13.6	21 %	$ 206.1	$ 183.1	$ 23.0	13 %
Internal research and development[2]	61.0	50.8	10.2	20 %	173.3	155.0	18.3	12 %
Share-based compensation expense[3]	11.1	8.4	2.7	32 %	27.4	23.4	4.0	17 %
Other[4]	130.0	4.8	125.2	NM[5]	156.9	49.0	107.9	220 %
Total research and development expense	**$ 279.2**	**$ 127.5**	**$ 151.7**	**119 %**	**$ 563.7**	**$ 410.5**	**$ 153.2**	**37 %**

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

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

(3) See *Share-Based Compensation* below.

(4) *Other* primarily includes costs to acquire certain IPR&D assets, 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. The increase in research and development expense for the three months ended September 30, 2026, as compared to the same period in 2025, was primarily due to: (1) an increase in IPR&D expense in connection with the acquisition of Thymmune, which we accounted for as an asset acquisition; (2) an increase in expenditures related to manufactured organ and organ alternative projects; and (3) an increase in expenditures related to cardiopulmonary treatment projects.

The increase in research and development expense for the nine months ended September 30, 2026, as compared to the same period in 2025, was primarily due to: (1) an increase in IPR&D expense in connection with the asset acquisition of Thymmune; (2) an increase in expenditures related to cardiopulmonary treatment projects; and (3) an increase in expenditures related to manufactured organ and organ alternative projects, partially offset by a decrease in milestone payments for drug delivery device technologies.

Selling, General, and Administrative

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

	Three Months Ended September 30,		Dollar Change	Percentage Change	Nine Months Ended September 30,		Dollar Change	Percentage Change
	2026	2025			2026	2025		
Category:								
General and administrative[1]	$ 143.1	$ 123.7	$ 19.4	16 %	$ 408.9	$ 372.9	$ 36.0	10 %
Impairment of property, plant, and equipment (**PP&E**)	–	–	–	– %	–	21.7	(21.7)	(100)%
Litigation accrual	(66.5)	0.8	(67.3)	NM[3]	(66.5)	2.2	(68.7)	NM[3]
Sales and marketing	41.0	28.3	12.7	45 %	107.0	85.9	21.1	25 %
Share-based compensation expense[2]	28.8	29.8	(1.0)	(3)%	87.8	82.5	5.3	6 %
Total selling, general, and administrative expense	**$ 146.4**	**$ 182.6**	**$ (36.2)**	**(20)%**	**$ 537.2**	**$ 565.2**	**$ (28.0)**	**(5)%**

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

(2) See *Share-Based Compensation* below.

(3) Calculation is not meaningful.

General and administrative, excluding impairment of PP&E, litigation accrual, and share-based compensation. The increase in general and administrative expense for the three months ended September 30, 2026, as compared to the same period in 2025, was primarily due to: (1) an increase in personnel expense due to growth in headcount; (2) an increase in legal expenses related to litigation matters; and (3) an increase in consulting expenses.

The increase in general and administrative expense for the nine months ended September 30, 2026, as compared to the same period in 2025, was primarily due to: (1) an increase in personnel expense due to growth in headcount; and (2) an increase in consulting expenses.

Impairment of PP&E. The decrease in impairment of PP&E during the nine months ended September 30, 2026, as compared to the same period in 2025, was primarily due to the impairment charge to write down the carrying value of certain PP&E in 2025, which did not recur in 2026.

Litigation accrual. The changes in litigation accrual for the three and nine months ended September 30, 2026, as compared to the same periods in 2025, were primarily due to the reversal of a previously accrued liability related to the Sandoz litigation matter, which we agreed to settle in October 2026 in connection with our Settlement Agreement with Liquidia. The Sandoz litigation matter was dismissed on October 28, 2026. See Note 12–*Litigation,* to our consolidated financial statements.

Sales and marketing, excluding share-based compensation. The increase in sales and marketing expense for the three months ended September 30, 2026, as compared to the same period in 2025, was primarily due to an increase in personnel expense due to growth in headcount.

The increase in sales and marketing expense for the nine months ended September 30, 2026, as compared to the same period in 2025, was primarily due to: (1) an increase in personnel expense due to growth in headcount; and (2) an increase in consulting expenses.

Share-Based Compensation

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

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2026	2025	Dollar Change	Percentage Change	2026	2025	Dollar Change	Percentage Change
Category:								
Stock options	$ 11.0	$ 11.3	$ (0.3)	(3)%	$ 35.3	$ 30.9	$ 4.4	14 %
Restricted stock units	29.1	27.1	2.0	7 %	80.3	76.5	3.8	5 %
STAP awards	–	–	–	– %	–	(0.8)	0.8	100 %
Employee stock purchase plan	0.9	0.7	0.2	29 %	2.7	2.1	0.6	29 %
Total share-based compensation expense	**$ 41.0**	**$ 39.1**	**$ 1.9**	**5 %**	**$ 118.3**	**$ 108.7**	**$ 9.6**	**9 %**

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

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2026	2025	Dollar Change	Percentage Change	2026	2025	Dollar Change	Percentage Change
Cost of sales	$ 1.1	$ 0.9	$ 0.2	22 %	$ 3.1	$ 2.8	$ 0.3	11 %
Research and development	11.1	8.4	2.7	32 %	27.4	23.4	4.0	17 %
Selling, general, and administrative	28.8	29.8	(1.0)	(3)%	87.8	82.5	5.3	6 %
Total share-based compensation expense	**$ 41.0**	**$ 39.1**	**$ 1.9**	**5 %**	**$ 118.3**	**$ 108.7**	**$ 9.6**	**9 %**

Interest Income

Interest income was $33.7 million and $46.4 million for the three months ended September 30, 2026 and 2025, respectively, and was $107.0 million and $148.8 million for the nine months ended September 30, 2026 and 2025, respectively. The decrease in interest income in both periods was primarily due to a decrease in marketable investments due to the sale of securities to fund our three accelerated share repurchase agreements with Citibank, N.A. (**Citi**): two agreements executed in March 2026 (the **March 2026 ASRs**) and one agreement executed in September 2026 (the **September 2026 ASR**).

Other Income, Net

Other income, net was $34.2 million and $6.1 million for the three months ended September 30, 2026 and 2025, respectively, and was $1.2 million and $1.7 million for the nine months ended September 30, 2026 and 2025, respectively. The changes in both periods were primarily due to net realized and unrealized gains and 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 nine months ended September 30, 2026 and 2025 was $197.3 million and $299.5 million, respectively. Our effective income tax rate (**ETR**) for the nine months ended September 30, 2026 and 2025 was 19 percent and 24 percent, respectively. Our ETR for the nine months ended September 30, 2026 decreased compared to our ETR for the nine months ended September 30, 2025, primarily due to increased excess tax benefits from share-based compensation, partially offset by nondeductible IPR&D expense related to the acquisition of Thymmune.

Share Repurchases

In July 2025, our Board of Directors (**Board**) approved a share repurchase program authorizing up to $1.0 billion in aggregate repurchases of our common stock. Subsequently, in March 2026, our Board approved a share repurchase program authorizing up to $2.0 billion in aggregate repurchases of our common stock. Under these share repurchase program authorizations, we executed a combination of accelerated share repurchases and Rule 10b5-1 trading plan repurchases. As of September 30, 2026, we had fully utilized the $3.0 billion authorized under the share repurchase programs approved by our Board in July 2025 and March 2026.

On October 21, 2026, our Board approved a share repurchase program authorizing up to $2.0 billion in aggregate repurchases of our common stock (plus the amount of any customary contingent settlement obligations that may arise upon the expiration or early termination of an accelerated share repurchase contract) through October 21, 2027.

See Note 9—*Stockholders' Equity—Share Repurchases,* to our consolidated financial statements.

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 2031, was zero as of September 30, 2026. See *Unsecured Revolving Credit Facilities* below for further details. In October 2026, we received $185.0 million from Liquidia under the Settlement Agreement. Liquidia is obligated to pay us an additional $145.4 million in two equal installments in the first half of 2027. On November 3, 2026, we entered into the Arena Amendment and made the required payment of $525.0 million to Arena, which we funded from cash on hand.

Cash and Cash Equivalents and Marketable Investments

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

	September 30, 2026	December 31, 2025	Dollar Change	Percentage Change
Cash and cash equivalents	$ 1,188.9	$ 1,557.1	$ (368.2)	(24)%
Marketable investments—current	879.0	1,363.2	(484.2)	(36)%
Marketable investments—non-current	1,467.8	1,776.7	(308.9)	(17)%
Total cash and cash equivalents and marketable investments	**$ 3,535.7**	**$ 4,697.0**	**$ (1,161.3)**	**(25)%**

Cash Flows

Cash flows comprise the following (dollars in millions):

	Nine Months Ended September 30,		Dollar Change	Percentage Change
	2026	2025		
Net cash provided by operating activities	$ 1,083.4	$ 1,215.0	$ (131.6)	(11)%
Net cash provided by (used in) investing activities	$ 320.6	$ (323.7)	$ 644.3	199 %
Net cash used in financing activities	$ (1,772.2)	$ (1,248.4)	$ (523.8)	(42)%

Operating Activities

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

The decrease of $131.6 million in net cash provided by operating activities for the nine months ended September 30, 2026, as compared to the same period in 2025, was primarily due to an upfront cash payment for the acquisition of Thymmune; partially offset by an increase in net cash received due to growth in sales of our commercial products.

Investing Activities

The increase of $644.3 million in net cash provided by investing activities for the nine months ended September 30, 2026, as compared to the same period in 2025, was primarily due to a $1.6 billion decrease in cash used to purchase marketable investments; partially offset by a $904.7 million decrease in cash provided by maturities and sales of marketable investments.

Financing Activities

The increase of $523.8 million in net cash used in financing activities for the nine months ended September 30, 2026, as compared to the same period in 2025, was primarily due to a $1.0 billion increase in cash used to repurchase our common stock; partially offset by: (1) a net $300.0 million decrease in cash used for our line of credit; and (2) a $207.1 million increase 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, which provided for: (1) an unsecured revolving credit facility of up to $1.2 billion; and (2) a second unsecured revolving credit facility of up to $800.0 million.

On April 25, 2025, we terminated the 2022 Credit Agreement and entered into the 2025 Credit Agreement, which provides for an unsecured revolving credit facility of up to $2.5 billion in the aggregate. On April 25, 2025, we borrowed $200.0 million under the 2025 Credit Agreement and used the proceeds to repay all outstanding indebtedness under the 2022 Credit Agreement in connection with its termination. During the second quarter of 2025, we repaid the remaining $200.0 million balance under the 2025 Credit Agreement, which brought our aggregate outstanding balance to zero as of June 30, 2025. Our aggregate outstanding debt balance remained zero as of September 30, 2026. 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 2025 Annual Report. There have been no material changes to our critical accounting policies and estimates as disclosed in our 2025 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, 2025.

Item 4. Controls and Procedures

Based on their evaluation, as of September 30, 2026, our Chairperson and Chief Executive Officer and our Chief Financial Officer and Treasurer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) are effective to provide reasonable assurance that information required to be disclosed by us in reports that we file or submit under the Exchange Act, 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 Report, which is incorporated herein by reference.

Item 1A. Risk Factors

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

Risks Related to Our Products and Our Operations

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

Sales of our treprostinil-based therapies – Tyvaso DPI, Nebulized Tyvaso, Remodulin, and Orenitram – comprise the vast majority of our revenues. Substantially decreased sales of any of these products could have a material adverse impact on our operations. A wide variety of events, such as withdrawal of regulatory approvals or substantial changes in prescribing practices or dosing patterns, many of which are described in other risk factors below, could cause sales of these products to materially decline, or to grow more slowly than expected. Pricing pressure as a result of competitive challenges, the IRA, MFN policies, and other drug price reduction initiatives could also have a material adverse impact on our net revenues. The availability of generic versions of our products and the approval and launch of new competitive therapies have negatively impacted our revenues, and these and additional products launched in the future may continue to do so. Sales may decrease if any third party that manufactures, markets, distributes, or sells our commercial products cannot do so satisfactorily, or we cannot manage our internal manufacturing processes. Finally, if demand for our Tyvaso products does not meet our expectations, the revenue opportunity for our treprostinil products could be significantly lower than we expect.

If our products fail in clinical trials, we will be unable to sell those products.

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

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

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

Competition could negatively impact our operating results. We compete with well-established drug companies for market share, as well as, among other areas, 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. 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. A generic version of Uptravi could launch as soon as 2027 for treatment of PAH, which would compete with ralinepag extended-release tablets (if approved). Our competitors are also developing numerous new products that may compete with ours, including products intended to treat PAH and/or PH-ILD. For example, Merck commercially launched Winrevair (sotatercept-csrk) in the United States shortly after FDA approval in March 2024, which competes with our treprostinil-based products. In June 2025 Liquidia launched U.S. sales of Yutrepia for PAH and PH-ILD, which now competes with our treprostinil-based products, but pursuant to the October 2026 Settlement Agreement, Liquidia is required to file with the FDA an amendment to its new drug application for Yutrepia to remove the PH-ILD indication and references to PH-ILD from the product's labeling. Additional treatments, such as Insmed Incorporated's TPIP and Liquidia's L606, are in late-stage clinical trials for treatment of PAH, IPF, and/or PH-ILD. Competition from the products that have launched to date has adversely affected our treprostinil-based product revenues, and competition from these and any future approved products could materially adversely affect our revenues. There are also three branded and two generic therapies approved for the treatment of IPF, including Boehringer Ingelheim's Jascayd® (nerandomilast), which was approved by the FDA in October 2025 for the treatment of IPF, and later for the treatment of PPF. A wide variety of additional therapies are being developed by other companies for the treatment of IPF, including admilparant, for which Bristol Myers Squibb announced positive phase 3 trial results. Existing and future approved IPF and PPF therapies would compete with Nebulized Tyvaso if it is approved for these indications, and any other products we may ultimately develop for the treatment of IPF and PPF. The introduction of lower-priced competing products may reduce both the price that we are able to charge for our products and the volume of products we sell.

Patients and doctors may discontinue use of our products if they perceive competing products as safer, more effective, less invasive, more convenient, and/or less expensive than ours. Doctors may reduce the prescribed doses of our products if they prescribe them in combination with competing products. In addition, many competing therapies are less invasive or more convenient than our products, and use of these competing therapies often delays or prevents initiation of our therapies.

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

The commercial success of our products depends, in significant part, on coverage by governmental payers such as Medicare and Medicaid, and private insurance companies. A reduction in the availability or extent of reimbursement from domestic or foreign government healthcare programs could have a material adverse effect on our business and results of our operations. Government and commercial payers are increasingly attempting to limit the price of medicinal products and frequently challenge the pricing of new or expensive drugs. In many markets outside the United States, governments control the prices of prescription pharmaceuticals through the implementation of reference pricing, price cuts, rebates, revenue-related taxes, and profit control. Financial pressures may cause United States government payers and/or private health insurers to implement policies that would reduce reimbursement rates for our products, limit future price increases, cap reimbursement rates for pharmaceuticals to rates paid internationally, require the automatic substitution of generic products, demand more rigorous requirements for initial coverage for new products, implement step therapy policies that require patients to try other medicines, including generic products, before using our products, or take other similar steps that could make it more difficult for patients to access our products. See, for example, the discussion of the IRA and the final GLOBE and proposed GUARD models 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 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 (such as the potential impact of the anticipated launch of generic versions of Uptravi on ralinepag). Similarly, pricing and rebating strategies for competitive therapies could put pressure on us to reduce the prices of our products and/or offer increased rebates to third-party payers. If commercial or government payers do not cover our products or limit payment rates, patients and physicians could choose competing products or products with lower out-of-pocket costs.

We have submitted an sNDA to the FDA seeking approval to add IPF to the labeled indications for Nebulized Tyvaso, based on the successful *TETON-1* and *TETON-2* results. Following any FDA approval, we then plan to submit a request to the Durable Medical Equipment Medicare Administrative Contractors (**DME MACs**) to revise the local coverage determination (**LCD**) that governs Medicare Part B coverage for Nebulized Tyvaso, to allow coverage for the use of Nebulized Tyvaso for the new IPF indication. DME MACs have significant discretion with respect to the overall timing to update the LCD; once the process is initiated, it could take well over a year to complete. Until such time as the LCD is updated, we expect revenues generated by sales of Nebulized Tyvaso for the new IPF indication could be limited, since we believe that most U.S. IPF patients are Medicare beneficiaries.

Our manufacturing strategy exposes us to significant risks.

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

Our internal manufacturing process subjects us to risks as we engage in increasingly complex manufacturing processes. We manufacture our entire supply of Orenitram and Unituxin without an FDA-approved back-up manufacturing site. We do not plan to engage a third party to manufacture Orenitram; however, we have initiated efforts to qualify a third party to manufacture Unituxin drug substance, which may not succeed or may take longer than we anticipate. 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 requirements of the FDA and its international counterparts, as applicable, current good tissue practices, and similar international regulatory standards, and other quality standards related to device manufacturing. Our ability to exercise control over regulatory compliance by our third-party manufacturers is limited.
- We and our third-party manufacturers may need to increase our respective manufacturing capacity by constructing new facilities, and/or expanding existing facilities, in order to continue meeting anticipated demand for our products. These efforts are often costly and time-consuming, and must meet rigorous regulatory requirements. These efforts could be unsuccessful or take longer or cost more than we anticipate, due to a variety of factors including the lead time needed to procure, install, and qualify the highly specialized equipment necessary to manufacture the product.
- We may experience difficulty designing and implementing processes and procedures to comply with applicable regulations as we develop manufacturing operations for new products.
- Our primary manufacturing facilities are located in rapidly growing biopharmaceutical manufacturing hubs. Competition for experienced technical and entry level operations personnel is intense, and we may experience difficulty in staffing both our existing and future manufacturing facilities, which could limit the capacity of our facilities and/or delay startup of new facilities.
- Unituxin is a chimeric monoclonal antibody that has stringent quality control and stability requirements. The drug substance manufacturing process involves a complex, multi-step cell culture and purification process. Many biologic products, including Unituxin, are particularly sensitive to the conditions under which they are manufactured. Supplier-driven changes to any of the raw materials or components used in the manufacture of Unituxin, such as discontinuation or alteration, could have unintended impacts on the quality and shelf life of Unituxin and may inhibit or prevent our ability to supply acceptable finished product in sufficient quantities or at all. Batches of Unituxin that fail to meet certain release specifications cannot be sold into the market. We have a limited capacity to produce batches of Unituxin. If a sufficient number of batches fail to meet release specifications, we could face a shortage of drug product. During 2025 we encountered limitations on our ability to supply Unituxin to our distributor in Japan, which caused our distributor to delay starting new patients on this therapy in Japan. Our efforts to obtain FDA approval to adjust certain manufacturing specifications for Unituxin to reduce the risk of a shortage in the United States may prove unsuccessful. Furthermore, Unituxin has a limited shelf life, which impacts our ability to stockpile inventory at comparable levels to our other commercial products.
- Natural and man-made disasters (such as fires, contamination, power loss, hurricanes, flooding, and other forms of severe weather (some of which could be exacerbated by climate change), earthquakes, terrorist attacks, and acts of war), disease outbreaks, and pandemics such as COVID-19 impacting our internal and third-party manufacturing and warehousing sites could cause a supply disruption.
- The chemical, microbiological, and physical quality attributes of our products could be substandard and such products could not be sold or used or could be subject to recalls.

- The FDA and its international counterparts could require new testing and compliance inspections of new manufacturers of our products, or new manufacturing facilities we operate.
- If we produce products that do not meet FDA-approved specifications and we fail to detect these issues prior to distribution of these products, our products may be the subject of safety alerts, product recalls, or other corrective actions, and we may be charged in product liability claims and lawsuits which, regardless of their ultimate outcome, could have a material adverse effect on our business and reputation and on our ability to attract and retain customers.
- Regulatory agencies may not be able to timely inspect our facilities, or those of our third-party manufacturers, which could delay necessary regulatory approvals for our products.
- Regulatory agencies may identify deficiencies when they inspect our facilities or those of our third-party manufacturers. For example, an FDA cGMP inspection of the facility of our sole-source supplier of ralinepag API, ScinoPharm, is currently classified as OAI by the FDA, which could result in delays in obtaining necessary regulatory approvals for our products.
- We may be unable to contract with needed manufacturers on satisfactory terms or at all.
- The supply of materials and components necessary to manufacture and package our products may become scarce or unavailable, which in the past has delayed, and in the future could delay, the manufacturing and subsequent sale of such products. Products manufactured with substituted materials or components must be approved by the FDA and applicable international regulatory agencies before they can be sold.
- Manufacturers of the devices used to administer our inhaled and infused therapies are subject to medical device requirements of the FDA and its international counterparts, as applicable. Any non-compliance, recall, or enforcement action issued against them could adversely impact our sales and operations.
- The infrastructure of our internal manufacturing facilities, along with certain facilities of our third-party manufacturers, is aging. These facilities have highly sophisticated and complex utility systems and manufacturing equipment. If any of these systems or equipment require long-term repair or replacement, the impacted facility may not be able to manufacture product for a substantial period of time.
- We and our third-party manufacturers rely upon local municipalities to supply our facilities with clean water, which is subsequently processed into high purity water and used as a key ingredient for several of our commercial drug products. If local municipalities are unable to supply water that meets relevant quality standards, we and our third-party manufacturers may be unable to manufacture these products until such a situation is remediated.
- We and our third-party manufacturers rely upon utility companies to supply our facilities with electrical power. The U.S. power grid is aging and demand for electrical power is rapidly increasing, including as a result of the construction of data centers in certain regions. If utility companies cannot reliably supply electrical power, we and our third-party manufacturers may be unable to operate our facilities at full capacity.
- Our supply chain for raw materials and consumables extends worldwide and is complex. Suppliers based in China, India, and Taiwan play a role in our supply chain to support our second- and third-tier suppliers. Political unrest or trade disputes involving China, India, Taiwan, or other countries in our supply chain could impact our ability and the ability of our third-party manufacturers to source raw materials and consumables. We also have limited visibility into the supply chains on which our primary suppliers rely; as such, we rely on our primary suppliers to have robust risk mitigation strategies to detect issues and prevent supply disruption. Our commercial active pharmaceutical ingredient and all of our finished commercial product are manufactured in the United States.
- We are closely monitoring global military conflicts including those involving Iran, Israel, and Ukraine. Although we do not directly source any raw materials or consumables from the directly impacted countries, our international suppliers and service providers in these regions could be impacted by extended conflicts or an escalation of these conflicts into neighboring countries. For example, high grade plastics, which are used ubiquitously in the pharmaceutical and biotech industry, rely heavily on the supply of petroleum. Although we have not observed supply issues, continued conflict in the Middle East constraining petroleum supply could evolve into shortages that impede our ability to manufacture our products.
- The cost of many key raw materials and consumables used in the manufacture of our products has increased due to significant inflationary pressure, and could increase further as a result of tariffs enacted by the Trump administration. Should the prices of raw materials and consumables further increase as a result of inflation or tariffs, we could see higher than average year-over-year increases in cost of goods sold. Tariffs and other trade barriers could also cause a substantial increase in the material costs associated with our construction activities.
- Any of our third-party manufacturers could undergo a change of control, causing a change in our business relationship with the relevant manufacturer. Such a change could impact our long-term supply outlook and cause us to seek alternatives that could require a lengthy regulatory approval process. Alternative suppliers may not be readily available, causing us to rely solely on internal capabilities to meet future demand.
- In 2024 we completed a DPF facility 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. In August and October 2026, we completed construction of two additional DPF facilities to mitigate operational risk and increase capacity for commercial products. We will need to construct additional DPF facilities at significant expense to support the development and commercialization of our xenotransplantation products. If

development of our xenotransplantation products fails or demand is significantly less than anticipated, we will not recoup our significant investment in these unique facilities as they would be difficult to repurpose. Conversely, if we do not construct a sufficient number of facilities prior to approval of our xenotransplantation products, it will limit the number of organs we are able to supply 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 approval or commercialization of new products, result in product liability claims and product recalls, and entail higher costs or lost revenues. Interruptions in our manufacturing process could be significant given the length of time and complexity involved in obtaining necessary regulatory approvals for alternative arrangements, through either third parties or internal manufacturing processes.

We rely in part on third parties to perform activities that are critical to our business.

Third parties assist us in activities critical to our operations, such as: (1) manufacturing our clinical and commercial products; (2) conducting clinical trials, preclinical studies, and other research and development activities; (3) obtaining regulatory approvals; (4) conducting pharmacovigilance and product complaint activities, including processing and reporting of adverse effects data (including adverse events and product complaints); (5) manufacturing and obtaining regulatory 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. We rely entirely on ICU Medical to manufacture the CADD-Solis pump, which is the primary pump used to administer intravenous Remodulin in the United States. We rely entirely on DEKA Research & Development Corp. and its affiliates to manufacture the Remunity and RemunityPRO Pumps, which are the primary pumps used to administer subcutaneous Remodulin in the United States. Additional ancillary supplies are used with these pumps, and there are a limited number of manufacturers that supply them.

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

We also rely on various sole-source suppliers for manufacturing activities related to ralinepag, including Corden Pharma GmbH as the sole manufacturer of finished ralinepag extended-release tablets and ScinoPharm as the sole supplier of ralinepag API. We are in the process of qualifying our Silver Spring facility to produce our primary commercial supply of ralinepag API, and our Research Triangle Park facility to produce our primary commercial supply of ralinepag extended-release tablets, if and when oral ralinepag is approved by the FDA. These efforts 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. In addition, any quality issues with either of these suppliers, or any other third party involved in the manufacture and testing of ralinepag, could prevent or delay FDA approval of ralinepag. An FDA cGMP inspection of ScinoPharm's facility is currently classified by the FDA as "Official Action Indicated" as a result of cGMP deficiencies. If these deficiencies are not timely resolved to the FDA's satisfaction, or if ScinoPharm fails to pass a reinspection or pre-approval inspection, the FDA may issue a CRL with respect to our ralinepag NDA, thereby delaying any potential approval and launch of ralinepag extended-release tablets.

For a further discussion of risks created by the use of third-party contract manufacturers, see the risk factor above entitled, *Our manufacturing strategy exposes us to significant risks*.

We rely heavily on third-party contract research organizations, contract laboratories, clinical investigative sites, and other third parties to conduct our clinical trials, preclinical studies, and other research and development activities. Third-party failure to conduct or assist us in conducting clinical trials in accordance with study protocols, quality controls, GCP, or other applicable requirements or to submit associated regulatory filings, could limit or prevent our ability to rely on results of those trials in seeking regulatory approvals.

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

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

Negative attention from special interest groups may impair our business.

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

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

The testing, manufacturing, marketing, and sale of drugs and diagnostics involve product liability risks. We may not be able to maintain our current product liability insurance at an acceptable cost, if at all. In addition, our insurance coverage may not be adequate for all potential claims. If losses significantly exceed our liability insurance coverage, we may experience financial hardship or potentially be forced out of business. Clinical testing and eventual marketing and sale of new products, reformulated versions of existing products, or use of existing products in new indications could expose us to new product liability risks that are not covered by our existing policies.

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

Members of our management team, including our founder, Chairperson and Chief Executive Officer, Dr. Martine Rothblatt, play a critical role in defining our business strategy and maintaining our corporate culture. The loss of the services and leadership of Dr. Rothblatt or any other members of our senior management team could have an adverse effect on our business. We do not maintain key person life insurance on our senior management team members. Failure to identify, hire, and retain suitable successors for members of our senior management team and to transfer knowledge effectively could impede the achievement of our business objectives. Our future success also depends on our ability to attract and retain qualified scientific and technical personnel. Competition for such personnel in our industries is intense. If we fail to attract and retain such employees, we may not be successful in developing and commercializing new therapies.

Risks Related to Legal Compliance

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

The products we develop must be approved for marketing and sale by regulatory agencies. Our research and development efforts must comply with extensive regulations, including those promulgated by the FDA, the U.S. Department of Agriculture, and their international counterparts, as applicable. The process of obtaining and maintaining regulatory approvals for new drugs, biologics, and medical devices is lengthy, expensive, and uncertain. The regulatory approval process is particularly uncertain for our organ manufacturing program. Once approved, the manufacture, distribution, advertising, and marketing of our products are subject to extensive regulation, including requirements related to product labeling, pharmacovigilance and adverse effect reporting and processing (including both adverse events and product complaints), storage, distribution, and record-keeping. Our product candidates have in the past and may in the future fail to receive regulatory approval. If granted, product approvals can be conditioned on the completion of post-marketing clinical studies, accompanied by significant restrictions on the use or marketing of a given product and withdrawn for failure to comply with regulatory requirements, such as post-marketing requirements and post-marketing commitments, or upon the occurrence of adverse effects subsequent to commercial introduction. Our ability to obtain regulatory approvals for our products has been, and in the future may be, materially impacted by the outcome and quality of our clinical trials and other data submitted to regulators, as well as the quality of our manufacturing operations and those of our third-party contract manufacturers and contract laboratories. In addition, third parties may submit citizen petitions to the FDA seeking to delay approval of, or impose additional approval conditions for, our products. Citizen petitions have in the past, and may in the future, significantly delay or prevent approval of our products.

In April 2025, the Trump administration announced a reduction in force at the U.S. Department of Health and Human Services, including layoffs at the FDA. These and other efforts to reduce the size of the FDA or its funding, combined with significant changes in FDA leadership, have resulted in slower FDA response times and longer review periods, and may lead

to less predictable outcomes. Future government shutdowns, funding disputes, reorganizations, furloughs, or reductions in resources or changes in priorities or focus may result in further delays. If response and review delays persist and/or worsen, they could potentially impact our ability to advance our pipeline efforts on a timely basis 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 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 healthcare 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 healthcare 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 healthcare 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 healthcare programs, like Medicaid or Medicare, may adversely impact our business, operations, or financial results. We cannot predict how future federal or state legislative or administrative changes related to healthcare reform will affect our business.

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

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

The IRA was enacted in 2022. Among other obligations, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare, with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); redesigns the Medicare Part D benefit (beginning in 2024); and replaces the Medicare Part D coverage gap discount program with a new manufacturer discounting program (beginning in 2025). The U.S. Centers for Medicare & Medicaid Services (**CMS**) has published the negotiated prices

for the initial ten drugs, which went into effect in January 2026, and the subsequent 15 drugs, which will first be effective in 2027. The IRA permits the Secretary of the Department of Health and Human Services (**HHS**) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has issued guidance, and is expected to continue to issue guidance, even while multiple lawsuits challenging the IRA negotiation requirement remain pending. While the impact of the IRA on the pharmaceutical industry cannot yet be fully determined, it is likely to be significant.

Under the Medicare Part D manufacturer discounting program that became effective January 1, 2025 pursuant to the IRA, manufacturers must give a 10 percent discount on Part D drugs in the initial coverage phase, and a 20 percent discount on Part D drugs in the so-called "catastrophic phase" (the phase after the patient incurs costs above the initial phase out-of-pocket threshold, which was $2,000 in 2025 and is $2,100 in 2026). 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 a specified small manufacturer.

Orenitram and Tyvaso DPI are both reimbursed under Medicare Part D, and the reimbursement amount is impacted by the 10 and 20 percent discounts under the IRA's manufacturer discounting program. These increased discounts 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 of the IRA's Part D redesign, which went into effect in 2025 and resulted in an increase in the number of patients able to afford these therapies. The amount of the offset, if any, is inherently uncertain and difficult to measure and predict.

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

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

The Trump administration is pursuing a two-fold strategy to reduce drug costs in the U.S. On the one hand, the Trump administration has threatened to impose significant tariffs on pharmaceutical manufacturers that do not adopt pricing policies such as MFN pricing, which would tie the price for drugs in the U.S. to the lowest price in a group of other countries. In response, multiple manufacturers have entered into confidential pricing agreements with the federal government. On the other hand, the Trump administration is pursuing regulatory pathways to impose drug pricing policies. CMS proposed two mandatory Center for Medicare and Medicaid Innovation drug payment models in December 2025, referred to as GLOBE, for Medicare Part B, and GUARD, for Medicare Part D. GLOBE, and, if finalized and adopted, GUARD, implement mandatory payment models under which manufacturers of eligible drugs would be required to pay rebates to the federal government on a portion of the units of their drugs that are reimbursed by Medicare, with the rebate amount based on MFN pricing. CMS published the GLOBE final rule on October 2, 2026, with an effective date of November 30, 2026 and a model launch date of January 1, 2027. Based on our understanding of the final GLOBE rule, we do not believe our current commercial products meet the criteria for inclusion in the GLOBE model. Imposing a rebate in the U.S. that is based on drug prices outside the U.S. would mark a drastic and unprecedented shift in the U.S. pharmaceutical market. The Trump administration policies are likely to have a significant negative impact on the pharmaceutical industry and may negatively affect our ability to receive revenues from sales of our commercial products. Even regulatory proposals or executive actions that ultimately are deemed unlawful or otherwise repealed could negatively impact the U.S. pharmaceutical sector and our business.

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

In October 2020, HHS and the FDA issued a final rule and guidance concerning two new pathways for importing lower-cost drugs into the United States. The final rule allows certain prescription drugs to be imported from Canada, and the guidance describes procedures for drug manufacturers to facilitate the importation of FDA-approved drugs and biologics manufactured abroad and originally intended for sale in a foreign country into the United States.

The 2026 Medicare Physician Fee Schedule final rule amended the Medicare Part B "average sales price" regulations, including by mandating that, as part of the manufacturer "bona fide service fee" determination, manufacturers submit reasonable assumptions and, for all new service vendor contracts as of January 1, 2026, obtain certifications from service vendors that they do not pass on service fees in whole or in part.

These legal reforms, as well as the IRA and other healthcare legislative or regulatory reform measures that may be adopted in the future, have resulted in, and may in the future result in, downward pressure on the payment for any of our approved products, and may adversely impact our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payment from commercial payers. Further state and federal healthcare reform measures adopted in the future could limit the amounts that state and federal governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

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

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

We participate in, and have certain price reporting obligations to, the Medicaid Drug Rebate program, the Medicare program for Part B drugs, and other governmental programs that require us to pay rebates or offer discounts on our products, or establish reimbursement rates based on our reported pricing and other data. 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. Agencies continue to pursue and implement price reporting regulatory reforms under these programs. Changes to these programs could negatively affect the coverage and reimbursement by these programs of our products or any future products for which we receive regulatory approval and could negatively impact our results of operations. Our failure to comply with these price reporting, rebate payment, or pricing requirements could adversely impact our financial results. Applicable laws and regulations, including the IRA, could affect our obligations in ways we cannot anticipate.

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

CMS, the U.S. Department of Veterans Affairs, 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 made by and distributed to 340B covered entities themselves. Our contract pharmacy policy preserves patient access, while addressing compliance and integrity concerns resulting from the proliferation of contract pharmacies. Nonetheless, HHS, in a non-binding (and now-retracted) Advisory Opinion, stated that manufacturers in the 340B program are obligated to sell their covered outpatient drugs at the 340B ceiling price to all contract pharmacies acting as agents of a covered entity. Certain covered entities have expressed the view that participating manufacturers are obligated to sell their covered outpatient drugs to all contract pharmacies of a covered entity.

We and certain other manufacturers initiated litigation challenging the Advisory Opinion and the U.S. Health Resources and 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 or another entity 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 through dispute mechanisms including the administrative dispute resolution pathway. We expect the compliance of policies like ours will continue to be litigated. We may also face enforcement action under the laws of certain states that are seeking to impose their own 340B contract pharmacy requirements. Such actions could, if determined adversely to us, result in penalties and other sanctions that could have a negative impact on our business. If we are unable to curb the proliferation of abuses caused by 340B contract pharmacies, we could see increased sales at 340B ceiling prices, which could have a material adverse impact on our revenues.

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

Company-sponsored patient assistance programs, including insurance premium and co-pay assistance programs and manufacturers' donations to third-party charities that provide such assistance, are subject to heightened scrutiny. The Department of Justice (**DOJ**) has taken enforcement action against pharmaceutical companies alleging violations of the Federal False Claims Act and other laws in connection with patient assistance programs. We have been, and may in the future be, subject to DOJ investigations with respect to our support of non-profit patient assistance programs, which can result in sanctions, fines, or other payments and agreements with respect to our compliance programs. As discussed in Note 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 healthcare programs. If any or all of 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.

Limitations on our intellectual property rights may limit our ability to prevent third parties from competing with our products, and we may not prevail in litigation to enforce or defend those rights.

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 in the United States under which generic versions of Remodulin have launched, a generic version of Nebulized Tyvaso is currently permitted to be launched, and generic versions of Orenitram are permitted to be launched in the future. 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 no issued patents or pending patent applications covering the Unituxin drug product. 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.*

Our patents have not prevented competitors from obtaining regulatory approval to market products that compete with our treprostinil-based products, and we cannot be sure that our existing or any new patents will effectively deter or delay competitors' efforts to bring additional 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, inter partes reviews, post-grant reviews, and interference proceedings, before the U.S. Patent and Trademark Office or other applicable patent filing offices, or other means.

Patent litigation has been, and may continue to be, time consuming, distracting, and costly, and the outcome may be difficult to predict and unfavorable to us. We have not always prevailed in the defense of our patents, and if we are unsuccessful in the defense of our remaining patents, our business could be negatively impacted.

We also rely on trade secrets to protect our proprietary know-how and other confidential technological advances. Our confidentiality agreements with our employees and others to whom we disclose trade secrets and confidential information may not necessarily prevent our trade secrets from being used or disclosed without our authorization, as we allege happened in our lawsuit against Dr. Roscigno. 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.

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. In 2024, we 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 service attacks, credential harvesting, social engineering, and other forms of unauthorized access or disclosure to, or disrupting the operation of, our networks and systems or those of our customers, suppliers, vendors, and other service providers, can cause the loss, destruction, or unauthorized access or disclosure of data, including personal information of employees or confidential or proprietary information, disruption of our manufacturing and other operations, and damage to our reputation and competitive position, any of which could be costly to address and remediate and adversely affect our business, financial condition, or results of operations. We are also subject to laws and regulations in the United States and abroad, such as the Health Insurance Portability and Accountability Act of 1996 and European Union regulations related to data privacy, which require us to protect the privacy and security of certain types of information. Therefore, cybersecurity incidents could expose us to significant civil and/or criminal penalties, as well as private litigation, all of which could adversely affect our business, financial condition, or results of operations.

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

Risks Related to Our Financing Capacity, Indebtedness, and Investments

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

We may be required to seek additional sources of financing to meet unplanned or planned expenditures. Unplanned expenditures could be significant and may result from necessary modifications to product development plans or product offerings in response to difficulties encountered with clinical trials. We may also face unexpected costs in preparing products for commercial sale, or in maintaining sales levels of our currently marketed therapeutic products. Our 2025 Credit Agreement contains affirmative and negative covenants that, among other provisions, limit our ability to incur additional indebtedness. If we are unable to obtain additional funding on commercially reasonable terms or at all, we may be compelled to delay clinical studies, curtail operations, or obtain funds through collaborative arrangements that may require us to relinquish rights to certain products or potential markets.

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

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

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

We seek to expand our business in part through acquisitions of complementary businesses, products, and technologies. The success of this strategy will depend on our ability to identify, and the availability of, suitable acquisition candidates. We may incur costs related to an acquisition but may be unable or unwilling to consummate the proposed transaction. Acquisitions involve numerous risks, including: the ability to realize anticipated synergies and manage the integration of personnel, products, and acquired infrastructure and controls; potential increases in operating costs; managing geographically remote operations; the diversion of management's attention from other business concerns; potential disruptions in ongoing operations during integration; risks inherent in entering markets and sectors in which we have limited or no direct experience; and the potential loss of key employees, customers, or vendors and other business partners of the acquired companies. External factors, such as compliance with law, may also impact the successful integration of an acquired business. Acquisitions could involve dilutive issuances of equity securities, the incurrence of debt, one-time write-offs of goodwill (or in-process research and development assets), and substantial amortization expenses of other intangible assets. We may be unable to obtain financing on favorable terms, or at all, if necessary to finance future acquisitions, which may make acquisitions impossible or more costly. The terms of financing we obtain may be onerous and restrict our operations. Further, certain acquisitions may be subject to regulatory approval, which can be time consuming and costly to obtain or may be denied, and if obtained, the terms of such regulatory approvals may limit our ongoing operations or require us to divest assets.

Risks Related to Our Common Stock

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

The price of common stock can be highly volatile within the pharmaceutical and biotechnology sector. Consequently, significant price and volume fluctuations in the market may not relate to operating performance. The price of our common stock could decline sharply due to general market conditions as well as the following factors, among others:

- quarterly and annual financial results and any failure to meet our expectations or those of securities analysts, including expectations regarding revenues for our existing products, new products, or new indications for existing products;
- timing of enrollment and results of our clinical trials;
- announcements regarding generic or other challenges to the intellectual property related to our products, the launch and successful commercialization of generic versions of our products or other competitive products, and the impact of competition from generic and other products on our revenues;

- announcements regarding litigation matters;
- announcements regarding our efforts to obtain regulatory approval of, and to launch commercial sales of, new products and new indications for existing 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 laws and regulations affecting reimbursement of our therapeutic products by government payers, changes in reimbursement policies of private insurance companies, including the implementation and impacts of the IRA and other governmental efforts to reduce drug prices, and negative publicity surrounding the cost of high-priced therapies;
- announcements of technological innovations or new products or announcements regarding our existing products, including in particular the development of new, competing therapies;
- substantial sales of our common stock by us or our existing shareholders, or concerns that such sales may occur;
- future issuances of common stock by us or other activity which could be viewed as being dilutive to our shareholders;
- rumors or incorrect statements by investors and/or analysts concerning our company, our products, or our operations;
- failures or delays in our efforts to obtain or maintain domestic or international regulatory approvals;
- discovery of previously unknown problems with our marketed products, or problems with our manufacturing, regulatory, compliance, promotional, marketing, or sales activities that result in regulatory penalties or restrictions on our products, up to the withdrawal of our products from the market; and
- accumulation of significant short positions in our common stock by hedge funds or other investors or the significant accumulation of our common stock by hedge funds or other institutional investors with investment strategies that may lead to short-term holdings.

Provisions of Delaware law, our charter, bylaws and employment and license agreements, among other factors, 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, and the paucity of judicial interpretation of 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, MannKind has the right to terminate our license agreements related to Tyvaso DPI and ralinepag DPI, 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 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

Issuer Purchases of Equity Securities

Period	Total Number of Shares (or Units) Purchased	Average Price Paid Per Share (or Unit)	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	Approximate Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs
July 1, 2026 - July 31, 2026	–	$ –	–	$ 500,000,000
August 1, 2026 - August 31, 2026[1]	240,401	536.06	240,401	487,792,765
September 1, 2026 - September 30, 2026[2]	739,993	492.61	739,993	–
Total	**980,394**	**$ 532.63**	**980,394**	**$ –**

(1) As announced on March 9, 2026, our Board approved a share repurchase program authorizing up to $2.0 billion in aggregate repurchases of our common stock, which program expires on March 9, 2027. Pursuant to this authorization, we entered into the March 2026 ASRs, comprised of a $750.0 million uncollared share repurchase agreement and a $750.0 million collared share repurchase agreement (the **March 2026 Collared ASR**), with Citi to repurchase approximately $1.5 billion of our common stock. The final settlement of the March 2026 Collared ASR occurred in August 2026, and we received 215,948 shares of our common

stock upon settlement. The average price paid per share over the term of the March 2026 Collared ASR was approximately $540.23, calculated by dividing the $750.0 million aggregate purchase price by the total of 1,388,287 shares of our common stock repurchased under the agreement. The final number of shares that we ultimately repurchased pursuant to the March 2026 Collared ASR was based on the average of the daily volume-weighted average price per share of our common stock during the repurchase period, less a discount and subject to a collar provision establishing the minimum and maximum share amounts and other adjustments pursuant to the terms and conditions of the March 2026 Collared ASR. In addition, under a Rule 10b5-1 trading plan, we repurchased 24,453 shares in August 2026 at a weighted-average price of $499.21 per share. The average price paid per share of $536.06 in the table reflects the final weighted-average price under the March 2026 Collared ASR and the weighted-average price under the Rule 10b5-1 trading plan, in each case weighted by the respective number of shares received or repurchased in August.

(2) Under the existing Rule 10b5-1 trading plan, we repurchased 20,617 shares in September 2026 at a weighted-average price of $492.61 per share for approximately $10.2 million. Subsequently, on September 8, 2026, we announced that we utilized the remainder of the previously announced $2.0 billion share repurchase authorization and entered into the September 2026 ASR with Citi to repurchase approximately $477.6 million of our common stock. We made an aggregate upfront payment of $477.6 million to Citi and received an initial delivery of 719,376 shares of our common stock on September 10, 2026, representing approximately 75 percent of the total shares that would be repurchased under the September 2026 ASR, measured based on the closing price of our common stock on September 8, 2026. The total number of shares ultimately repurchased pursuant to the September 2026 ASR, and the average price paid per share, will be determined upon final settlement and will be 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 September 2026 ASR. At the final settlement of the September 2026 ASR, we may be entitled to receive additional shares of our common stock, or, under certain limited circumstances, be required to make an additional cash payment to Citi or, if we so elect, deliver shares of our common stock to Citi. The final settlement of the September 2026 ASR is expected to occur in the fourth quarter of 2026. The average price paid per share in the table excludes the 719,376 initial shares received under the September 2026 ASR because the final weighted-average price under that ASR is not yet determinable.

Item 5. Other Information

(a) Entry into License Agreement Amendment

On November 3, 2026 (the **Amendment Effective Date**), we entered into the Arena Amendment, which amends the Exclusive License Agreement, dated November 15, 2018 (the **License Agreement**), with Arena. Under the License Agreement, we hold exclusive rights to develop, manufacture, and commercialize ralinepag.

In exchange for these rights, we agreed to pay Arena (1) an upfront payment of $800.0 million, which was paid on January 24, 2019; (2) a one-time milestone payment of $250.0 million upon the first marketing approval, if any, in the United States of an inhaled version of ralinepag to treat pulmonary arterial hypertension; (3) a one-time milestone payment of $150.0 million upon the first marketing approval, if any, in any of Japan, France, Italy, the United Kingdom, Spain, or Germany of an oral version of ralinepag for any indication; and (4) low double-digit, tiered royalties on net sales of any pharmaceutical product containing ralinepag as an active ingredient, subject to certain adjustments for third-party license payments.

Under the Arena Amendment, we paid Arena a lump-sum, non-refundable payment of $525.0 million on the Amendment Effective Date (the **Royalty Substitution Payment**) in exchange for the elimination of our obligation to pay royalties on net sales of any product containing ralinepag, including, if approved, ralinepag extended-release tablets and ralinepag DPI. Milestone payment obligations remain in place.

We expect to recognize the $525.0 million Royalty Substitution Payment as research and development expense, during the fourth quarter of 2026.

The foregoing description of the Arena Amendment does not purport to be complete and is qualified in its entirety by reference to the Arena Amendment, a copy of which is filed as Exhibit 10.1 to this Quarterly Report on Form 10-Q and incorporated herein by reference.

(c) Trading Plans

During the three months ended September 30, 2026, 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	Eleventh Amended and Restated Bylaws of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed January 22, 2026
4.1	Reference is made to Exhibits 3.1 and 3.2
10.1*+	Amendment to Exclusive License Agreement, dated as of November 3, 2026 by and between Arena Pharmaceuticals, Inc. and the Registrant
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 September 30, 2026, filed with the SEC on November 4, 2026, formatted in Inline Extensible Business Reporting Language (iXBRL): (1) our Consolidated Balance Sheets as of September 30, 2026 and December 31, 2025; (2) our Consolidated Statements of Operations for the three- and nine-month periods ended September 30, 2026 and 2025; (3) our Consolidated Statements of Comprehensive Income for the three- and nine-month periods ended September 30, 2026 and 2025; (4) our Consolidated Statements of Stockholders' Equity for the three- and nine-month periods ended September 30, 2026 and 2025; (5) our Consolidated Statements of Cash Flows for the nine-month periods ended September 30, 2026 and 2025; and (6) the Notes to our Consolidated Financial Statements.
104*	Cover Page Interactive Data File (embedded within the iXBRL document)

+ Certain identified information has been omitted pursuant to Item 601(b)(10) of Regulation S-K because it is both not material and the type that the Registrant treats as private or confidential.

* Filed herewith.

** Furnished 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

November 4, 2026

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)